Missing Data in Group Design Studies: Revisions in WWC Standards Version 4.0

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Learning Goals for This Webinar

After this webinar, you will be able to:

- Identify methods the WWC considers acceptable for addressing missing data in group design studies
 - Randomized controlled trials (RCTs) and quasi-experimental designs (QEDs)
- Assess potential bias due to missing or imputed outcome data
- Assess baseline equivalence in the presence of missing or imputed baseline data





Learning Goals for This Webinar

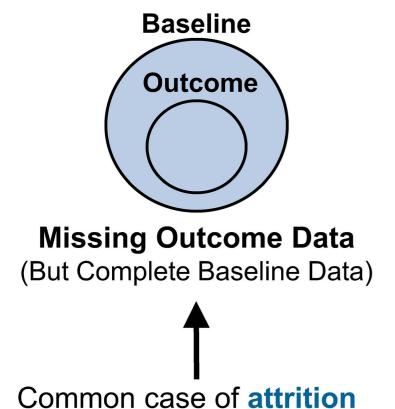
- This webinar does NOT aim to present every possible missing data scenario and all relevant mathematical formulas.
- However, by the webinar's end, you should know where to look for additional resources to review other potential scenarios.

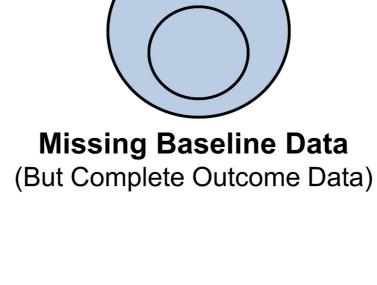




Why Missing Data Are Important

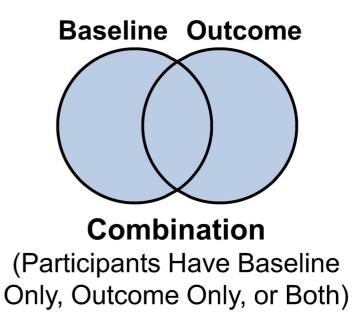
Missing data are extremely common in research studies.





Outcome

Baseline





Why Missing Data Are Important

Missing data can introduce bias and other analytic issues if participants with missing data systematically differ from those with observed data.

- In high school intervention studies, missing outcome data could represent students who have dropped out and who may be lower performing than students with observed data.
- In QEDs and high-attrition RCTs, missing baseline data present challenges in assessing whether intervention and comparison groups are similar at baseline.





Major Revisions to the WWC's Missing Data Standards

WWC Group Design Standards V3.0

- Only low-attrition RCTs can impute missing data and be eligible to meet WWC group design standards.
- Must use an acceptable approach to address all missing data in the analytic sample.

Studies can satisfy baseline equivalence only by using non-imputed data for the entire analytic sample.

WWC Group Design Standards V4.0

- All eligible group design studies can impute missing data and be eligible to meet WWC group design standards under certain circumstances.
- Must use an acceptable approach to address all missing data in the analytic sample (additional guidance given; dummy imputation added to the list).
- Studies can satisfy baseline equivalence using data on a subset of the analytic sample or imputed data for the analytic sample.

Source: WWC Standards Handbook Version 4.0, pages 36-46.

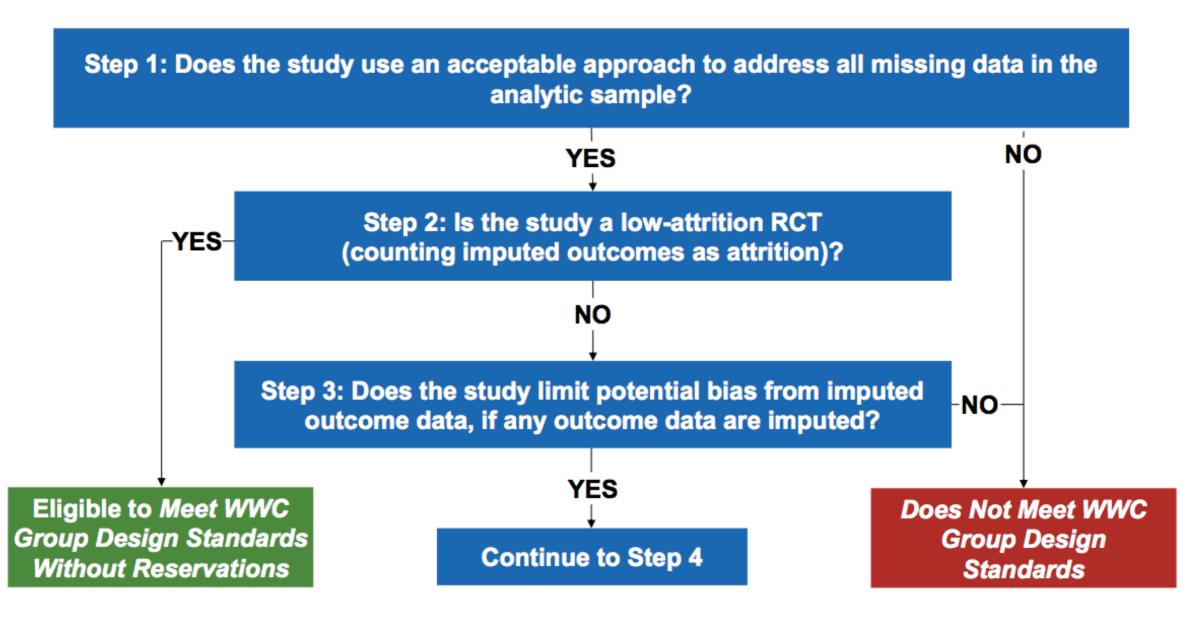


Three Driving Questions for Reviewing Studies With Missing or Imputed Data

- **1. Acceptable method:** Is the approach for addressing missing data acceptable?
- 2. Limited outcome bias: Is bias due to missing or imputed outcome data limited?
- **3. Baseline equivalence:** Are the intervention and comparison groups comparable, accounting for missing or imputed baseline data?



Overview of the Procedures for Studies With Missing Data

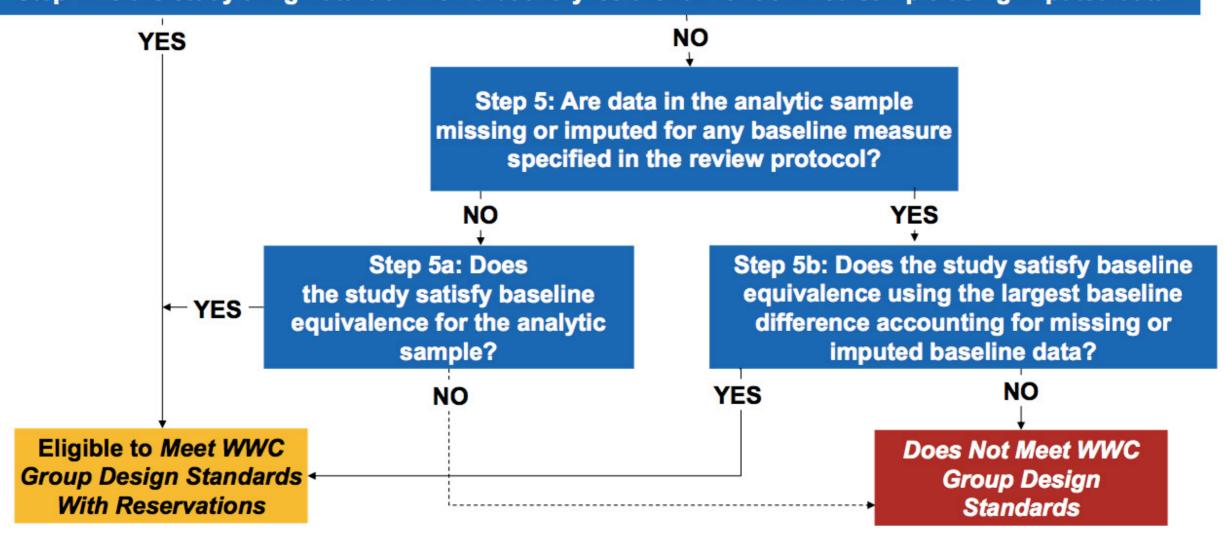


Source: WWC Standards Handbook Version 4.0, page 37.



Overview of the Procedures for Studies With Missing Data

Step 4: Is the study a high-attrition RCT that analyzes the full randomized sample using imputed data?



Source: WWC Standards Handbook Version 4.0, page 37.







Step 1. Acceptable Methods for Addressing Missing Data

- 1. Complete case analysis: Only analyze observations for which all data are not missing
 - Apply standard procedures for assessing attrition and baseline equivalence
- 2. Regression imputation: Replace missing values using a regression model
- **3. Dummy imputation:** Replace missing values with a constant (e.g., mean for non-missing observations) **AND** include a missing data indicator in the impact model
 - Mean imputation without an indicator variable is NEVER acceptable.
- 4. Maximum likelihood: Use an iterative routine to estimate model parameters while accounting for missing data (e.g., using full information maximum likelihood)
- 5. Non-response weights: Weight data based on the estimated probability of an individual having a missing outcome (more weight given to higher probabilities of missingness)
- Other methods: The WWC may consider other methods acceptable if supported by a citation to a peer-review journal article or textbook. Consult review team leadership.



Step 1. Acceptable Conditions for Applying the Methods

Can be used to include participants with missing...

Method	Study design	Baseline data	Outcome data	Additional (see Handbook)
Complete case analysis	All			
Regression imputation	All			3 requirements for imputation model (will be discussed in slide 14)
Dummy imputation	Non-compromised RCTs only*			
Maximum likelihood	All			Use standard statistical package or include relevant citations
Non-response weights	All		/ †	2 requirements for missing outcome data models (see <i>Handbook</i>)

^{*}However, for QEDs and compromised RCTs, dummy imputation can still be applied to baseline measures NOT specified in the review protocol as required to assess baseline equivalence.

Source: WWC Standards Handbook Version 4.0, pages 39-40.

[†]With non-response weights, participants without observed outcome data will not be included in impact estimation models, but participants with observed outcome data will be weighted so that they resemble the full sample with and without outcome data.



Study Example Used Throughout This Webinar

JOURNAL OF RESEARCH ON EDUCATIONAL EFFECTIVENESS 2016, VOL. 9, NO. 4, 473–502 http://dx.doi.org/10.1080/19345747.2016.1164777

INTERVENTION, EVALUATION, AND POLICY STUDIES

Assessing Impacts of *Math in Focus*, a "Singapore Math" Program

Andrew P. Jaciw^a, Whitney Michelle Hegseth^b, Li Lin^a, Megan Toby^a, Denis Newman^a, Boya Ma^a, and Jenna Zacamy^a

- Evaluated a core mathematics program, Math in Focus, used in 400+ U.S. districts
- Cluster RCT assigned 22 grade-level teams to receive the program or business as usual
- Webinar will focus on main outcome variable, Stanford Achievement Test 10 (SAT-10), measured before and after the intervention
- Study reported three approaches for handling both missing baseline and outcome data

Source: https://eric.ed.gov/?id=ED562089



Step 1. Application to Math in Focus study

- ❖ Complete case analysis: "We analyzed impact for the subsample of students with nonmissing pretest and posttest scores."
 - Eligible. Review of this analysis proceeds to Step 2.
- ❖ Dummy imputation: "We retained all students with a posttest, and used the dummy variable approach to impute missing values for the covariates."



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 - Eligible. Review of this analysis proceeds to Step 2.
- ❖ Dummy imputation: "We retained all students with a posttest, and used the dummy variable approach to impute missing values for the covariates."
 - Eligible. The study is a non-compromised RCT, and the method is applied to only missing baseline, but not outcome, data. Review proceeds to Step 2.
- ❖ Multiple imputation: "Allowed us to include as much of the randomized sample as possible in the impact analysis...We used SAS PROC MI (SAS Institute, 2006)."



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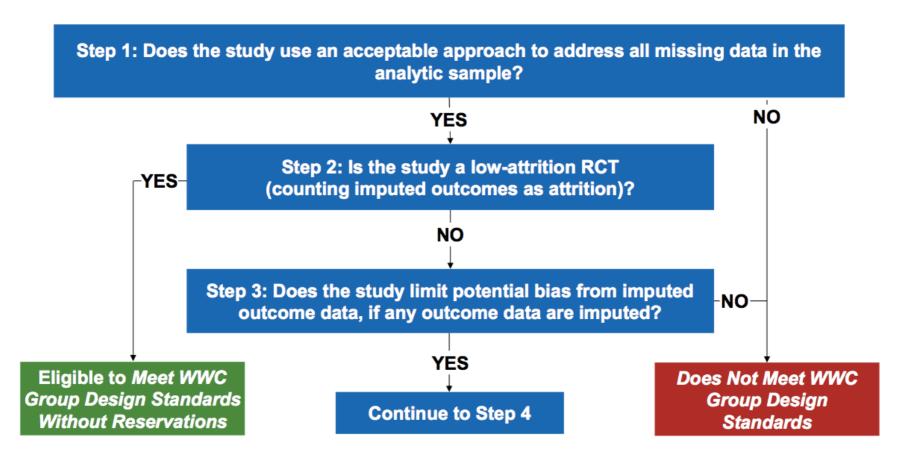
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 - Eligible. The study is a non-compromised RCT, and the method is applied to only missing baseline, but not outcome, data. Review proceeds to Step 2.
- ❖ Multiple imputation: "Allowed us to include as much of the randomized sample as possible in the impact analysis...We used SAS PROC MI (SAS Institute, 2006)."
 - Need more information. Send author query to see if the imputation regression model (a) was
 conducted separately by condition or included an indicator variable for condition, (b) included all
 covariates used for adjustment in the impact model, and (c) included the outcome when imputing
 missing baseline data (the 3 additional requirements referenced in slide 12).
 - After author query, it's ineligible. The authors told us that the imputation model did not include
 the outcome when imputing missing baseline data (requirement C above).



Potential WWC Ratings After Step 1

- If the study does not use an acceptable approach to address all missing data in the analytic sample, then it receives the Does Not Meet WWC Group Design Standards rating.
 - Applies to the multiple imputation analyses in the Math in Focus study.
- Review continues if the study uses an acceptable method for addressing missing data.





Knowledge Check 1

Which of the following CANNOT meet WWC group design standards?

- A. A high-attrition RCT that imputes missing baseline and outcome data using regression imputation
- B. A QED that uses dummy imputation to account for missing data on a baseline measure that is NOT required for assessing baseline equivalence
- C. A low-attrition RCT that imputes missing baseline data using the mean for non-missing observations
- D. A compromised RCT that uses maximum likelihood to analyze a sample with missing baseline and outcome data
- E. All of the above can meet WWC group design standards.



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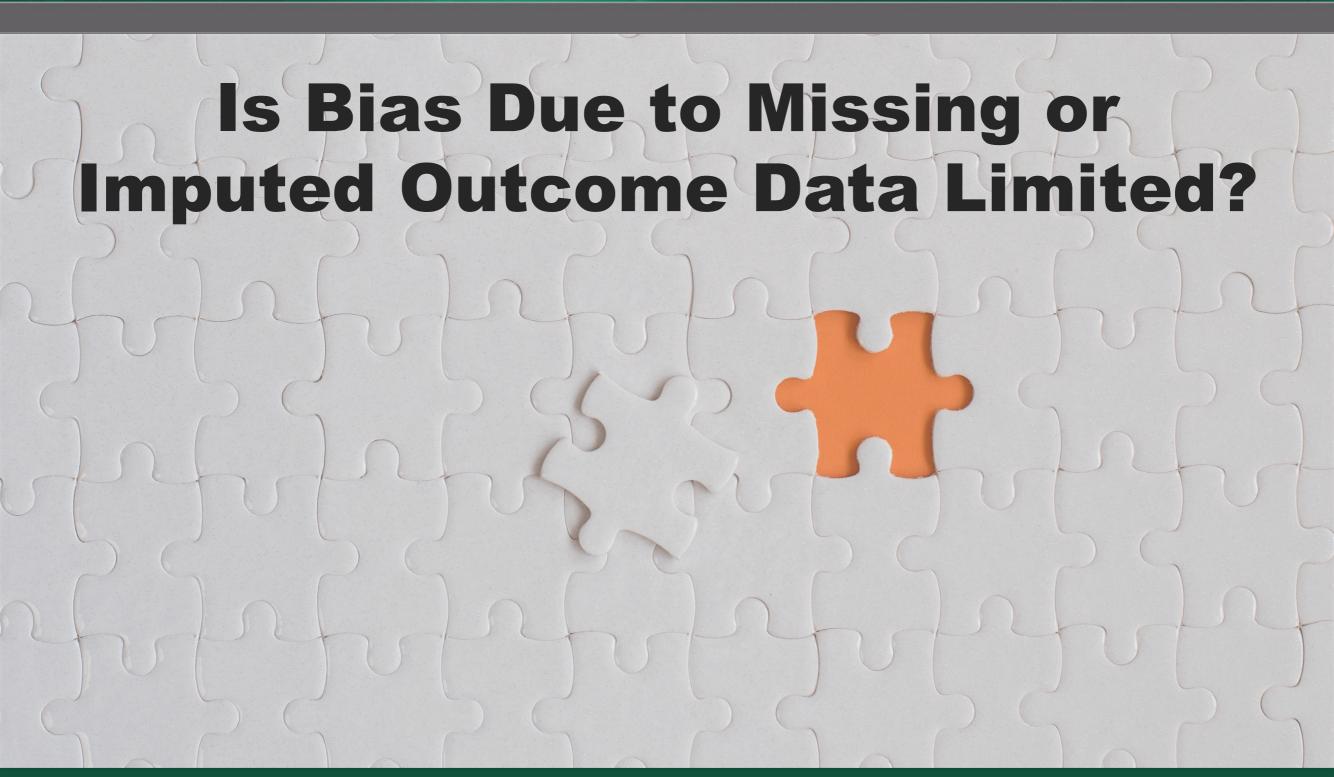
[†]With non-response weights, participants without observed outcome data will not be included in impact estimation models, but participants with observed outcome data will be weighted so that they resemble the full sample with and without outcome data.



Answer to Knowledge Check 1

- C is the correct answer. Mean imputation must include a dummy variable to indicate missingness. Mean imputation without a dummy variable is not acceptable for any group design.
- A is an incorrect answer. This is a high-attrition RCT that uses an acceptable method of imputation. Unless there are other design issues, this study is eligible to receive the *Meets WWC Group Design Standards With Reservations* rating.
- **B is an incorrect answer.** For QEDs, dummy imputation can still be used to account for missing data on measures that the review protocol does not require for assessing baseline equivalence. Unless there are other design issues, this study is eligible to receive the *Meets WWC Group Design Standards With Reservations* rating.
- D is an incorrect answer. Maximum likelihood is an acceptable method for accounting for missing data for any study design. Unless there are other issues, this compromised RCT is eligible to receive the *Meets WWC Group Design Standards With Reservations* rating.
- E is an incorrect answer. As noted above, option C does not meet WWC Group Design Standards.





Step 2. Is the Study a Low-Attrition RCT?

- If the study is a low-attrition RCT, no further review about missing or imputed data needed.
 - Eligible for highest rating, Meets WWC Group Design Standards Without Reservations, if the method for addressing missing data is acceptable (step 1) and no other issues (e.g., confounds, measurement issues) would reduce the rating.
 - If attrition is low, potential bias due to imputed outcome data is considered minimal.
 - Due to random assignment, groups are considered equivalent at baseline.
- ❖ IMPORTANT: Imputed outcome data count as attrition.
 - Denominator is based on the full randomized sample.
 - Numerator is based on the analytic (sub)sample with observed outcome data.
- QEDs, high-attrition RCTs, and compromised RCTs must proceed to Step 3.

Step 2. Application to Math in Focus Study

- ❖ 22 grade-level teams were randomly assigned (12 intervention; 10 comparison)
- One intervention team and one comparison team had no pretest and posttest data.
- Two other intervention teams had no posttest data.

	Intervention	Comparison
Randomized sample	12 teams	10 teams
Complete case (had pre and post)	9 teams	9 teams
Dummy imputation (had post)	9 teams	9 teams
Multiple imputation (had pre or post)	11 teams	9 teams

- ❖ In all reported analyses, total attrition is 4 / 22 = 18%. Even though multiple imputation included two more teams, their outcome data were imputed, which counts as attrition.
- Differential attrition is 15%, making this study a high-attrition RCT, even under the optimistic attrition boundary. Review proceeds to Step 3.

Knowledge Check 2

Researchers randomly assigned 50 students to an intervention group and 50 to a comparison group. By visiting schools one day before and one day after the intervention, researchers obtained data for the following numbers of students. Using a regression imputation model meeting WWC standards, the analytic sample included students who had pretest and/or posttest data.

	Intervention	Comparison
Randomized	50	50
Had pretest	43	41
Had posttest	45	40
Had pre AND post	41	38
Had pre OR post	47	43

What is the overall rate of attrition?

- \Box **A.** 5 / 84 = 6%
- □ B. 10 / 100 = 10%
- □ **C.** 15 / 100 = 15%
- □ **D.** 21 / 100 = 21%



Answer to Knowledge Check 2

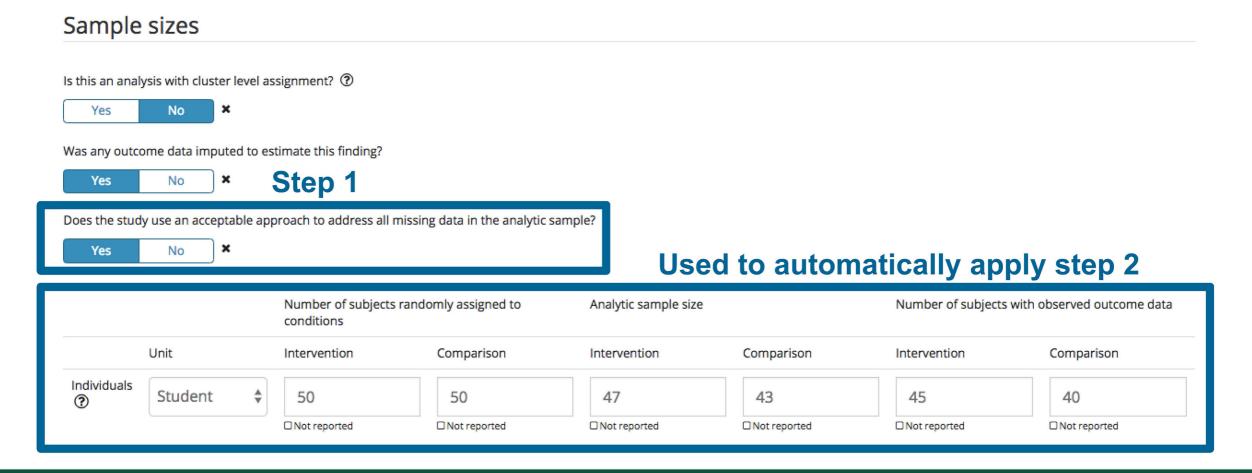
	Intervention	Comparison	
Randomized	50	50	
Had pretest	43	41	Analytic subsample with
Had posttest	45	40	← observed (nonimputed)
Had pre AND post	41	38	outcome data
Had pre OR post	47	43	← Analytic sample

- C is the correct answer (15%). The difference between the randomized sample and analytic sample with observed outcome data should be used to compute attrition. Researchers randomly assigned 100 students, and 85 had observed outcome data in the analytic sample (45 + 40 = 85). Hence, the overall rate of attrition is (100 85)/100 = 15%.
- A, B, and D are incorrect answers. The attrition rates for other options result from incorrectly treating randomly assigned students without pretest data (answer A), students with imputed posttest data (answer B), and students with imputed pretest data (answer D).
 - However, if analyses were restricted to the complete case sample, D (21%) would be correct because only 41 + 38 = 79 students would be in the analytic sample.



Steps 1 & 2. Using the Online Study Review Guide (SRG)

- The online SRG will help walk you through every step of this review process. https://ies.ed.gov/ncee/wwc/StudyReviewGuide
- Steps 1 & 2 are addressed after entering an outcome measure:



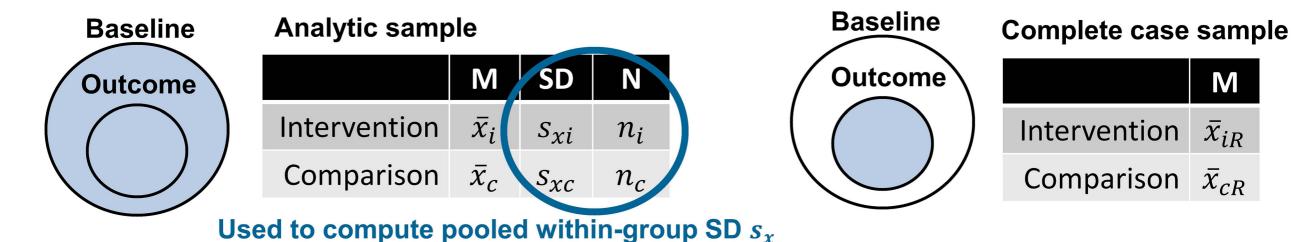
Step 3. Does the Study Limit Potential Bias From Imputed Outcome Data, If Any Outcome Data Are Imputed?

- Impact estimates may be biased if missing values depend on unmeasured factors.
- ❖ WWC requires bias due to imputed outcome data to be <0.05 standard deviations.</p>
- General idea: use observed data from other measures to bound the bias due to imputation.
 - For this step, use observed baseline data to bound the potential imputed outcome bias.
 - For a later step, use observed outcome data to bound the potential baseline difference.
- Correlation between the baseline and outcome measure is critical.
 - Higher correlation = better imputation = potential bias is more limited
- Formulas adapted from methodological work on item-level survey nonresponse.
 - Andridge, R. R., & Little, R. J. A. (2011). Proxy pattern-mixture analysis for survey nonresponse. Journal of Official Statistics, 27(2), 153–180.



Step 3. Does the Study Limit Potential Bias From Imputed Outcome Data, If Any Outcome Data Are Imputed?

- ❖ To answer this question, must know the following information about the baseline measure specified in the review protocol, as required for assessing baseline equivalence.
- Let's first focus on the scenario with no missing baseline data for the analytic sample:

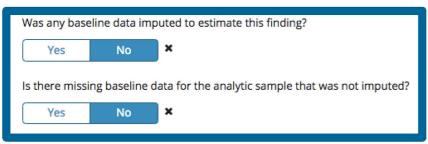


- Must also know the baseline-outcome correlation ρ:
 - Can be estimated based on complete case sample or an outside study if a content expert judges the settings to be similar.
 - Must not be estimated using imputed data.

Source: WWC Standards Handbook Version 4.0, page 42.



In the Online SRG, the Needed Information for Step 3 Is Entered After Entering a Baseline Measure

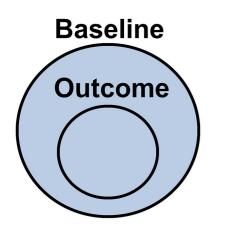


If any baseline data are missing or imputed, additional boxes will appear below asking for more information

	Subjects used to assess baseline equivalence		Subjects with observed baseline and outcome data			
	Intervention	Comparison	Intervention	Comparison		
Sample size	927	834	744	702		
	□ Not reported	□ Not reported	□ Not reported	□ Not reported		
Baseline Mean	-0.191	0.016	-0.097	0.052		
	□ Not reported	☐ Not reported	☐ Not reported	☐ Not reported		
	Subjects with observed baseline data					
	Intervention	Comparison				
Standard deviation	1.012	0.931				
	☐ Not reported	☐ Not reported		☑ Notes		
Correlation between baseline measure	outcome and			□ Notes		
.76						

Source: https://ies.ed.gov/ncee/wwc/StudyReviewGuide

Step 3. Does the Study Limit Potential Bias From Imputed Outcome Data, If Any Outcome Data Are Imputed?



	M	SD	N
Intervention	\bar{x}_i	S_{ix}	n_i
Comparison	\bar{x}_c	S_{CX}	n_c

Baseline Outcome Compute pooled within-group SD s_x

	M
Intervention	\bar{x}_{iR}
Comparison	\bar{x}_{cR}

Baseline-outcome correlation p

- The SRG will automatically apply formulas, but it helps to understand the basic approach.
- Assuming complete baseline data, all three following conditions must be met:

$$B1 = \omega \left(\frac{1 - \rho^2}{\rho}\right) \left(\frac{\bar{x}_c - \bar{x}_{cR}}{S_X}\right) < 0.05$$
Smaller for larger correlations
$$B2 = \omega \left(\frac{1 - \rho^2}{\rho} * \frac{\bar{x}_i - \bar{x}_{iR}}{S_X}\right) < 0.05$$

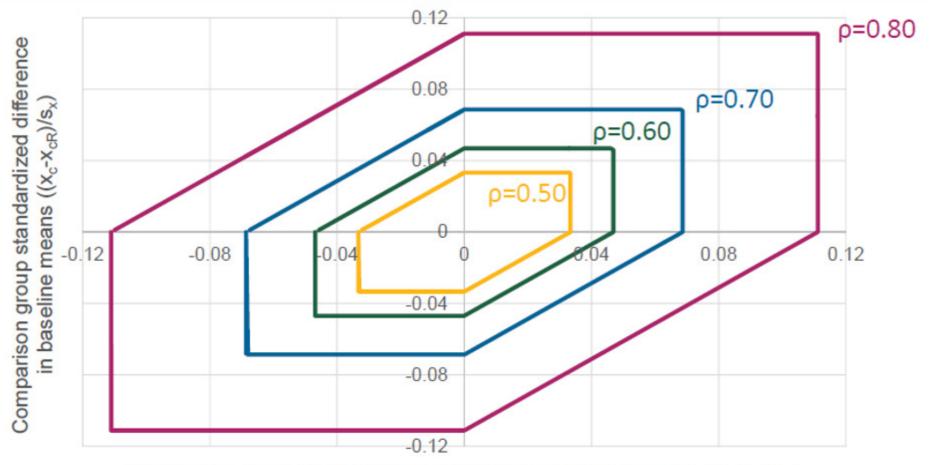
$$B3 = \omega \left(\frac{1 - \rho^2}{\rho} * \frac{(\bar{x}_i - \bar{x}_{iR}) - (\bar{x}_c - \bar{x}_{cR})}{S_X}\right) < 0.05$$

$$Where \omega = 1 - \frac{3}{4N - 9}$$

Source: WWC Standards Handbook Version 4.0, page B-3.

Step 3. Largest Differences in Baseline Means That Limit Potential Bias From Imputed Outcome Data

• For no missing or imputed baseline data (where ρ is the baseline-outcome correlation):



Intervention group standardized difference in baseline means ((x_i-x_{iR})/s_x)

Source: WWC Standards Handbook Version 4.0, page B-3 (inferred from formulas, ignoring the small-study correction term ω). This figure came from the WWC Reviewer Recertification Training webinar hosted on 1/12/18.

Knowledge Check 3

- Complete case analysis: "We analyzed impact for the subsample of students with nonmissing pretest and posttest scores."
- **Dummy imputation:** "We retained all students with a posttest, and used the dummy variable approach to impute missing values for the covariates... For each covariate with missing values, a dummy variable is added to the impact model."
- **Multiple imputation:** "Allowed us to include as much of the randomized sample as possible in the impact analysis... We used SAS PROC MI (SAS Institute, 2006) to carry out the Multiple Imputation step, and HLM Version 7.1 to estimate impact."

For the Math in Focus study, for which methods do we need to apply Step 3?

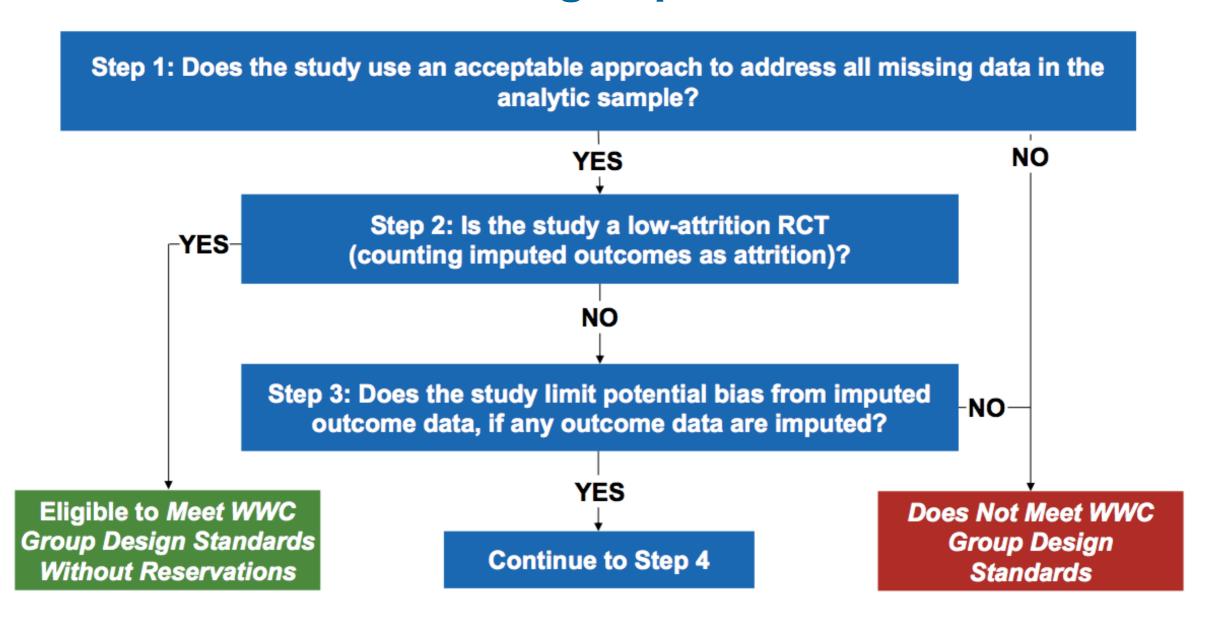
- A. Only dummy imputation
- B. Only multiple imputation
- C. Dummy and multiple imputation
- □ D. All three methods
- E. None of the methods



Answer to Knowledge Check 3

- **E** is the correct answer (none of the methods).
 - Only multiple imputation involved imputing outcome data. However, Step 3 is not required in this case because, from Step 1, we know that analysis will receive the *Does Not Meet WWC Group Design Standards* rating.
- A, B, C, and D are incorrect answers. For dummy imputation, only missing baseline (but not outcome) data were imputed. No data were imputed for complete case analysis.

Procedures After Assessing Imputed Outcome Data Bias



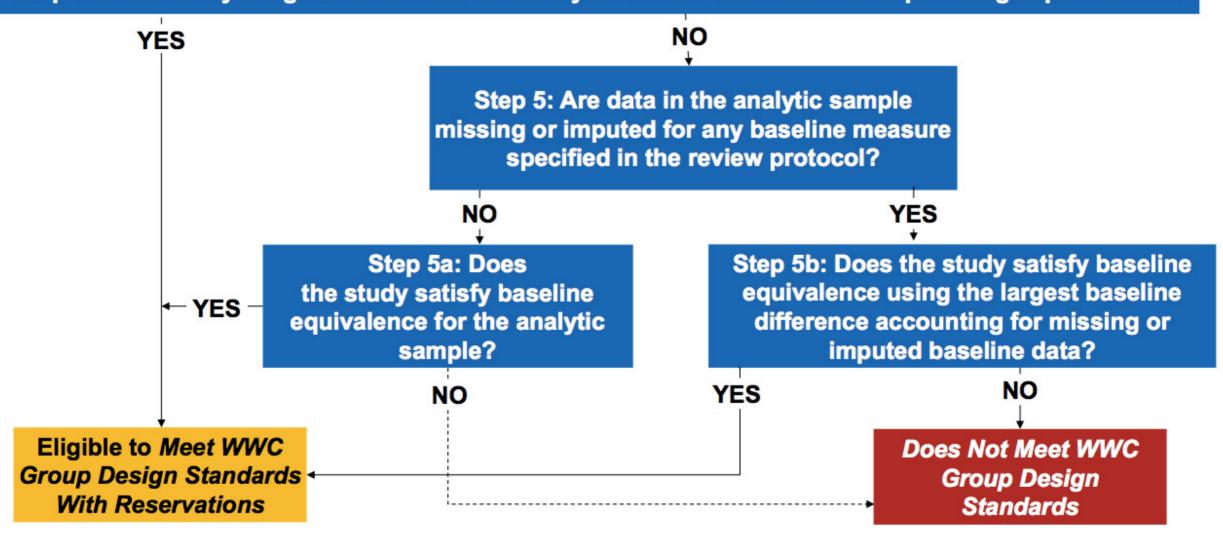
Source: WWC Standards Handbook Version 4.0, page 37.





Steps for Assessing Baseline Equivalence

Step 4: Is the study a high-attrition RCT that analyzes the full randomized sample using imputed data?



Source: WWC Standards Handbook Version 4.0, pages 37.

Step 4. Is the Study a High-Attrition RCT That Analyzes the Full Randomized Sample Using Imputed Data?

- Authors can analyze the full randomized sample by imputing all missing data.
 - Example: 100 students were randomly assigned, 80 had observed outcome data, and data were imputed for the 20 students with missing outcome data.
 - With the full randomized sample, groups are assumed to be equivalent at baseline due to randomization. Baseline equivalence does not need to be assessed.
- A high-attrition RCT can receive the Meets WWC Group Design Standards With Reservations rating if the full randomized sample is analyzed.
 - Assuming step 1 (acceptable method of imputation) and step 3 (limited bias due to imputed outcome data) have already been met.
- Does not apply to the Math in Focus study because randomized students who had both missing baseline and missing outcome data were not included in any analysis (e.g., two clusters did not contribute any baseline or outcome data).



Step 5a. Does the Study Satisfy Baseline Equivalence for the Analytic Sample?

- If the analytic sample includes no participants with missing or imputed data for the measures required by the protocol to satisfy baseline equivalence, use the usual WWC procedures to assess baseline equivalence.
 - For the Math in Focus study, this applies only to the complete case analysis.
- Reminder: baseline equivalence should be assessed for each analytic sample.
 - Example: A QED with three outcomes that each have different missingness
 - Baseline equivalence must be assessed for at least three analytic samples (unless analyses are restricted to those with complete data for all outcomes).
- Use Step 5b instead if some data are missing or imputed for a baseline measure that the review protocol requires for assessing baseline equivalence.



Step 5b. Is Baseline Equivalence Satisfied Accounting for Missing or Imputed Baseline Data?

- Baseline equivalence for the analytic sample cannot be assessed directly if some baseline data are missing or imputed.
- However, formulas are provided for estimating how large the baseline difference could be based on a set of reasonable assumptions.
- Only apply these formulas if data are missing or imputed for the baseline measure(s) that the review protocol specifies as necessary for assessing baseline equivalence.
 - Otherwise, apply standard procedures (i.e., Step 5a), even if data were missing or imputed for other baseline measures.



Step 5b. Needed Information About Outcome Measure If Baseline Data Are Missing or Imputed

- Always must know the baseline-outcome correlation ρ
- Essentially the same information as in Step 3, but instead for the outcome measure
- Let's first focus on the simple scenario of no missing or imputed outcome data:

Outcome					Outcome
Baseline		M	SD	N	Baseline
	Intervention	$ar{y}_i$	s_{iy}	n_i	
	Comparison	\bar{y}_c	s_{cy}	n_c	

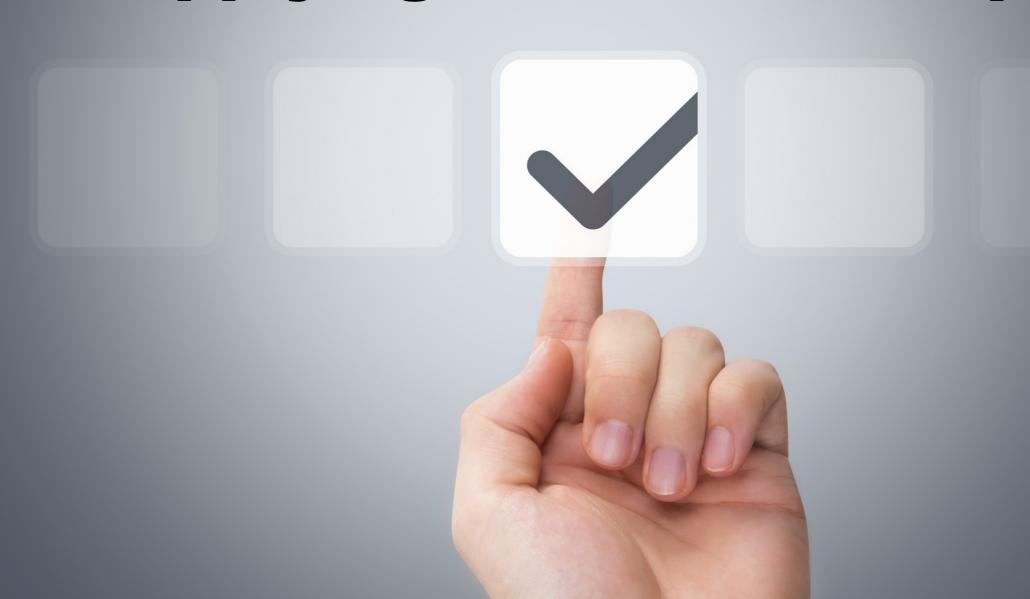
Outcome		
Baseline		M
	Intervention	$ar{y}_{iR}$
	Comparison	\bar{y}_{cR}

- Also need to compute the baseline standardized mean difference, either for the imputed sample (left figure) or the complete case sample (right figure).
 - Separate baseline equivalence formulas are used depending on what's reported.
 - Standard deviations, however, must be based on the observed baseline sample.

Source: WWC Standards Handbook Version 4.0, pages 45-46, C-3, C-4.



Applying All Review Steps



Complete Review of Math in Focus Study

Step 1: Is the method for addressing missing data acceptable?

- Yes, for complete case analysis and dummy imputation.
- No, for multiple imputation, because the imputation model did not include the outcome when imputing missing baseline data.

❖ Step 2: Is the study a low-attrition RCT?

No, attrition is high for all analytic samples.

Step 3: Is potential bias from imputed outcome data limited?

 Not a necessary step for complete case analysis and dummy imputation. Also not necessary for multiple imputation because, from Step 1, the imputation model did not meet WWC standards.

Step 4: Is the full randomized sample analyzed using imputed data?

No, randomized students with neither baseline nor outcome data were excluded from analysis.



Complete Review of Math in Focus Study

- Step 5: Are any baseline data (needed to assess equivalence) missing or imputed?
 - No, for complete case analysis. Assess baseline equivalence as normal (Step 5a).
 - \triangleright Baseline difference is g = 0.08 according to the reported information.
 - Outcome model adjusts for this baseline difference.
 - > Eligible for Meets WWC Group Design Standards With Reservations.
 - Yes, for dummy imputation. Apply Step 5b. Ask authors for information about the outcome measure to assess baseline equivalence using the formulas in the Handbook's Appendix C.
 - ➤ Highest possible rating is *Meets WWC Group Design Standards With Reservations*.
- Even without an author query, study is eligible to receive Meets WWC Group Design Standards With Reservations rating given the complete case analysis.



Using the Online SRG to Simplify Complex Scenarios

- One of the most complex possible scenarios:
 - High-attrition RCT
 - Imputed baseline AND imputed outcome data
 - But still some randomized participants were not analyzed due to missing both baseline and outcome data (hence, Step 4 does not apply and baseline equivalence must be assessed)
- This scenario describes the multiple imputation analyses in the *Math in Focus* study (if the imputation model had satisfied Step 1).
- With the online SRG, you simply enter the needed information; the SRG does the rest (e.g., automatically apply formulas and review steps).



Source: https://ies.ed.gov/ncee/wwc/StudyReviewGuide



Knowledge Check 4

A high-attrition RCT assigned 60 students to the intervention group and 60 to the comparison group. Outcome data are available for 50 students in the intervention group and 45 students in the comparison group. Baseline data are available for 45 students in the intervention group and 50 students in the comparison group. The authors imputed all missing baseline and outcome data using an acceptable approach; the analytic sample consisted of 60 intervention students and 60 comparison students.

Which of the following is true?

- A. Study is eligible to receive *Meets WWC Group Design Standards Without Reservations* rating if it limits the possible bias from imputed outcome data.
- B. Study is eligible to receive *Meets WWC Group Design Standards With Reservations* rating if it limits the possible bias from imputed outcome data and satisfies baseline equivalence using the largest baseline difference accounting for missing and imputed data.
- □ C. Study is eligible to receive Meets WWC Group Design Standards With Reservations rating if it limits the possible bias from imputed outcome data.

Answer to Knowledge Check 4

- C is the correct answer. The study uses an acceptable approach to address all missing data in the analytic sample (Step 1), is a high-attrition RCT (Step 2), and analyzes the full randomized sample (Step 4). Therefore, it is eligible to receive the *Meets WWC Group Design Standards With Reservations* rating if it demonstrates that the potential bias from analyzing imputed outcome data is limited (Step 3).
- A is an incorrect answer. Even though the study uses an acceptable method of imputation (Step 1) to analyze all participants in the full randomly assigned sample (Step 4), participants with imputed outcome data count as missing data when calculating attrition (Step 2). In this case, attrition is high. Therefore, the study is not eligible to receive the *Meets WWC Group Design Standards Without Reservations* rating.
- B is an incorrect answer. A high-attrition RCT that analyzes the full randomly assigned sample using imputed data does not need to satisfy the baseline equivalence requirement to be eligible to receive the rating *Meets WWC Group Design Standards With Reservations* (Step 4).



Questions & Answers



Submit questions in the chat box window if you have not already done so.



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