

# **REPORTING GUIDE** for Study Authors

Handbook of Standards and Procedures, Version 2.0

October 2024

OPRE Report #2024-340

# TITLE IV-E PREVENTION SERVICES CLEARINGHOUSE REPORTING GUIDE FOR STUDY AUTHORS Handbook of Standards and Procedures, Version 2.0

# OPRE Report 2024-340

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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 design studies<sup>1</sup> 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. This guide reflects the standards and procedures described in the *Title IV-E Prevention Services Clearinghouse Handbook of Standards and Procedures, Version 2.0 (Handbook Version 2.0).* 

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, supplementary material, 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, Version 2.0*.

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 use prevention and treatment services and in-home parent skill-based programs, as well as kinship navigator programs.

<sup>1</sup> 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 *Handbook Version 2.0*).



# **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 relevance of studies during title and abstract screening primarily by examining whether they describe an evaluation of the program or service under review and assessing whether a randomized or quasi-experimental study design was used. Staff determine final eligibility by reviewing the full text of studies identified as relevant. Studies must be publicly available (*Handbook Version 2.0*, Section 4.1.2). Include the following information in the title or abstract to facilitate accurate screening:

- State the name of the program or service under 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. If the name of the program or service in the study differs from the name given by program developers, it is helpful to provide both names.
- 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, placebo or attention control, 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.



#### Intervention Condition<sup>2</sup>

- 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 book, manual, or other documentation used to guide and implement the program or service delivery. If multiple books, manuals, or other documentation were used, describe them.
  - 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 4.1.9 in *Handbook Version 2.0*).

### **Program or Service Implementation**

- Describe the intended and actual dosage and intensity of the 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 7.2.3 in *Handbook Version 2.0*). This may include, but is not limited to, information about a time point when participants have received a majority of services as defined in the manual, a time point when a majority of participants achieve stability during a program or service, or a time point at which services taper off or transition into a maintenance phase.
- 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 of experience).
- Indicate any required training the practitioners received, as indicated by the manual or program or service developer.

<sup>&</sup>lt;sup>2</sup> The intervention condition is the program or service relevant to the work of the Prevention Services Clearinghouse that is intended to provide enhanced support to children and families and prevent foster care placements. Studies may have more than one intervention condition.



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#### **Program or Service Implementation**

- Specify how many different practitioners delivered the program or service.
- Indicate the number of organizational or agency units (e.g., number of clinics) involved in implementation.
- Describe the format (e.g., group, one-on-one, self-directed) and delivery modality of the program or service (e.g., in-person, online).

#### Consider also including the following information:

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

### Setting

- Describe when and where the study took place and key characteristics of the setting (e.g., hospital, communitybased, outpatient, inpatient, home-based, online).
  - Confirm that the setting of the study is congruent with the recommended or required implementation settings indicated in the manual, book, or available documentation for the program or service.
  - ◆ Specify if the study took place in a usual care setting.<sup>3</sup>
- 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 4.1.7 in the *Handbook Version 2.0*). If applicable, provide this level of detail about all comparison conditions in the study.

Specify if the comparison condition is no intervention, untreated group or waitlist<sup>4</sup>, minimal intervention<sup>5</sup>, placebo or attention control<sup>6</sup>, treatment as usual<sup>7</sup>, or a head-to-head comparison.<sup>8</sup>

<sup>&</sup>lt;sup>8</sup> *Head-to-Head* comparison conditions are those in which the comparison condition is intended to be an alternative intervention, active intervention, active control intervention or comparator intervention.



<sup>&</sup>lt;sup>3</sup> 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 7.2.2 in Handbook Version 2.0 for additional information.

<sup>&</sup>lt;sup>4</sup> No intervention, untreated or waitlist 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.

<sup>&</sup>lt;sup>5</sup> *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.

<sup>&</sup>lt;sup>6</sup> Placebo or attention control comparison conditions are those in which psychological or pharmacological placebo or nonspecific therapy is used to control for expectancy effects or time effects.

<sup>&</sup>lt;sup>7</sup> 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

# **Comparison Condition**

- 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).
- 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 received in the comparison condition.
  - Indicate if the same individual or individuals *also* delivered the intervention condition in the study.

#### 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 eligibility or 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).



#### **Study Participants**

- Describe the sociodemographic characteristics of the analytic sample by condition, including gender, age, race and ethnicity, socioeconomic status of both children and adults (if applicable).
- Describe whether the sample includes children, youth, young adults, and/or families receiving child welfare services (or populations similar to those receiving child welfare services or at-risk for receiving child welfare services).
- Describe the extent to which participants are from underserved communities.

#### Consider also including the following information:

- Illustrate the flow of participants through the study with a clear flow chart diagram.
- The Prevention Services Clearinghouse displays the locations, year, and participant characteristics for studies that receive moderate or high ratings on design and execution and that report the information. If applicable, include any additional available information on the following characteristics of study participants: for children, those who are involved with the child welfare system, experiencing homelessness or ran away from home, victims of sexual abuse, sexual or juvenile offenders, identify as having a disability, or identify as Lesbian, Gay, Bisexual, Transgender, Queer or Questioning, Intersex, and more (LGBTQI+); for adults, those who are parents/caregivers, pregnant, involved with the child welfare system, have experienced intimate partner violence, are single parents, are experiencing homelessness, identify as having a disability, or identify as Lesbian, Gay, Bisexual, Transgender, Queer or Questioning, Intersex, and more (LGBTQI+); for adults, those who are parents/caregivers, pregnant, involved with the child welfare system, have experienced intimate partner violence, are single parents, are experiencing homelessness, identify as having a disability, or identify as Lesbian, Gay, Bisexual, Transgender, Queer or Questioning, Intersex, and more (LGBTQI+). For more information, see the Clearinghouse's <u>Resource Guide on Study Participant Characteristics and Settings</u>.



# Design

- Specify the study design (e.g., block randomized controlled trial; quasi-experimental design using propensity score matching; controlled before-and-after design).
- 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.
- Describe any planned subgroup analyses.
- 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 assignment, matched comparison).

# Consider also including the following information:

- Provide a clear flow chart diagram illustrating how participants flow through the study.
- ◆ 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 any differences in assignment probabilities 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 type of design used (e.g., natural experiment, before-after-control-impact, difference-indifference).
  - 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 book, manual, or other documentation describing
  the program or service.
- If an analysis of statistical power was conducted, report the power analysis and the magnitude of effect the study was designed to be able to detect with the targeted (or actual) sample size.

# **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 (pretest, posttest, and follow-up).
- For QEDs:
  - Provide analytic sample sizes by condition for each outcome at each measurement point (pretest, posttest, and follow-up).

### Measures

- For each outcome measure:
  - ◆ Identify the instrument and subscale (if relevant).
  - Specify the source of the data (e.g., questionnaire, administrative record), reporter or informant, and scaling of data (e.g., binary, categorical, counts, continuous scaling). If an outcome measure is categorical, indicate if participants can be in multiple categories.
  - Specify the construct the instrument or subscale intends to measure.



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#### Measures

- 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., whether higher scores indicate better or worse outcomes, what an optimal score or range is, what indicates a clinical range or cutoff, etc.).
- Provide information about the level of measurement (e.g., individual, community, population-level, family, dyad).
- Provide references about measure development and psychometrics, including reliability and validity, and state whether the measure has been normed. This includes psychometrics for measures used to establish baseline equivalence, if applicable.

#### 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., start of treatment, mid-treatment, end of 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 (direct pretests) by condition for each analytic sample<sup>9</sup> in the study (see Table Shells 1 and 3).
- Provide descriptive statistics by condition for each analytic sample for other measures that were collected at baseline, such as measures that are correlated with the outcome (i.e., correlated pretest) or in the same or similar domain to the outcome (i.e., pretest alternative). For baseline measures that are not direct pretests, report the correlation between the baseline measures and the outcome (see section 5.7 in *Handbook Version 2.0*).
- Provide available sociodemographic characteristics at baseline for both adults and children (if applicable) by condition for each analytic sample (see section 5.7.1 in *Handbook Version 2.0*) such as:
  - Racial and ethnic background
  - ♦ Socioeconomic status
  - Household composition

<sup>&</sup>lt;sup>9</sup> 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.



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#### **Baseline Equivalence**

- ◆ Age
- Neighborhood race or ethnicity, socioeconomic status, and household composition
- To use sociodemographic characteristics for establishing baseline equivalence, the Prevention Services Clearinghouse requires an affirmative description demonstrating that the intervention and comparison conditions substantially overlap on characteristics that determine intervention eligibility or on study recruitment criteria. Provide information on characteristics used as recruitment criteria for the study or as eligibility criteria for the intervention for *both intervention and comparison conditions*.

#### 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.
- The Prevention Services Clearinghouse may use correlated pretests to establish baseline equivalence and uses correlations between baseline variables and outcomes when calculating potential bias due to missing or imputed data. Consider providing a correlation matrix of baseline and outcome variables.

# **Data Analysis and Findings**

 Describe in detail the method used to estimate program impacts (e.g., linear regression, analysis of variance, etc.).

# Consider also including the following information:

- Display the equation for the full impact analysis model(s) being estimated, including any covariates in the model.
- Describe all control variables or weights used in the analysis, including methods for statistical controls for pretest measures (see section 5.8 in *Handbook Version 2.0*).
- Clearly indicate the unit of analysis (individual or cluster) and, if applicable, explain how clustering was addressed in the analysis.

#### **Statistical Significance and Effect Sizes**

When the Clearinghouse calculates the statistical significance or effect size for a finding, certain data elements are needed.

For outcomes that are measured on a continuous scale, the Clearinghouse prefers a model coefficient from an adjusted impact model and unadjusted standard deviations or adjusted means and unadjusted standard deviations for each condition. If those statistics are not available, the Clearinghouse will use unadjusted means and unadjusted standard deviations for both pretests and posttests for each condition.

For binary outcomes, the Clearinghouse prefers model coefficients from logistic models or model-adjusted proportions. If those statistics are unavailable, the Clearinghouse will use unadjusted proportions for both pretests and posttests for each condition.

For more information, please refer to Chapter 6 in *Handbook Version 2.0.* 



# **Data Analysis and Findings**

- Describe whether any participants or units of analysis were excluded from the analysis and, if so, why.
- Report descriptive statistics (e.g., unadjusted means, standard deviations, proportions) and sample sizes by condition for each outcome measure at each time point (see Table Shells 2 and 4).
- Report results from impact models, including model coefficients for the treatment indicator and all covariates, standard errors, and exact p-values (see Table Shells 2 and 4).
  - Report model-adjusted means or proportions for each outcome measure at each timepoint for each condition and, for outcomes measured on a continuous scale, report the unadjusted standard deviations for each outcome measure at each time point for each condition (see Table Shells 2 and 4).
- If relevant, clearly specify when analyses are full-sample sensitivity analyses or subgroup analyses.
- For impacts estimated from repeated measures models and variations of growth modeling analysis (e.g., growth curve analyses, latent growth models, etc.):
  - Report the statistical significance of the time by intervention interaction for each outcome measurement occasion included in the model (e.g., posttest, 3-month follow-up, 6-month follow-up).
  - Provide unadjusted and adjusted means, unadjusted standard deviations, and sample sizes for each measurement time point (see Section 6.3.2 in Handbook Version 2.0).
- For impacts estimated from variations of survival analysis (e.g., hazard ratio, relative risk). For more information see the Time-to-Event Outcomes sections in Chapter 6 of *Handbook Version 2.0*.
  - 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 Data<sup>10</sup>

- 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.

<sup>&</sup>lt;sup>10</sup> For more information on the Prevention Services Clearinghouse missing data standards, refer to *Handbook Version 2.0* (Section 5.9.4). The Prevention Services Clearinghouse missing data standards are based on the What Works Clearinghouse missing data standards (What Works Clearinghouse Procedures and Standards Handbook, Version 5.0), which can be found online at <u>whatworks.ed.gov</u>.



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# STUDY DATA TABLE SHELLS • TABLE SHELLS FOR STUDIES WITH ONE POSTTEST 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.

<b>1. Sample size</b> of the intervention condition analytic sample for this measure at posttest or follow-up.	<b>2.</b> The unadjusted baseline <b>mean</b> and <b>standard deviation</b> of the intervention condition analytic sample at posttest or follow-up.	3. Sample size of the condition analytic same asure at posttest	ample for this	<ol> <li>The unadjusted baseline mean and standar deviation of the comparison condition analy sample at posttest or follow-up.</li> </ol>			prete	es other than direct relation between and the outcome.	
Table Shell 1. Informatio	n to Include for Establishing Basel	ine Equivalence	,		7				
6. If different		Intervention	Condition–Ana	lytic Sample	Comparison	Conditio	n–Ana	lytic Sample	Correlation
outcomes have	Measure –	- Sampla ciza	Mean		Sample size	Mea	n		with Outcome

<b>o.</b> If different					Companioon	Correlation		
outcomes have different sample sizes	Measure	Sample size	- Mean	(SD)	Sample size	Mean	• (SD)	with Outcome
(as shown in Table	Analytic Sample for Outcome 1							
Shell 2), provide baseline information	-Pretest	350	84.42	(17.5)	420	80.80	(16.4)	
separately for each analytic sample.	Other baseline measure (correlated pretest or pretest alternative)	350	990	(58)	420	1000	(62)	- 0.64
7. Repeat this row	-Race/ethnicity (% minority)	350	0.45	n/a	420	0.46	n/a	
for each available baseline measure.	-Low income (%)	350	0.77	n/a	420	0.72	n/a	
8. If a direct pretest	Analytic Sample for Outcome 2							
is either impossible	Pretest	327	84.42	(17.5)	415	80.80	(16.4)	
or not feasible and a correlated pretest or pretest alternative	Other baseline measure (correlated pretest or pretest alternative)	327	990	(58)	415	1000	(62)	- 0.71
is not available, baseline equivalence	Race/ethnicity (% minority)	327	0.43	n/a	415	0.47	n/a	
must be established	Low income (%)	327	0.77	n/a	415	0.72	n/a	
using multiple sociodemographic	Analytic Sample for Outcome 3							
characteristics	Pretest	310	84.42	(17.5)	409	80.80	(16.4)	
(see Section 5.7 of Handbook Version 2.0).	Other baseline measure (correlated pretest or pretest alternative)	310	990	(58)	409	1000	(62)	0.73
	Race/ethnicity (% minority)	310	0.40	n/a	409	0.47	n/a	
	Low income (%)	310	0.77	n/a	409	0.72	n/a	
			<i></i>					

**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.



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# STUDY DATA TABLE SHELLS • TABLE SHELLS FOR STUDIES WITH ONE POSTTEST 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 Condition						Estimated Effect						
Outcome Measure	Sample size	Unadjusted Mean	Adjusted Mean	Unadjusted (SD)	Sample size	Unadjusted Mean	Adjusted Mean	Unadjusted (SD)	Impact	,	Standard error	<i>p</i> -value	Effect Size
Outcome 1	350	4.10	4.21	(1.09)	420	3.97	3.98	(1.14)	0.22		0.03	.0843	0.15
Outcome 2	327	19.2	18.6	(48.1)	415	46.9	47.5	(74.1)	-28.9		0.15	.0002	-0.33
Outcome 3 (%)	310	.039	0.042	n/a	409	.063	0.069	n/a	-0.027		0.01	.2328	-0.07

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.

**1. Sample size** of the intervention condition analytic sample for this outcome measure.

2. Unadjusted outcome mean, adjusted outcome mean, and unadjusted outcome standard deviation of the intervention condition analytic sample. 3. Sample size of the comparison condition analytic sample for this outcome measure. 4. Unadjusted outcome mean, adjusted outcome mean, and unadjusted outcome standard deviation of the comparison condition analytic sample.

	_				
5. Estimated impact of assignment to intervention		7. p-valu test of sta significan impact.	atistical	of e imp star	Effect size estimated pact in ndard
condition				dev	riation units.
on outcome measure.		Standard e impact est			



# STUDY DATA TABLE SHELLS • TABLE SHELLS FOR STUDIES WITH MORE THAN ONE POSTTEST 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.

Analytic	Interv	vention Cond	ition	Comp	Correlation		
Time Point	Sample size	Mean	(SD)	Sample size	Mean	(SD)	with Outcome
6 mos	350	3.98	(1.04)	420	3.99	(1.01)	
12 mos	315	3.96	(1.03)	382	3.96	(0.98)	
6 mos	345	990	(58)	419	1000	(62)	0.61
12 mos	310	991	(52)	410	997	(63)	0.62
6 mos	348	0.60	n/a	416	0.61	n/a	
12 mos	327	0.59	n/a	409	0.61	n/a	
6 mos	348	0.77	n/a	416	0.72	n/a	
12 mos	327	0.74	n/a	409	0.73	n/a	
	Sample Time Point 6 mos 12 mos 6 mos 12 mos 6 mos 12 mos 6 mos 6 mos	Sample         Sample size           Time Point         Sample size           6 mos         350           12 mos         315           6 mos         345           12 mos         310           6 mos         348           12 mos         327           6 mos         348	Sample Time Point         Sample size         Mean           6 mos         350         3.98           12 mos         315         3.96           6 mos         345         990           12 mos         310         991           6 mos         348         0.60           12 mos         327         0.59           6 mos         348         0.77	Sample Time Point         Sample size         Mean         (SD)           6 mos         350         3.98         (1.04)           12 mos         315         3.96         (1.03)           6 mos         345         990         (58)           12 mos         310         991         (52)           6 mos         348         0.60         n/a           12 mos         327         0.59         n/a           6 mos         348         0.77         n/a	Sample Time Point         Sample size         Mean         (SD)         Sample size           6 mos         350         3.98         (1.04)         420         420           12 mos         315         3.96         (1.03)         382           6 mos         345         990         (58)         419           12 mos         310         991         (52)         410           6 mos         348         0.60         n/a         416           12 mos         327         0.59         n/a         409           6 mos         348         0.77         n/a         416	Sample Time Point         Sample size         Mean         (SD)         Sample size         Mean           6 mos         350         3.98         (1.04)         420         3.99           12 mos         315         3.96         (1.03)         382         3.96           6 mos         345         990         (58)         419         1000           12 mos         310         991         (52)         410         997           6 mos         348         0.60         n/a         416         0.61           12 mos         327         0.59         n/a         409         0.61           6 mos         348         0.77         n/a         416         0.72	Sample Time Point         Sample size         Mean         (SD)         Sample size         Mean         (SD)           6 mos         350         3.98         (1.04)         420         3.99         (1.01)           12 mos         315         3.96         (1.03)         382         3.96         (0.98)           6 mos         345         990         (58)         419         1000         (62)           12 mos         310         991         (52)         410         997         (63)           6 mos         348         0.60         n/a         416         0.61         n/a           12 mos         327         0.59         n/a         409         0.61         n/a

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

**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.

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

2. Repeat this row for each available baseline measure.

**3.** If a direct pretest is either impossible or not feasible and a correlated pretest or pretest alternative is not available, baseline equivalence must be established using multiple sociodemographic characteristics (see Section 5.7 of Handbook Version 2.0).



direct pretests, report the correlation between the baseline measure and the outcome.

4. For baseline measures other than

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# STUDY DATA TABLE SHELLS • TABLE SHELLS FOR STUDIES WITH MORE THAN ONE POSTTEST 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.

	Follow- Intervention Condition						Comparisor	Estimated Effect					
Outcome Measure	Time Point	Sample size	Unadjusted Mean	Adjusted Mean	Unadjusted (SD)	Sample size	Unadjusted Mean	Adjusted Mean	Unadjusted (SD)	Impact	Standard error	<i>p</i> -value	Effect Size
Outcome 1	6 mos	350	4.19	4.21	(1.09)	420	4.01	3.98	(1.14)	0.22	0.03	.0843	0.15
Outcome 1	12 mos	315	4.43	4.48	(1.24)	382	4.41	4.39	(1.25)	0.09	0.01	.3352	0.05
	6 mos	345	18.4	18.6	(48.1)	419	47.0	47.5	(74.1)	28.9	0.12	.0002	0.33
Outcome 2	12 mos	310	18.7	18.5	(47.3)	410	46.0	46.5	(73.1)	28.0	0.14	.0004	0.31
Outcome 3(%)	6 mos	348	0.41	0.42	n/a	416	0.50	0.51	n/a	0.09	0.02	.0032	0.22
Outcome 3 (%)	12 mos	327	0.43	0.46	n/a	409	0.52	0.53	n/a	0.07	0.01	.0197	0.17

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

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.

<b>1. Sample size</b> of the intervention condition analytic sample for this outcome measure.	2. Unadjusted outcome mean, adjusted outcome mean, and unadjusted outcome standard deviation of the intervention condition analytic sample.	condition sample this outo	omparison n analytic for come	4. Unadjusted out adjusted outco unadjusted out deviation of the condition analyti	me mean, and come standard comparison	5. Estimate impact of assignmen intervention condition	t to		7. p-va of test statistic signific of impa	of al ance	8. Effect size of estimated impact in standard deviation	*
		measure	e.			on outcom	e				units.	
						measure.		6. Sta	andard err	or of		

6. Standard error of the impact estimate.



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# 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 *Handbook Version 2.0*). The Prevention Services Clearinghouse uses the WWC v5.0 missing data standards when there are missing data on eligible outcome measures, pretests, correlated pretests and pretest alternatives, or sociodemographic characteristics (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
<ol> <li>The outcome is imputed for some individuals in the analytic sample and the baseline measure is observed for all individuals in the analytic sample</li> </ol>	✓	
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 or missing for some individuals in the analytic sample	$\checkmark$	✓



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

Under Scenario I, where an outcome measure has some imputed values but the corresponding baseline measure(s) (i.e., pretest, correlated pretest, pretest alternative, or sociodemographic characteristics) 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 pretests, correlated pretests, or pretest 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 sociodemographic characteristics** (see Section 5.7 of the *Handbook Version 2.0*), 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 for cases where direct pretests, correlated pretests, or pretest alternatives are expected to be used for baseline equivalence.

		Intervention Condition	1			Correlation between	
Sample	Number of observations	Mean of protect SD of protect		Number of observations	Mean of pretest	SD of pretest	the pretest and outcome:
Entire analytic sample							not applicable
Sample for which both the outcome and pretest are observed		1	not needed	Ī		not needed	
1. The analytic sample	2. Measures	3.	This is the complete cases s	ample.			
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.						



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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 conditions or a single regression that includes an indicator variable for intervention status are acceptable. The set of baseline measures must include the demographic characteristics expected to be used for baseline equivalence and may include other baseline measures. Use the regression model(s) to predict outcome values for both 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 conditions 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 for cases where demographic characteristics are expected to be used for baseline equivalence.

		Interventio	n Condition			Compariso		R-squared from	
Sample	Number of observations	Mean of observed outcome	Mean of predicted outcome value	SD of predicted outcome value	Number of observations	Mean of observed outcome	Mean of predicted outcome value	SD of predicted outcome value	regression model(s)
Entire analytic sample		not needed				not needed			not applicable
Sample for which both the outcome and baseline measures are observed		T	not needed	not needed	Ī		not needed	not needed	
3. The analytic sample is the sample of participants			5. This is the com	plete cases sample.					
the sample of participants included in an analysis of the impact of the program or service on an outcome.	<b>4.</b> Measures are if they are not m imputed.								



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

Under Scenario II, where an outcome measure is observed for all individuals in the analytic sample and the corresponding baseline measure(s) (i.e., pretest, correlated pretest, pretest alternative, or sociodemographic characteristics) 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 pretest, correlated pretest, pretest alternative, or sociodemographics 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 pretest 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 missing and not imputed or missing baseline observations are imputed and study authors wish to report baseline descriptives with unimputed baseline data.

		Inte	ervention Condi	tion			Со	nparison Condi	tion		
Sample	Number of observations	Mean of pretest	SD of pretest	Mean of outcome	SD of outcome	Number of observations	Mean of pretest	SD of pretest	Mean of outcome	SD of outcome	Correlation between the pretest and outcome:
Entire analytic sample		not needed	not needed				not needed	not needed			not applicable
Sample for which both the outcome and pretest are observed		Ţ	-	T	not needed		Ţ	Ī	Ţ	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	sizes, means, and	standard deviatio	ns indicated for the	e complete cases	sample.		between	the correlation the pretest and me using only ted data.



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**Table A-5.** Scenario II, Option 2: Information to include for each baseline measure for which any missing observations are imputed and for which baseline descriptives using imputed data are reported.

		Inte	ervention Condi	lion							
Sample	Number of observations	Mean of pretest	SD of pretest	Mean of outcome	SD of outcome	Number of observations	Mean of pretest	SD of pretest	Mean of outcome	SD of outcome	Correlation between the pretest and outcome:
Entire analytic sample			not needed					not needed			not applicable
Sample for which both the outcome and pretest are observed		T	Ţ	Ţ	not needed	Ţ	Ţ	Ţ	Ţ	not needed	Ţ
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 of imputed.		port the samples s	izes, means, and	standard deviatio	ns indicated for the	e complete cases	sample.		between	the correlation the pretest 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 pretest as the dependent variable and the outcome as the independent variable. Either separate regressions for the intervention and comparison conditions 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 pretest 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 pretest 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 conditions are performed, report the average R-squared from the separate regressions.

Table A-6. Scenario II, Option 3: Information to include if the imputation model for the pretest included baseline measures in addition to the outcome.

		Inte	ervention Condi	tion			R-squared from				
		Observed pretest		Predicted pretest value				Observed pretest		Predicted pretest value	
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		Ī		not needed	not needed		Ī	Ī	not needed	not needed	
3. The analytic sample is the sample of participants included in an analysis of the impact of the program or service on an outcome.	4. Measure observed if are not mis imputed.	s are they	ort the samples siz	es, means, and st	andard deviations	of the pretest for	the complete case	es sample.			24



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# 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., pretest, correlated pretest, pretest alternative, or sociodemographic characteristics) 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 pretest, correlated pretest, pretest alternative, or sociodemographic characteristics 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 pretest 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-7.** Scenario III, Option 1: Information to include for each outcome-baseline measure pair for which the baseline measure is missing and not imputed and the outcome measure is imputed.

	Intervention Condition						Сог				
Sample	Number of observations	Mean of pretest	SD of pretest	Mean of outcome	SD of outcome	Number of observations	Mean of pretest	SD of pretest	Mean of outcome	SD of outcome	Correlation between the pretest and outcome:
Sample for which the pretest 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 pretest are observed			not needed		*			not needed		*	Ţ
Sample for which <b>only</b> the pretest is observed			not needed	not needed	not needed			not needed	not needed	not needed	not applicable
<b>4.</b> This is the concases sample.										e correlation betwo ome using only no	

**6.** This is the sample for which the pretest is observed and the outcome is missing or imputed.



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**1.** The sample for which the pretest 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 in which missing baseline and missing outcome data are imputed and the study reports baseline descriptives with imputed baseline data.

		Intervention Condition					Comparison Condition					
Sample	ob	lumber of servations	Mean of pretest	SD of pretest	Mean of outcome	SD of outcome	Number of observations	Mean of pretest	SD of pretest	Mean of outcome	SD of outcome	Correlation between the pretest and outcome:
Sample f which the pretest is observed	e S				not needed	not needed				not needed	not needed	not applicable
Sample f which the outcome observed	e • is		not needed	not needed		* 🛌		not needed	not needed		_ <b>_</b> *	not applicable
Sample f which bc the outco and preto are obse	oth ome est			not needed		*			not needed		*	
Entire an sample	alytic			not needed	not needed	not needed			not needed	not needed	not needed	not applicable
4. This is cases sa	the complet	te									e correlation betw	veen the pretest

**6.** Report the sample sizes and means of the pretest using the analytic sample *including imputed values*.



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