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# A Practical Guide on Designing and Conducting Impact Studies in Education: Lessons Learned From the What Works Clearinghouse (Phase I)

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## Introduction

The What Works Clearinghouse (WWC) was established in 2002 by the U.S. Department of Education's Institute of Education Sciences (IES) to evaluate and synthesize research evidence for the effectiveness of educational interventions and to serve as a central and trusted source of scientific evidence for what works in education. The purpose of this paper is to provide practical guidance on critical design, implementation, analysis, and reporting issues for impact studies in education and related fields, drawing upon our five years of experience with the first phase of the WWC as well as state-of-the-art knowledge of the field. We will also illustrate, with real examples from the WWC reviews, common pitfalls to avoid in designing and conducting impact studies. Unless otherwise noted, discussions related to the WWC pertain only to WWC's work during its first five years.

This paper is not meant to be a comprehensive handbook about research design, but rather a quick reference guide highlighting some of the key issues in impact studies based on our WWC experience. The audience for this paper is researchers—primarily novice researchers and even some experienced researchers—who design and conduct impact studies in education and other social science fields. Information presented in this paper also may help consumers of such research (e.g., peer researchers, policy makers, intervention developers, and practitioners) make better informed judgments about the quality of the research and the credibility of the evidence produced from the research.

This paper is organized in the order in which an impact study is typically conducted. We will first discuss issues related to sampling design, and then issues pertaining to study implementation, data analysis, and reporting. The paper ends with concluding remarks.

# Sampling Design

#### Overview

The quality of an impact study hinges critically upon its sampling design, particularly on whether a comparison group is used and if so, the nature of the comparison group. Impact studies that employ one-group pretest-posttest designs are subject to serious threats to internal validity (Shadish, Cook, & Campbell, 2002). It is widely recognized that the use of a comparison group that is similar to the intervention group is essential, although not necessarily sufficient, for drawing valid inference about an intervention's impact. This is because a comparison group that did not receive the intervention but was otherwise similar to the intervention group allows us to

<sup>&</sup>lt;sup>1</sup> The first phase of the WWC was administered by IES through a five-year contract with the American Institutes for Research<sup>®</sup> and the Campbell Collaboration. The clearinghouse is currently operated by Mathematica Policy Research, Inc.

<sup>&</sup>lt;sup>2</sup> By "impact studies," we refer to studies that are designed to assess the impact of an intervention—which may be a program, a product, a practice, or a policy—on certain outcomes, such as student achievement.

infer what would have happened in the absence of the intervention, which provides the basis for estimating the causal effect of the intervention.<sup>3</sup>

This paper, therefore, focuses on designs of impact studies that incorporate a comparison group created through either random or nonrandom sample allocation. In the remainder of this section, we discuss issues related to sample allocation for both randomized controlled trials (RCT) and quasi-experimental designs (QED) with equating, which are rigorous designs most commonly used for impact studies in education and the focus of the WWC Phase I standards development and study reviews. We will also discuss issues related to statistical power and sample size, which, although not the focus of WWC standards or reviews, are other key aspects of sampling design for impact studies.

## Sample Allocation for Randomized Controlled Trials

Random assignment is the hallmark of RCTs. It refers to the assignment of units (e.g., students, classrooms, schools, or districts) to different study conditions based entirely on chance. Random assignment ensures that prior to the intervention, participants in the intervention group are similar on both observed and unobserved characteristics to their counterparts in the comparison group. If random assignment is successfully implemented, then differences between the two groups observed after the intervention are more likely to be caused by the intervention rather than their preexisting differences. In the absence of random assignment, however, the study groups may differ in important characteristics prior to the intervention. As a result, inferences about the intervention's causal effects based on the observed differences between groups after the intervention are necessarily more tentative, because we will be unable to rule out alternative explanations (e.g., preexisting differences between the groups) for the observed differences.

By means of random assignment, RCTs provide the most reliable study design for causal inference, and are considered the "gold standard" for impact studies. Although nonrandomized experiments often incorporate design features to approximate RCTs, they could not always replicate the results generated by RCTs. The impact estimates based on randomized experiments and nonrandomized experiments testing the same interventions often produce different results; the differences are sometimes substantial and often unpredictable (Bloom, Michalopoulos,

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<sup>&</sup>lt;sup>3</sup> The causal effect of an intervention, under Rubin's potential outcomes framework of causality, is the average difference between the outcomes that were observed for subjects who received the intervention and the outcomes that would have been observed had the subjects not received the intervention (Rubin, 1974; Little & Rubin, 2001). <sup>4</sup> QEDs also include regression discontinuity designs and single-case designs. Regression discontinuity designs are designs in which participants are assigned to the intervention and the comparison conditions based on a cutoff score on a preintervention measure that typically assesses need or merit. Single-case designs are designs that involve repeated measurement of a single subject in different conditions or phases over time. As the WWC standards for these special QED designs are still under development, we will not address them in this paper. Studies reviewed by the WWC were judged against the WWC Evidence Standards (WWC, 2006a). Well designed and implemented RCTs Met Evidence Standards. QEDs with equating and no severe design or implementation problems and RCTs with severe design or implementation problems Met Evidence Standards With Reservations, Studies providing insufficient causal evidence for an intervention's effect Did Not Meet Evidence Screens. <sup>5</sup> To be more precise, randomization equates groups on expectation; that is, on the mean of the distribution of sample means resulting from all possible random assignments of units to conditions (Shadish et al., 2002). In reality, it is possible that the randomized groups may differ on observed characteristics by chance; such differences can be substantial, particularly when the sample size is small.

& Hill, 2005; Fraker & Maynard, 1987; Glazerman, Levy, & Myers, 2003; and Kunz & Oxman, 1998). It is generally agreed that nonrandomized experiments are no substitute for RCTs, although nonrandomized experiments may produce impact estimates that are comparable to those based on RCTs under certain circumstances (Cook, Shadish, & Wong, 2008).

## Methods of Random Assignment

Random assignment of study participants to different study conditions is often carried out by means of a random number table or a random number generator, the flip of a coin, or the roll of a die. What these procedures have in common is that the determination of each participant's assignment is completely based on chance and is totally unpredictable and, hence, "random." The random assignment can be arranged so that the number of participants allocated to each study condition is the same (i.e., balanced sample allocation). It may also be arranged so that participants are allocated to study conditions based on a pre-specified ratio (e.g., two comparison units for every intervention unit). Unbalanced sample allocation may be justified in certain situation. For example, an intervention may be deemed too expensive to implement across a large group of participants; the researcher therefore may choose to assign more participants to the comparison group than to the intervention group under budget constraints.

Random assignment can be carried out across the full sample or *within* blocks or strata that consist of participants with similar characteristics. A study of a teacher professional development program, for instance, may randomly assign teachers to the program group or the comparison group within each participating school rather than across all participating schools. This type of design is often referred to as a multisite design, where each block (school in the example) can be viewed as a distinct study site and the overall study viewed as a series of site-specific replications. The use of blocking ensures that all blocks are properly represented in each study condition. Moreover, it may help improve the precision of the impact estimates, as will be explained in the section on statistical power.

## Functionally Random Assignment

Sometimes researchers form study groups through *haphazard assignment*, a procedure that is not formally random but is ostensibly irrelevant to the characteristics of the study participants or outcomes. Some haphazard assignment procedures may approximate random assignment reasonably well in certain circumstances and may be considered *functionally* random. For example, a researcher may first order students by an identification code (e.g., social security number) and then alternate assignment by the last digit of the identification code (e.g., "evens" are placed into Group A and "odds" Group B). Since students whose identification code ends with an even number are unlikely to be systematically different from students whose identification code ends with an odd number, this method of assignment can be considered functionally random. Other examples of haphazard assignment that might be functionally random include (a) alternating alphabetically by last name (e.g., Acosta is placed into Group A,

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<sup>&</sup>lt;sup>6</sup> Cook et al. (2008) suggest three conditions under which a nonrandomized experiment *may* produce causal estimates that are comparable to those based on a randomized experiment: (1) It uses a regression discontinuity design; (2) it matches intact treatment and comparison groups on at least the pretest; or (3) it properly models the selection process.

and Aguilera Group B) and (b) alternating by date of birth (e.g., January 5 is placed into Group A, January 7 Group B, January 13 Group A, and so on).

As Rosenbaum (1999) points out, however, haphazard is not random, and ostensibly haphazard assignment can produce severe and undetected biases that would not be present with truly random assignment. Examples of haphazard assignment that are unlikely to be functionally random include (a) placing birth months January–June into Group A, birth months July–December into Group B; (b) placing participants with a last name beginning with A–M into Group A, and last names beginning with N–Z into Group B; and (c) placing the first 20 arrivals into Group A, and the last 20 arrivals into Group B. These seemingly haphazard assignment methods may actually result in systematically different study groups. In the last example, for instance, the early arrivals are likely to have a stronger interest in the event and more motivated to attend the event than late arrivals, and such differences may introduce selection bias that confounds the intervention's effects.

A special type of haphazard assignment procedure adopted by some education researchers is to assign students to different study conditions using a class-scheduling software program. Although assignment based on scheduling programs could be functionally random, very often it is not, because there are typically pre-specified rules or constraints in the scheduling process. For example, certain types of students or classes (e.g., gym, band, and art classes) might be first entered into the scheduling system before the other students are randomly assigned. This might mean, for example, that all students who take band are not eligible for placement in the intervention class(es), but are placed in the comparison class(es). Such nonrandom rules or constraints imposed on an otherwise random scheduling process is likely to compromise the randomness of sample assignment unless (1) such rules or constraints are completely unrelated to student characteristics or outcomes, or (2) the analytic sample of the impact analysis is limited to students not affected by the nonrandom scheduling rules or constraints.

Unlike random assignment, which is based on fact, haphazard assignment involves judgment, and it is often difficult to determine what is functionally random and what is not. The use of haphazard assignment, therefore, should generally be avoided, particularly given that true random assignment is often feasible in situations where haphazard assignment is feasible.

## Level of Random Assignment

Random assignment can take place at different levels. In individual randomized trials, individuals are randomly assigned to the intervention condition and the comparison condition. In cluster randomized trials (CRT), which are also referred to as group randomized trials or place-based randomized trials, entire clusters or groups of individuals (e.g., classrooms, schools, or districts) are randomly assigned to different conditions. The randomization of clusters ensures that the study groups will be equivalent on expectation (i.e., on the average values across all possible randomized samples) in both cluster and individual characteristics, even if randomization is not carried out at the individual level. Nevertheless, individuals could be randomly assigned to clusters before clusters are randomly assigned to conditions, which will lead to improved statistical power and greater precision of the impact estimate (Schochet, 2008a).

In education as well as other social science fields, CRTs have become a popular design choice for a number of reasons (Bloom, 2005). First, most educational interventions are intended to be implemented at the cluster level (e.g., whole-school reform operates across the school). It is therefore logical to carry out the assignment at the cluster level as well. Second, a major problem with individual randomized trials is treatment diffusion or spillover, which occurs when individuals in the intervention condition influence individuals in the comparison condition through, for instance, sharing intervention information or experiences. Because the comparison group receives some of the same treatment given to the intervention group, spillover weakens the intervention/control contrast and therefore dilutes the intervention's effect. By creating a spatial separation between individuals in different study conditions, randomization at the cluster level can potentially minimize the occurrence of spillover effects and maintain the integrity of random assignment. Finally, from a practical point of view, randomizing clusters, such as whole schools, instead of individual students, is likely to incur less political opposition and logistical challenges and is thus often a more viable option.

CRTs, however, have drawbacks as well. During our WWC Phase I reviews, we found that most CRTs in education were based on a limited number, sometimes only a handful, of clusters. One obvious consequence of having too few clusters is the lack of statistical power. As will be explained later, the statistical power of a CRT depends primarily on the number of clusters rather than the number of individuals within clusters. As a result, CRTs generally need a much larger sample size and incur higher costs in order to achieve the same level of power as RCTs with individual-level assignment.

Another potential problem with CRTs is that when very few clusters are randomly assigned, randomization may fail to balance all sample characteristics, and the differences in covariate distributions across study conditions may introduce selection bias that confounds the intervention's effect. This is because randomization relies on the law of large numbers and equates groups on the *expected* values of pre-intervention characteristics over all possible randomized samples, but not necessarily on the *observed* values of a particular sample. When only a small number of units are randomized, it is quite possible that the study groups will differ in important ways due to large sampling errors. In extreme cases, a study sample may include only two clusters (e.g., teachers, classrooms, or schools), with one cluster randomly assigned to each condition. Such "N=1" studies are particularly problematic in that randomization in this case is completely ineffective in removing preexisting differences between the study groups, as we will explain in further detail under Scenario (1) in the section to follow.

#### The "N=1" Problem

"N=1" studies include CRTs with only two clusters as well as other types of RCTs and QEDs with only one cluster per condition. A major problem with such studies is that the intervention's effects may be completely confounded with cluster effects (e.g., teacher effects or school effects), which makes it impossible to draw a valid conclusion about the intervention's effects unless it is reasonable to assume that cluster effects are negligible. This assumption, however, is often untenable (e.g., in a study of classroom practice, it is equivalent to assuming that there are no teacher effects). Surprisingly, such "N=1" studies are by no means rare. Over 70 QEDs of beginning reading interventions, for example, that went through WWC Phase I reviews failed to

meet the WWC evidence screens because of this confounding problem. In general, "N=1" studies may fall under three scenarios. <sup>7</sup> We discuss each in turn in the following paragraphs. Scenario (1): RCTs with one teacher or school randomly assigned to each condition and students not randomly assigned, and analogous QEDs

In this scenario, two intact clusters (e.g., two classrooms and their teachers or two schools) are randomly assigned to the intervention and the comparison conditions. Although such a study still qualifies as an RCT, it suffers a serious internal validity threat because randomization in this case cannot remove any of the preexisting group differences at either the teacher level or the student level. Such differences may confound the intervention's effects because outcome differences between the study groups may reflect a mix of the intervention's effects and preexisting differences in both teacher and student characteristics between the groups.

In addition to the internal validity problem, designs with one intact cluster per condition also have an estimation problem, because a correct statistical analysis that properly takes into account the clustering of students within classes or schools (i.e., a multilevel analysis) cannot be done with only two clusters and, hence, zero degree of freedom. Although a few options are available for analyzing such data, they are all imperfect and rely on strong and untestable assumptions (Varnell, Murray, & Baker, 2001). It is for these reasons that RCTs with one cluster randomly assigned to each condition generally did not meet WWC evidence screens.

During the WWC Phase I reviews, we found that Scenario (1) was relatively rare for RCTs, but much more common for QEDs. Of the approximately 1,400 QEDs that were rated as "*Does Not Meet Evidence Screens*" during the WWC Phase I reviews, 118 failed to meet the evidence screens because there was only one teacher or school assigned in a nonrandom way to each study condition and there was no evidence that the teacher or school effects were negligible (see Exhibit 1 for an illustrative example).

#### **Exhibit 1. A QED With One School per Condition**

#### Summary of Study Design

The purpose of the study is to assess the effects of a whole-school reform on the reading achievement of students with limited English proficiency. The study sample consisted of one elementary school that had already started the reform prior to the beginning of the study and a comparison school selected from the same district. The two schools were similar in overall achievement levels, but differed substantially in school size and demographic composition. The researchers assessed the reform's impact by comparing the reforming school and the comparison school in student performance on a series of reading tests using multivariate analysis of variance, followed by univariate analyses of variance, at the student level.

## **Design Flaw**

The main problem with this study is that with only one school per condition, the reform's effects were totally confounded with school effects. In other words, it is impossible to know whether any of the observed differences in student outcomes between the two schools were caused by the reform or simply reflective of the preexisting differences between the two schools in school size, demographic composition, and possible differences in other unmeasured school characteristics (e.g., school climate, teacher quality, school resources, or school policy).

<sup>&</sup>lt;sup>7</sup> The WWC technical guidance on <u>Teacher-Intervention Confound</u> provides a detailed discussion about this issue, which can be found at WWC's Web site: <a href="http://ies.ed.gov/ncee/wwc/pdf/teacher\_confound.pdf">http://ies.ed.gov/ncee/wwc/pdf/teacher\_confound.pdf</a>.

Scenario (2): RCTs with one teacher or school per condition and students randomly assigned to conditions<sup>8</sup>

While random assignment is carried out at the cluster level in Scenario (1), it is carried out at the individual level in Scenario (2). In some studies, one teacher may teach the intervention condition and a different teacher may teach the comparison condition. Students are then randomly assigned to the two teachers/conditions. This design is seriously flawed because the intervention's effects are completely confounded with teacher effects and the impact estimates represent a mix of these two types of effects. If, for example, the more experienced teacher delivers the intervention, then it would not be appropriate to attribute the differences in student outcomes between the two conditions exclusively to the intervention, as such differences may be due to the intervention, due to the difference in teacher experience, or most likely due to both.

In certain circumstances, it is possible that teacher effects are negligible. For instance, a computer instruction program may be relatively freestanding and require little teacher engagement in the actual programmatic instruction and measurement of outcomes. In a comparison of two such computer programs, teachers might have little effect on either condition and the potential bias due to teacher-intervention confound may be considered negligible or limited. If this is the case, then the study would not have been downgraded during the WWC Phase I reviews for the "N=1" problem, if it did have other design or implementation problems. This, however, is not the case in the example shown in Exhibit 2.

#### **Exhibit 2. An RCT With Teacher-Intervention Confound**

#### Summary of Study Design

This RCT was designed to test the effect of a math curriculum software program on high school students' math achievement. It took place in one high school, where all ninth-grade students enrolled in Algebra I in the study year were randomly assigned to either intervention classes or traditional classes. The intervention classes were taught by a teacher trained in the use of the curriculum software program and the traditional classes were taught by a regular classroom teacher using a traditional textbook. At the end of the semester, all students took the state-mandated, end-of-course test. The researcher then compared the percentage of students passing the test in the two study groups using a chi-square test.

#### Design Flaw

This study design is flawed because it does not allow the researcher to separate out intervention effects from teacher effects, which were unlikely to be negligible because the teachers were deeply involved in both conditions. The difference in students' passing rate on the state test might well be explained by the differences between the two teachers rather than the differences between the curricula in the two study conditions. Therefore, the internal validity of this study is highly questionable even though the study did employ random assignment.

<sup>8</sup> Analogous QEDs are not discussed under this scenario because they are the same type of QEDs discussed under Scenario (1) (i.e., QEDs with one cluster per condition and nonrandom assignment of clusters and students).

Scenario (3): RCTs with one teacher teaching both conditions and students randomly assigned to conditions, and analogous QEDs

In some RCTs, one teacher may teach both the intervention and the comparison conditions, and students are randomly assigned to the two conditions. Such a study is a fair test of the intervention if it is reasonable to assume that (a) the teacher's ability and motivation to teach students in the intervention condition is the same as his or her ability and motivation to teach students in the comparison condition, or (b) teacher effects are negligible because the intervention requires very little input on the part of the teacher. The study is not a fair test of the intervention if neither assumption is tenable and should be downgraded according to WWC standards, because the teacher-intervention confound would pose a serious threat to the internal validity of the study (see Exhibit 3 for an example).

#### **Exhibit 3. An RCT With One Teacher Teaching Both Conditions**

#### Summary of Study Design

The purpose of this study was to test the effectiveness of a particular math instructional approach in improving the math achievement of middle school students. Participants in the study were sixth graders from one middle school who were randomly assigned to two classes. One class was randomly assigned to be the experimental class and the other the control class. The researcher taught both classes. He taught the experimental class using the experimental instructional approach and taught the control class using the traditional instructional approach. The relative effects of the two instructional approaches on students' math achievement were assessed using independent-samples t-tests and ANOVA.

#### **Design Flaws**

As the researcher himself noted in the study report, researcher bias for or against the experimental instructional approach because of his previous knowledge of the intervention could have affected the outcome of the study. Indeed, the teacher-intervention confound posed a potential threat to the internal validity of the study, as the differences in student outcomes between the two conditions could not be attributed conclusively to the differences in instructional approach. The impact estimates from this study may well depend on the capability of the teacher to deliver the instruction as intended in the two different study conditions.

The potential problem with one teacher teaching both conditions also applies to QEDs. Unless there was strong evidence that teacher effects were negligible, QEDs in which one teacher taught both conditions would generally be downgraded to "*Does Not Meet Evidence Screens*" based on the WWC standards.

### Sample Allocation for QEDs

Although random assignment of cases to conditions is ideal for causal inference, it is not always feasible for practical or ethical reasons. Very often, the evaluation of an intervention's impact employs a quasi-experimental design (QED), a design for impact studies in which units are not randomly assigned to conditions. Lacking random assignment, QEDs are vulnerable to internal validity threats because systematic differences—which can be observed or unobserved—may exist between the nonrandomly formed study groups, and such differences (i.e., selection bias) may confound the intervention's effects. Researchers can, however, reduce selection bias and enhance the internal validity of QEDs through thoughtful choices of design features, particularly design features that improve group equivalence or comparability. Two of the most commonly

used and potentially effective design features for improving group equivalence are matching at the sampling stage and statistical adjustment at the data analysis stage.

## **Equating Groups Through Matching**

Matching refers to a collection of methods for creating a comparison group that is as similar as possible to the intervention group on covariates that are likely correlated with the outcome. If a QED relies on matching as the primary strategy for reducing selection bias, then at a minimum matching should be done on a pre-intervention measure (pretest) of the outcome or a close proxy measure for the pretest. In addition to pretest, it is advisable that matching also be done on other preexisting variables that are strongly related with the outcome (e.g., student age, ethnicity, and socioeconomic status, or school demographic composition). The appropriate matching variables are likely to vary depending on the nature of the intervention (e.g., a beginning reading curriculum or an early childhood education program), the outcomes of interest (e.g., reading achievement or school readiness), and the units of matching (e.g., student-level matching or school-level matching).

An important task for the design of a QED is thus to identify—based on substantive knowledge of the field and existing empirical evidence—a set of key covariates that are most likely to introduce selection bias and make sure that the study groups are equivalent on these potential confounders through either matching or statistical adjustment. The review protocol for each WWC topic area, for instance, specified a set of sample characteristics that should be equated for QEDs. While all topic areas require that participants in different study groups of a QED must be equated on a pretest, a good proxy of pretest, or prior achievement, some of the additional required equating variables are topic-specific. The review protocol for the topic area of English language learners, for example, requires that study groups in QEDs must be equated not only on pretest or a proxy of pretest, but also on level of English language skills and grade level. For the early childhood education topic area, although QEDs are required to demonstrate group equivalence only in pretest or a proxy of pretest, the review team will also consider whether study groups are equivalent along the dimensions of age and prevalence of developmental delays and disabilities, among others.

Matching can be done at different levels (e.g., school level or student level). There has been evidence that matching of intact groups (e.g., whole schools) instead of, or prior to, matching of individuals is particularly effective in reducing selection bias in QEDs (Cook et al., 2008). Moreover, where appropriate, the comparison units should be selected from the same geographic area as the intervention units to which they are matched so as to maximize the comparability of the intervention and the comparison groups (e.g., match reforming schools and comparison schools within the same district). <sup>10</sup>

<sup>&</sup>lt;sup>9</sup> The WWC topic areas include beginning reading, elementary school math, middle school math, English language learners, early childhood education, character education, and dropout prevention. The review protocol that guides the WWC review in each topic area can be found at the WWC's Web site: <a href="http://ies.ed.gov/ncee/wwc/">http://ies.ed.gov/ncee/wwc/</a>.

<sup>&</sup>lt;sup>10</sup> It may not be advisable, however, to match schools within the same district if the reforming schools are a highly select group of schools that are clearly different from the other schools in the district.

A simple way to implement matching is through blocking or stratification, where units with similar values on a matching variable are first grouped into blocks or strata and then assigned to different study conditions within blocks or strata. This strategy can effectively equate groups on a single matching variable, but quickly becomes impractical as the number of variables to be matched increases. For matching on multiple variables simultaneously (i.e., multivariate matching), two common approaches are propensity score matching (Rosenbaum & Rubin, 1983; Rubin & Thomas, 2000) and matching based on Mahalanobis distance (Cochran & Rubin, 1973; Rosenbaum & Rubin, 1985; Rubin, 1979, 1980). Both approaches identify matched units based on a multivariate measure of similarity (or "distance") in terms of covariate values so that the matched groups have balanced covariate distributions.

In propensity score matching, the balanced distributions of multiple covariates are achieved through matching on a single summary index—the propensity score, which, in Rosenbaum and Rubin's (1983) seminal work, is defined as "the conditional probability of assignment to a particular treatment given a vector of observed covariates" (p. 41). <sup>11</sup> Clearly, the ability to balance a large number of covariates simultaneously is a major strength of propensity score matching. Matching methods based on propensity scores, however, are not without limitations. The effectiveness of propensity score matching depends critically on the quality of the data available. Unlike randomization, propensity score matching can only reduce bias due to observed covariates, but cannot remove bias due to unobserved covariates, except to the extent that the unobservables are correlated with the observables. Thus, where causality is concerned, propensity score matching can only approximate, but not substitute for, randomization.

Another limitation of propensity score matching is that its effectiveness depends on sample size. If only a small pool of potential comparison units is available, then it may be difficult to find a good match for every intervention unit. Propensity score matching does not work well either for studies with a limited number of intervention units. This is because the estimation of propensity scores is based on a logit or probit model and is highly unreliable if the number of intervention units is too small relative to the number of covariates used to predict the propensity scores. As a rule of thumb, the number of parameters in a logistical regression model should not exceed m/10, where m is the number of cases with a value of the dichotomous outcome that is less likely to be observed (Peduzzi, Concato, Kemper, Holford & Feinstein, 1996). It implies that there should be at least 10 intervention units for each covariate included in a propensity score model. This requirement sometimes renders propensity score matching inappropriate for interventions implemented on a limited scale.

For studies with a limited sample size, Mahalanobis metric matching may provide a more viable alternative (Cochran & Rubin, 1973; Rosenbaum & Rubin, 1985; Rubin, 1980). Instead of matching on propensity scores, Mahalanobis metric matching matches on Mahalanobis distance, which is a measure of overall similarity between two units with respect to a set of covariates and is calculated based on the covariate differences between the units and the sample variance-covariance matrix. Since it does not involve statistical modeling, Mahalanobis metric matching requires few assumptions and is very flexible, particularly in situations where matching

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<sup>&</sup>lt;sup>11</sup> Other than matching, propensity scores can also be used to reduce selection bias through subclassification, reweighting samples, or regression adjustment (D'Agostino, 1998; Rosenbaum & Rubin, 1983).

is to be done on a relatively small set of key covariates.<sup>12</sup> It can be used alone or in combination with propensity score matching where appropriate. A number of empirical studies have found, for instance, that Mahalanobis metric matching within boundaries ("calipers," in technical terms) defined by the propensity score to be superior to either method used alone (Gu & Rosenbaum, 1993; Rosenbaum & Rubin, 1985; Rubin & Thomas, 2000).

## **Equating Groups Through Statistical Adjustment**

While matching is often used to create a comparison group that is similar to the intervention group on preexisting characteristics at the sampling stage, statistical adjustment (e.g., covariate adjustment through regression-based models, such as analysis of covariance) attempts to equate existing non-equivalent groups statistically at the data analysis stage. Like matching variables, the appropriate covariates for statistical adjustment are potential confounders, i.e., variables that might be responsible for the observed outcome differences between study groups. They may include a pretest measure or a close proxy for the pretest and other covariates such as student or school demographic variables. Statistical adjustment may not only help reduce selection bias due to preexisting group differences, but also improve the statistical power of the impact analysis, as will be explained in the section to follow.

Statistical adjustment as a strategy for reducing selection bias, however, has limitations. Obviously, it can only adjust for observed covariates but not unobserved covariates. QEDs that rely solely on covariate adjustment for equating groups therefore cannot rule out alternative explanations for the observed effects due to unobserved covariates.

Further, it has been well recognized in the statistical literature that regression-based covariate adjustment is not always trustworthy. When substantial differences in covariate distributions exist between the study groups, covariate adjustment may overcorrect or undercorrect for the initial bias, because it relies heavily on extrapolation and strong model assumptions (Cochran & Rubin, 1973; Rubin, 2001). Serious lack of overlap between treatment and control conditions in the covariate distribution often goes unnoticed in regression analysis with covariate adjustment; however, it can be easily detected in propensity score matching. As a single summary index of an entire collection of covariates, propensity scores allow a straightforward assessment of the degree of overlap in covariate distributions between the intervention and comparison groups (Rubin, 1997). Insufficient overlap in covariate distributions indicates that the two study groups are too different to warrant a valid estimation of the intervention's effects. Propensity scores thus provide an important diagnostic tool for assessing the quality of the comparison group and the validity of the intervention effect estimates.

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<sup>&</sup>lt;sup>12</sup> Mahalanobis metric matching becomes less effective as the number of covariates increases, as it is attempting to obtain balance on all possible interactions of the covariates, which is very difficult in a multivariate space. See Stuart and Rubin (2008) for an excellent review on various matching methods for causal inference, and Rubin (2006) for a comprehensive collection of publications authored by Rubin and his colleagues on matched sampling. <sup>13</sup> See Rubin (2001, p. 174) for a discussion of the basic distributional conditions that must be met for regression-based adjustment to be trustworthy. Based on Ho, Imai, King, and Stuart (2007), the recently released Version 2 WWC standards require that for both RCTs with severe attrition and QEDs, baseline differences on each important covariate must be less than 0.25 of a standard deviation based on pooled sample. Otherwise, they *Do Not Meet Evidence Standards* even with statistical adjustment (WWC, 2008).

Even if sufficient overlap in covariate distributions exists, propensity score matching methods may still be superior to regression-based adjustment, which requires assumptions about the functional form of the relationships between covariates and outcomes that may be difficult to test (Morgan, 2001). Propensity score methods, on the other hand, rely on weaker and often more plausible assumptions and are more robust to misspecification than regression-based models (Drake, 1993). It thus comes as no surprise that propensity score methods have been gaining popularity as a strategy for reducing selection bias and improving the validity of causal inference in nonexperimental studies across disciplines (e.g., Foster, 2003; Heckman, Ichimura, & Todd, 1997; Hill, Waldfogel, Brooks-Gunn, & Han, 2005; Hong & Raudenbush, 2006; Imbens, Rubin, & Sacerdote, 2001; Rosenbaum, 1986).

As a matter of fact, one does not have to choose between matching and statistical adjustment, which are best viewed as complementary rather than competing strategies. Research has shown that matching combined with covariate adjustment is more effective in removing selection bias than either method used alone (Rubin, 1973, 1979; Rubin & Thomas, 2000). Matched sampling ensures that the study groups are at least roughly comparable on the observed covariates, and covariate adjustment may be able to reduce the remaining differences on the observed covariates between the matched groups and improve the precision of the impact estimates.

#### **Exhibit 4. A QED Lacking Baseline Equivalence**

#### Summary of Study Design

This study assessed the impact of a federally funded program designed to promote high school graduation and college enrollment among low-income students. The intervention group consisted of a sample of students who participated in the program during a 10-year period. The comparison group consisted of a sample of students who were eligible for the program but *chose* not to participate. The two groups differed significantly in certain background characteristics. The percentage of students whose mothers had at least some college education, for example, was more than twice as high in the intervention group as in the comparison group. The study authors assessed the program's impact by comparing the postsecondary enrollment rate of the program participants and the rate for the comparison students with a chi-square test.

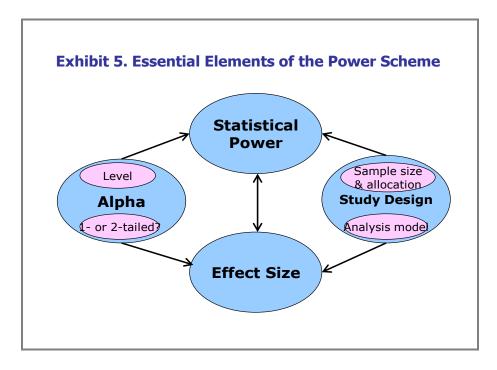
#### Design Flaw

This study provides a typical example of selection bias—students in the intervention group chose to participate in the program and students in the comparison group chose not to. The sample characteristics confirm the lack of baseline equivalence of the study groups, which, however, was left unaddressed in the impact analysis. Therefore, the internal validity of the study was in jeopardy, as one cannot be sure that the different postsecondary enrollment rates of the two groups were caused entirely by program participation. The different background characteristics of the study groups may well constitute a reasonable alternative explanation.

## **Statistical Power and Sample Size**

In addition to sample allocation methods, another key decision regarding the sampling design of a study is the sample size needed to achieve adequate statistical power. Put simply, statistical power is the probability that a statistical test will yield a statistically significant result, given a true effect of a specified magnitude (Cohen, 1988). For impact studies, power can be defined as the probability of detecting an intervention's impact of a given magnitude at a pre-specified significance level (i.e., alpha, or the Type I error rate) under a given study design. Adequate power is essential for statistical conclusion validity because insufficient power may lead a researcher to incorrectly conclude that the intervention does not have a significant impact when it actually does. Determining sample size based on a proper power analysis also prevents wasting resources on collecting and analyzing data from a sample larger than necessary. Therefore, we feel it is important to include the issue of statistical power in our discussion about sampling design in primary studies, even though it was not the focus of the WWC Phase I reviews. <sup>14</sup>

Power analyses are usually conducted to determine the sample size needed for a study to have a reasonable chance of correctly rejecting a false null hypothesis (i.e., avoid making a Type II error). Power is affected by more than sample size; rather, it depends on a set of interrelated parameters or design elements related to the study. As shown by the "power scheme" depicted in Exhibit 5, power is determined by alpha, study design, and the true effect of the intervention being tested (effect size). In the remainder of this section, we discuss in detail how power is related to each of the elements in the power scheme, and suggest strategies for increasing power. Our discussion focuses on continuous outcomes such as students' test scores.



<sup>&</sup>lt;sup>14</sup> It is an exception rather than a norm for study authors to report the statistical power of their study, or the methods and assumptions used in their power analysis. Therefore, the WWC did not systematically assess the adequacy of the statistical power of individual studies.

## Power and Study Design

## **Power and Sampling Plan**

Power is affected by study design, which has two dimensions: the sampling plan and the analysis model. The sampling plan has two further elements: the total sample size and the allocation of the sample to different study conditions. Power not only depends on sample size, but also on the methods of sample allocation; in particular, on whether the assignment of units to study conditions is carried out at the individual level or the cluster level and whether blocking or stratification is used in the assignment process. If assignment occurs at the cluster level, then the number of clusters will be a much more important determinant of power than the number of individuals within clusters, particularly for data exhibiting a nontrivial degree of clustering as measured by the intra-class correlation (ICC). 15 Whether the assignment is random or not, however, does not directly affect power.

Another sampling design feature that affects power is blocking or stratification used in multisite studies where the assignment of participants is carried out within blocks or strata that consist of participants with similar characteristics (e.g., assignment of students within schools). Blocking is a popular strategy for improving power, because it increases the precision (i.e., reduces the standard error) of the impact estimate by removing the outcome variance attributable to differences between blocks. 16 It is particularly effective when a large proportion of the outcome variance exists between blocks as opposed to within blocks. There is a trade-off, however, in that the gains in precision resulting from blocking may be offset to some extent by the loss of degrees of freedom due to the incorporation of block effects in the impact analysis, particularly if blocks are treated as random effects rather than fixed effects (see the following section for further discussion about this issue).

## **Power and Analysis Model**

Since power is the probability of detecting a statistically significant intervention effect, it is obviously affected by the statistical model of the impact analysis. In particular, it is affected by whether covariate adjustment is used and whether blocks or sites in multisite designs are treated as fixed effects or random effects, assuming that the impact analysis is based on the proper unit of analysis and properly takes multiple comparisons, if relevant, into account.<sup>17</sup>

Covariate adjustment has been widely recognized as an effective strategy for increasing power in impact studies (Bloom, Richburg-Hayes, & Black, 2007; Raudenbush, 1997; Raudenbush, Martinez, & Spybrook, 2007). Intuitively, covariate adjustment reduces the "noise" in the data

<sup>&</sup>lt;sup>15</sup> ICC is a measure of the correlation or dependence among units within the same clusters. For two-level clustered data, it is computed as the proportion of the total variance of the outcome that lies between clusters. Power is negatively related and highly sensitive to the value of ICC, which varies with the type of outcome and the type of clusters. See Hedges and Hedberg (2007) for a compilation of ICC values for achievement outcomes in designs involving school-level assignment.

<sup>&</sup>lt;sup>16</sup> Blocking has another benefit—improved face validity, for blocking ensures that the different study groups are

perfectly balanced in all block characteristics.

17 See Critical Issues in Data Analysis section for further discussions about the issues of unit of analysis and multiple comparisons.

caused by the covariates and thus makes it easier to detect the "signal" (i.e., intervention effect). In technical terms, covariate adjustment increases power by reducing the amount of unexplained variance of the outcome and hence improving the precision of the impact estimate. As a result, a smaller sample size is needed to achieve a given level of power. The reduction in sample size can be substantial if the covariates included in the impact analysis, such as a pretest, are strongly related to the outcome (Bloom et al., 2007). It is for this reason that covariate adjustment is recommended not only for QEDs but also for RCTs, even if the study sample is well balanced on the covariates as a result of random assignment.<sup>18</sup>

For studies with cluster-level assignment, the covariates adjusted can be at either the individual or the cluster level. In general, individual-level covariates are preferable because they can reduce the outcome variance at both the individual and cluster levels, whereas cluster-level covariates can only reduce the outcome variance at the cluster level. <sup>19</sup> Moreover, individual-level covariates do not affect the degrees of freedom of the impact analysis, whereas each cluster-level covariate will cost at least one degree of freedom, which may decrease power if the number of clusters is small. Cluster-level covariates, however, are likely to be more easily available and can potentially be as effective as individual-level covariates in boosting power (Bloom et al., 2007).

For multisite designs, power is also affected by another analytic decision, i.e., whether sites are treated as fixed or random effects in the impact analysis. This decision should also be made based on the nature of the sites and the purpose of the statistical inference. If the study sites are regarded as unique entities (for example, as in a purposive sample) and the focus of the study is on the impact just for the sites in the study sample, then it is appropriate to treat sites as fixed effects. If, however, the researcher views the study sites as a random sample drawn from a larger population of all possible sites, and wishes to generalize the impact findings from the study sites to the larger population of sites, then the random-effects model may be more appropriate.<sup>20</sup>

The distinction between fixed-effects and random-effects models has important power implications. In fixed-effects models, both the average outcome and the intervention effect are assumed to be fixed across sites. Between-site variance is assumed to be zero and thus does not enter the variance calculations for the impact estimates. In random-effects models, however, both the average outcome and the intervention effect are assumed to vary randomly across sites; hence, between-site variance can be a major source of variance for the impact estimate. As a result, impact estimates based on random-effects models tend to be less precise than those based on fixed-effects models. Moreover, the number of degrees of freedom associated with the significance test also tends to be smaller in random-effects models than in fixed-effects models, because degrees of freedom are mainly determined by the number of sites for random-effects

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 $<sup>^{18}</sup>$  If the covariates are not balanced, as in a QED with inadequate matching, the variance of the impact estimate will be inflated by a factor of  $1/(1-R^2)$  due to the correlation (R) between the covariate(s) and the intervention status.

<sup>&</sup>lt;sup>19</sup> Reducing cluster-level variance is much more important for improving power than reducing individual-level variance, because cluster-level variance is the binding constraint on power in cluster randomized trials. Nevertheless, the reduction of individual-level variance may also have an appreciable effect on power, particularly in studies with relatively few individuals per cluster and studies with a low degree of clustering.

<sup>&</sup>lt;sup>20</sup> Schochet (2008a) argues that fixed-effects models are usually more realistic for evaluations of education interventions, because the sites in most multisite studies are purposively selected and limited in number. Therefore, it is often not appropriate to assume that the study sites are representative of a larger, well defined population.

models and by the total number of clusters (in studies with cluster-level assignment) or the total number of individuals (in studies with individual-level assignment) for fixed-effects models. Therefore, a multisite study often needs to recruit a much larger sample to achieve the same level of power if site effects are to be treated as random rather than fixed.

## Power and Alpha

Another key element in the power scheme is the significance level, alpha (or the Type I error rate), for the statistical test. All else equal, the higher the alpha, the easier it is to achieve statistical significance, and hence the more powerful the design will be. By convention, alpha is usually set at .05 in a power analysis based on a two-tailed test, which is more conservative and less powerful than a one-tailed test.

In some cases, it may be justifiable to use a one-tailed (or directional) statistical test. A one-tailed test, for example, is often chosen when there are strong a priori reasons to expect an effect in a certain direction. Alternatively, one may argue that a one-tailed test should be used when a statistically significant finding in the opposite direction to the one hypothesized would have the same implications as a null finding (Cohen, 1988). For example, if the purpose of a program evaluation is to inform decisions about whether to support a particular program or not, a one-tailed test would be justified—assuming that the program will be supported only if it produces beneficial effects. If, however, a statistically significant finding in the direction opposite to the one hypothesized has different implications than a null result, a two-tailed test should be used for the impact analysis and for power calculations. An example might be a study that is designed to assess the relative effectiveness of two reading interventions. In this study, a significant finding in one direction would indicate that one reading intervention was more effective, and a significant finding in the opposite direction would indicate that the other reading intervention was more effective. Both types of findings are meaningful and should be distinguished based on a two-tailed test.

#### Power and Effect Size

Last, but not least, power depends on an intervention's effect on the outcome of interest. Intuitively, other things being equal, the larger the effect of an intervention, the easier it is to detect it, and the greater the statistical power. In practice, an intervention's effect is commonly expressed in a standardized metric—the effect size metric—to adjust for the different and often arbitrary units of measurement of different outcome measures. For impact studies, the most commonly used effect size index is standardized mean difference, which is defined as the difference between the mean outcome of the intervention group and the mean outcome of the comparison group divided by the pooled within-group standard deviation of the outcome (Lipsey & Wilson, 2001).<sup>21</sup>

<sup>&</sup>lt;sup>21</sup> Under certain circumstances (e.g., when the standard deviation of the outcome for the intervention group is affected by the intervention), it is preferable to use the standard deviation of the comparison group rather than the pooled standard deviation to compute the effect size, because presumably the standard deviation of the comparison group is unaffected by the intervention and is therefore a better estimate of the population standard deviation.

It is worth noting that effect size in the power scheme is a population parameter, which, like other population parameters, is usually unknown and difficult to guess. If researchers have a good idea about the effect size of the intervention to be tested (e.g., based on experience or evidence from prior research), then they can use this expected effect size as the basis for estimating the sample size needed to achieve the target level of power at a given level of alpha. A more common approach to power analysis, however, is to compute the "minimum detectable effect size" (MDES) based on desired alpha and power level under a given study design, and adjust the sample size so that the MDES meets a desired target. Very often, the target MDES is established based on what the researcher believes is the smallest policy-relevant or practically meaningful effect size that the study should be designed to detect rather than a guess of the true effect size of the intervention.

## Conducting Power Analysis Based on MDES

More formally, MDES represents the smallest intervention effect, expressed in the effect size metric, that can be detected as being statistically significant at the pre-specified alpha level and power level for a given study design (Bloom, 1995, 2005). Conventional practice in social science research sets alpha at .05 for a two-tailed test and target power at 80%, which ensures a reasonably good chance of detecting a true intervention effect, but is not so high that the sample size needed would be prohibitively large (Cohen, 1988). With both alpha and power set by convention, a power analysis typically centers on the relationship between sample size and MDES. It attempts to answer the question: What is the sample size needed to achieve the target MDES based on the pre-specified alpha and power level under the given study design? For a given alpha level and power level, MDES is a function of the standard error of the impact estimate, which in turn is a function of the sample size and variance components at different levels of the data.

To acquire the basics for conducting a power analysis, readers are referred to Schochet (2008a), which provides an excellent primer of power analysis for various types of study designs. The documentation for Optimal Design, a freely available power analysis software program, provides a more extensive explication of both conceptual and technical backgrounds of power analysis, as well as easy-to-follow tutorials for conducting power analysis under different scenarios using the Optimal Design program (Spybrook, Raudenbush, Congdon, & Martinez, 2009). For simpler designs (i.e., those that do not involve a multilevel design), Web-based power calculators are also available (e.g., Lenth, 2006-9).

# **Study Implementation**

Having discussed the key elements in the sampling design of an impact study, we now move on to study implementation. We will examine a number of important issues that one needs to consider when carrying out an impact study: measurement of outcomes, implementation fidelity, and attrition.

#### **Measurement of Outcomes**

The outcome measures in an impact study are useful only if they have adequate construct validity; that is, if they capture well the relevant underlying constructs that they are intended to

measure.<sup>22</sup> The construct validity of outcome measures matters because measures with weak construct validity (e.g., a poorly designed reading test) may provide very little useful, and even misleading, information about the underlying construct that they are intended to measure (i.e., student reading achievement). As a result, incorrect conclusions may be drawn about the impact of the intervention under study, even if the study employs a design with strong internal validity. The WWC considered several issues related to the construct validity of outcome measures:

- Explication of constructs<sup>23</sup>
  - o "Grain size": Is the construct identified at too specific a level? Is the "grain size" of the measure appropriate? Does the measure purport to measure a broad construct, but in fact measure a narrower construct (i.e., construct underrepresentation)?
  - Face validity and reliability of outcome measures: Does the outcome measure demonstrate face validity and adequate reliability?
- Construct confounding
  - Overalignment: Does the study confound exposure to the measure with improvement of the construct? In more specific terms, is the measure overaligned with the intervention?

## **Explication of Constructs: Grain Size**

Researchers sometimes analyze very narrowly defined constructs. For example, a researcher might only measure students' improvement in a very specific skill, phonemic awareness, in a study of a reading intervention. This is appropriate if the intervention is specifically designed to improve students' phonemic awareness and if the goal of the study is to provide evidence on the effect of the intervention on this narrow outcome. However, practitioners are often more interested in whether an intervention has an impact on broader constructs, such as general reading achievement. Therefore, a study that focuses only on a very narrow construct is likely to have limited practical applicability.

Alternatively, researchers may be concerned about broad constructs, but use narrow measures that only relate to some aspects of the broad constructs. This is known as construct underrepresentation. For example, a researcher may measure students' improvement in phonemic awareness with the intent of demonstrating that the intervention improves overall reading achievement. This is problematic because reading is composed of many subskills, and improvement in only one of those subskills—phonemic awareness—does not necessarily mean improvement in reading more generally. Drawing conclusions about an intervention's impact on a broader construct (e.g., reading achievement) based on very narrow outcome measures is unwarranted at best and misleading at worst.

<sup>&</sup>lt;sup>22</sup> The notion of construct validity refers to the validity of making inferences from the sampling particulars of a study—persons, settings, treatments, and measures—to the higher-order constructs that they represent (Shadish et al., 2002). In the WWC, and in this paper, we focus on the construct validity of outcome measures.

<sup>&</sup>lt;sup>23</sup> See Shadish et al. (2002, p. 73–81) for a more extensive discussion of threats to construct validity. The WWC focused on several of these threats, especially inadequate explication of constructs and construct confounding.

In a third common scenario, researchers may analyze a large number of micro-level outcomes which, together, comprise a larger construct, but report the individual findings separately rather than as a factor representing the larger construct. As an extreme example, one study reviewed by the WWC reported as many as 77 item-level findings in a single study report. Studies that report many micro-level findings, rather than findings at the construct level, are problematic for the following reasons:

- 1. It is hard to interpret large numbers of findings. If, for example, a study reports an intervention's effects on 30 items from a survey, some positive and some negative, some statistically significant and some not, it is difficult for the reader to understand in any global sense the effectiveness of the intervention.
- 2. It is easy for a reader to focus on the statistically significant positive findings as indicators of positive effects when, in fact, they may be only important at a micro level. For example, a study of a reading intervention might analyze 20 items related to reading comprehension and find that the intervention has a statistically significant positive effect on one of those items, but no effect on the remaining 19 items or on the scale composed of the 20 items. If the study author reports only the item-level findings (or, as is sometimes done in data mining, only the statistically significant findings), it is tempting for readers to incorrectly conclude that the intervention improves reading comprehension overall.
- 3. When a large number of analyses are conducted, there is an increased chance that some findings will turn out to be statistically significant when, in fact, there is no true effect (i.e., inflated Type I error rate), unless some correction is made (see Critical Issues in Data Analysis section for further discussion about the multiplicity problem).

Ideally, a well designed study specifies beforehand the outcome constructs that it intends to measure and the specific measures that it will use to measure those constructs, using multiple measures to fully capture each construct.24 It is also advisable that multiple measures of the same construct be combined through, for example, a factor analysis, into a composite scale and study findings be reported at the scale level. In general, a composite scale created with multiple items is likely to have better psychometric properties (higher reliability in particular) and provide a better representation of the often multi-faceted outcome construct than individual items (Cortina, 1993; Shadish et al., 2002). If the researcher decides to analyze large numbers of micro-level findings individually, he or she should correct for multiple hypothesis testing as appropriate and should indicate, a priori, which items are of central importance and which are more peripheral to aid in interpretation.

## Explication of Constructs: Face Validity and Reliability of Outcome Measures

Valid and reliable outcome measures are a prerequisite to valid conclusions about the effects of an intervention on the constructs that the intervention is intended to affect. At a minimum, an outcome measure should demonstrate face validity; that is, "on its face" the measure should

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<sup>&</sup>lt;sup>24</sup> See, for example, the discussion of mono-operational bias and mono-method bias in Shadish et al. (2002), p. 75–76. The WWC reported on whether the study looked at a variety of types of outcome measures, but this information did not factor into the evidence rating.

appear to be a good representation of the construct that it is intended to measure. An outcome measure should also demonstrate adequate reliability or consistency. A measure is considered reliable if it would produce the same result over and over again, assuming what is measured is not changing.

Although most researchers agree that validity and reliability are important properties of outcome measures, there is a lack of clear and consistent guidelines on how to quantify validity and on what constitutes acceptable levels of validity and reliability. Therefore, the WWC, in its first phase, set a low bar for the validity and reliability of outcome measures for pragmatic reasons (most importantly, few studies reported validity information for their outcome measures). It only required that, to be eligible for WWC reviews, a study should have at least one relevant outcome measure with face validity or adequate reliability. The default reliability requirement was that an outcome measure was considered reliable if it met at least one of the following thresholds: (1) internal consistency of .60, (2) temporal stability/test-retest reliability of .40, or (3) inter-rater reliability of .50. Each WWC review team, however, could adjust these default values as appropriate for the specific topic area.

The WWC assumed that outcome measures based on standardized tests had adequate validity and reliability as a result of the standardization process. Studies that measured outcomes using nonstandardized tests, however, had the burden of proof and were required to provide information about the validity or reliability of the outcome measures. Essentially, most outcome measures met WWC standards, with the rare exception of nonstandardized measures that were clearly not relevant or did not provide enough information to judge face validity or reliability as in the study illustrated below.

#### **Exhibit 6. A QED With No Valid, Reliable Outcomes**

#### Summary of Study Design

This study assessed the effects of a character education intervention on students' reasoning about human relationships and implications of individuals' actions. The study sample included students from one intervention class and students from a matched comparison class from the same urban middle school.

#### Design Flaw

In this study, outcomes were assessed with a short test adapted specifically for the study. The primary outcomes, reasoning about human relationships and implications of an individual's actions, were assessed through seven short answer items administered at both pretest and posttest. The researcher indicated that students' reading ability may have limited the validity of the test. However, the researcher did not provide any other information about the validity or reliability of the test. Given the lack of evidence for demonstrating that the test provided reliable or valid measures for the outcome constructs, the study was excluded from the WWC review.<sup>25</sup>

# Construct Confounding: Overalignment of Outcome Measures

When a study focuses on micro-level outcomes that were specifically chosen because they reflect the focus of the intervention, there is a risk of overalignment. Overalignment between the

<sup>25</sup> This study also has the "N=1" problem, as the intervention's effect was completely confounded with the differences between the two classes.

intervention and the outcome measure occurs when "the outcome measures assess skills taught in the experimental group but not the control group" (Slavin, 2008, p. 11). The most serious type of overalignment occurs when the intervention group is exposed to the outcome measure during the intervention, but the comparison group is not. For example, students in the intervention group completed a vocabulary worksheet during class, but the comparison students did not. Both groups were then tested using that vocabulary worksheet and their scores were compared. The problem with this study is that it is not possible to separate the effect of exposure to the outcome measure from the effect of the intervention itself, and it is very likely that the estimate of the intervention's effect would be biased toward the intervention group.

A second type of overalignment occurs when the outcome measure evaluates a skill that was taught to the intervention group but not the comparison group. For example, in one study reviewed by the WWC, students in the intervention group were taught phonemic awareness, and students in the comparison group were not. The study found that students in the intervention group outperformed students in the comparison group on a phonemic awareness test. This study demonstrates the effect of exposure to phonemic awareness through this intervention, rather than the effect of the intervention per se, on students' phonemic awareness skills. It is not appropriate to conclude that the intervention is more effective than other phonemic awareness interventions or business as usual (Crawford & Snider, 2000; Slavin, 2008; Van Dusen & Worthen, 1994; Ysseldyke, Spicuzza, Kosciolek, Teelucksingh, Boys, & Lemkuil, 2003).

In general, if a study is designed to test the effect of an intervention on a particular skill, both the intervention and the comparison groups should be exposed to the skill and the difference between the two groups should be limited to the intervention's *approach* to teaching that skill. Another way of thinking about this is that the outcome measure should not be overaligned with the intervention—it should focus on skills taught in both the intervention and the comparison groups.

## Implementation Fidelity

Impact studies vary, sometimes by design, in the degree to which the intervention is fully implemented under well controlled conditions. Some impact studies are designed to test the effects of an intervention in optimal conditions, to determine whether the intervention can have an impact under ideal circumstances (i.e., efficacy studies). Other impact studies are designed to test the effects of an intervention under typical conditions, to determine whether the intervention is likely to have an impact when implemented as it would be if delivered at scale (i.e., effectiveness studies). Although these two types of studies may differ in terms of implementation fidelity—how closely the intervention-as-implemented resembles the intervention-as-designed—both address valid questions. <sup>26</sup>

IES recommends a hierarchy of impact research in which an intervention is first tested for efficacy (can it work?) and then, if it seems to work under ideal circumstances, tested for

<sup>&</sup>lt;sup>26</sup> The WWC was concerned with the impact of interventions implemented under varied conditions and therefore included both efficacy studies and effectiveness studies in its review.

effectiveness (*does* it generally work?).<sup>27</sup> If an intervention has been found effective under ideal conditions, and the intervention itself has not changed substantially from what was tested in efficacy trials, the next logical step is to assess its impact under typical implementation conditions. Therefore, a researcher should review existing impact research on an intervention before deciding whether to conduct an efficacy or effectiveness study.

Regardless of whether a study is designed to test the impact of an intervention under optimal conditions or in real-world applications, it is advisable to collect data on implementation. Such data are valuable to (1) explore the mechanisms through which the intervention achieved its impact or the lack thereof; (2) support claims of causality (if the intervention was implemented with high fidelity and the intervention and control conditions differed); (3) challenge claims of causality (if the intervention was implemented with low fidelity or the intervention and control conditions were very similar); (4) identify challenges to future implementation and scale-up; and (5) examine the relationship between implementation and intervention effects.

Implementation data are particularly important for understanding what actually occurred in both the intervention and the comparison conditions, which can help researchers accurately describe the nature of the comparison and explore *how* the intervention caused the outcomes. For example, in many studies of comprehensive school reform, comparison schools implemented reforms that were similar to the intervention being tested. In those cases, "business as usual" was an alternative intervention rather than "no intervention." It is essential for the researchers to make it clear that the reported impact estimates represent the impact of the reform being tested relative to the reform being implemented in the comparison schools.

Data on implementation may also shed light on what may actually account for the observed impact or the lack of impact. If, for instance, an impact study found that a particular reform program had an impact relative to the comparison condition, and the data on implementation reveal that schools in both conditions used the same curriculum, one would hypothesize that some element of the intervention other than curriculum was responsible for the observed impact.

#### Attrition

Attrition refers to "any loss of response from participants" (Shadish et al., 2002, p. 323). Sometimes attrition is due to participants being unable or unwilling to continue participation and sometimes is due to decisions by the researcher to exclude participants. In either case, attrition can pose a threat to internal validity because attrition rarely occurs at random and the cause of the attrition may be correlated in some unknown way with the intervention. Consider, for example, an evaluation of a tutoring program which included initially low- and initially high-achieving students in the sample. Suppose low-achieving students assigned to the program failed to improve, became discouraged, and dropped out of the program and study. Analysis based only on the high-achieving students who remained in the program and the mix of students in the control group might incorrectly indicate that the program worked for all students, including

<sup>&</sup>lt;sup>27</sup> This framework was originally developed in health-care research and subsequently adopted by IES (Flay, 1988; Starfield, 1977). See a description of research goals for IES-supported research programs at <a href="http://ies.ed.gov/funding/pdf/2009/84305A.pdf">http://ies.ed.gov/funding/pdf/2009/84305A.pdf</a>, p. 9.

initially low-achieving students. Research suggests that attrition is often systematic rather than random, and can lead to biased impact estimates because it introduces the possibility that the intervention and control groups differ on some important characteristics other than exposure to the intervention (Shadish et al., 2002).

Attrition may also be a threat to external validity. If the subjects who leave the study differ systematically from those who stay (e.g., leavers are mostly highly mobile students with lower socioeconomic status than stayers), it is not longer appropriate to generalize the findings to people similar to those leavers. Consequently, the findings may apply only to a narrower population than originally intended.

#### Differential Versus Overall Attrition

Differential attrition occurs when one study group has a higher attrition rate than the other group. Differential attrition is a serious problem because it suggests that some factor—other than the intervention itself—is influencing the intervention group and the comparison group in different ways. That factor provides a competing explanation for differences in outcomes between the groups; thus it is no longer safe to assume that the intervention alone is responsible for those differences.

For WWC Phase I reviews, severe differential attrition was defined as a difference in attrition rates between the intervention and comparison groups greater than 7%. The WWC Phase I Technical Advisory Group concluded that there was no empirical basis for a clear cut point (see Valentine, 2009), but general agreement among researchers was that differential attrition rates between 5 and 10% would be problematic. Therefore, the WWC adopted a value in that range. If the difference in attrition rates was less than or equal to 7%, the WWC assumed that the bias associated with it was minimal. If it was greater than 7%, the study had to show that the differential attrition did not bias the impact estimate through, for instance, demonstrating post-attrition group equivalence on a pretest; otherwise the study would be downgraded according to the WWC Evidence Standards<sup>29</sup>.

Severe overall attrition occurs when there is a substantial amount of attrition across the overall study sample. Severe overall attrition is a problem because it may introduce differential attrition—if a large number of participants leave the study, there may be some underlying, nontrivial differences between those who leave the intervention group and those who leave the comparison group. For WWC Phase I reviews, severe overall attrition was generally defined as greater than 20% sample loss. <sup>30</sup> If the overall attrition rate was less than or equal to 20%, the WWC assumed that the bias associated with it was minimal. If it was greater than 20%, the study

<sup>&</sup>lt;sup>28</sup> Differential attrition may also occur when participants in the intervention and comparison conditions drop out for different reasons or if the dropouts in the two conditions have different characteristics that are related to the outcome, even if the attrition rates in the two conditions are the same. This type of differential attrition was not addressed in WWC Phase I, because data for assessing such attrition were rarely available from study reports.

<sup>&</sup>lt;sup>29</sup> The Version 2 of the WWC standards judges attribution bias based on a more sophisticated model that takes into account both differential attrition and overall attrition simultaneously (see WWC, 2008).

<sup>&</sup>lt;sup>30</sup> The WWC recommended default values for acceptable levels of overall and differential attrition. However, the WWC Principal Investigators in different topic areas could propose alternative values if the nature of the topic might affect attrition rates in ways that would not jeopardize the validity of the study.

had to show that the overall attrition would not bias the impact estimate; otherwise it would be downgraded according to the *WWC Evidence Standards* (see Exhibit 7 for an example).

#### **Exhibit 7. An RCT With Severe Overall Attrition**

#### Summary of Study Design

The purpose of this study was to assess the effects of a dropout prevention intervention on pregnant and parenting teens. In this study, almost 5,000 students in four counties were randomly assigned to the intervention and control groups using their Social Security numbers. Of those students, slightly more than half responded to the survey one year after they entered the program. After the survey, the study excluded sample members who lost custody of their children, moved to a nonresearch county or out of state, left welfare, or did not receive welfare for at least six months, resulting in a sample of less than half of the original sample. The study administered a second survey two years after program entry, with only one-third of the original sample responding.

#### **Attrition Problem**

In addition to the low response rates, the WWC had reservations about the study because sample members were excluded from the second survey based on conditions that could have been affected by the intervention, such as high school completion within six months of random assignment. As a result, the baseline equivalence established through randomization at the beginning of the study might no longer hold for participants in the intervention and comparison groups who took the follow-up surveys.

## Systematic Versus Random Causes of Attrition

Some types of attrition are more likely to introduce bias into a study than others. Attrition in which a participant decides not to participate after assignment to a condition is particularly problematic. It is likely that a person who chooses to participate in an intervention is systematically different from a person who chooses not to participate. Nonconsent is a specific example of this. If a study requires active consent on the part of participants, the consent should be obtained before participants are assigned to conditions. If handled this way, willing participants should be equally distributed across the conditions. If, on the other hand, participants are first assigned to conditions and then asked to consent to participate, it is likely that the assignment will affect the participants' willingness to be involved. For example, busy students may decline to participate if they are assigned to the comparison group because they don't want the burden of study participation if they will not get the benefit of the program. These students would then be underrepresented in the comparison group, but not in the intervention group. If they had committed to the study before sample assignment, they would be equally represented in both groups.

While attrition often occurs in systematic ways, it may occur randomly by design, as is the case with selective testing. In order to save time or reduce costs, some studies collect outcomes data from only a subsample of participants in the study. Although sometimes characterized as attrition, selective testing can be done in a way to minimize bias due to the purposive exclusion of participants, through, for example, matrix sampling or random selection of subsamples (see Exhibit 8). If the selection or exclusion of participants for outcome collection is done randomly, no bias would be introduced and the resulting sample loss would not count as true attrition in the WWC reviews.

#### **Exhibit 8. A QED With Sample Loss Due to Selective Testing**

#### Summary of Study Design

This study assessed the effects of a character education intervention on outcomes such as service learning based on a student survey. The study was carried out in more than 20 schools in several states. To reduce burden on students, students were assigned to complete two of the three outcome measures. The researchers used matrix sampling to ensure that every student was given two outcome measures and that each outcome measure was completed by enough students.

#### Computation of Attrition Rates

In this study, selective testing was done in a way that was unlikely to introduce systematic differences between the analytic samples in the two study conditions. Therefore, although fewer students took each test than participated in the study, the sample loss was not counted as true attrition. Attrition rates for each measure were therefore computed based on the numbers of students intended to complete that measure, rather than the total number of students in the study.

## Replacement of Dropouts After Randomization

When faced with attrition after random assignment, some researchers choose to make up for the sample loss by replacing the dropouts with new participants. While replacement after randomization may increase the precision of the impact estimate by increasing the sample size, it cannot eliminate the potential bias introduced by attrition unless the dropouts and their replacements share the same characteristics—both observed and unobserved—that are related to the outcomes (Shadish et al., 2002). This condition, however, is unlikely to hold because one can match replacements with dropouts on observed characteristics, but not on unobserved characteristics. In fact, even if the replacements are randomly selected from the same pool of potential participants as those in the original randomized sample and deemed "similar" to the dropouts, the initial randomization may still be compromised because the dropouts and their replacements are likely to differ systematically, at least in their willingness to participate in the condition to which they are assigned. Exhibit 9 provides one such example. If the participants who opt out are not replaced, this can be considered a straightforward attrition issue.

#### Exhibit 9. An RCT With Replacement of Dropouts After Randomization

#### Summary of Study Design

The purpose of this RCT was to test the effects of a character education program on student behavior and achievement. The researchers stratified the eligible schools based on demographic variables, randomly selected two schools from each stratum, and randomly assigned the two schools to the intervention and comparison conditions. If a school did not agree to participate in the condition to which it was assigned, it was replaced with another school randomly selected from the remaining schools within the same stratum.

## Design Flaw

The problem with this design is that the replacement schools differed from the schools being replaced, because the replacement schools were willing to participate in the condition assigned and the schools being replaced were not. Thus, the assignment took into account an important factor other than chance: the schools' willingness to participate in the conditions they were assigned to (a self-selection issue). Moreover, the refusal of participation was intervention-related, as more schools assigned to the intervention condition than schools assigned to the control condition refused to participate—due to political pressure, according to the authors. This suggests the possibility that the dropouts from the intervention condition differed systematically from those from the comparison condition, which could not be addressed by random selection of replacements.

# **Critical Issues in Data Analysis**

A well designed and well implemented impact study will not produce credible evidence without sound data analysis. We highlight in this section two analytic issues that are particularly important for the statistical conclusion validity of impact studies and that surfaced in many of the studies that the WWC reviewed: choice of unit of analysis for clustered data and adjustment for multiple comparisons.

## **Proper Unit of Analysis for Clustered Data**

The "unit of analysis" problem has been a well-known and once intractable problem to social science researchers who often work with clustered data. When the data are of a clustered structure (e.g., students clustered or nested within classes and schools), analysis at either the individual level or the cluster level is problematic. Individual-level analyses ignore the clustering of individuals within higher-level units (i.e., the design effect). Students in the same class, for instance, often share characteristics (e.g., all high-achieving students are in the same class due to tracking) or experiences (e.g., all students in a class are regular computer users due to their teacher's emphasis on computer-assisted learning) that may affect outcomes. This leads to the violation of the independence of observations assumption underlying traditional hypothesis tests. Such analyses often yield underestimated standard errors and misleadingly high levels of statistical significance, with p-values much smaller than they should be. In other words, this may lead to claiming a statistically significant effect when there is none.

Indeed, failure to take into account clustering in impact analysis has been a common problem encountered by WWC reviewers. To address the problem, Larry Hedges, a member of the WWC Phase I Technical Advisory Group, developed a method for correcting a significance test that incorrectly ignored clustering. Based on results from the incorrect test, the method would generate the p value that would have been obtained had the impact analysis properly taken clustering into account (see Hedges, 2007, for technical details). The WWC had been routinely applying the clustering correction method to studies that ignored clustering, and identified many findings that the authors claimed to be statistically significant but were in fact not significant once corrected for clustering. An Excel program for implementing Hedges' clustering correction method can be found in the *Clustering\_Correction* workbook in the *WWC (Phase I)*Computation Tools that accompanies this paper.

Analysis at the cluster level, or aggregated analysis, may also be problematic.<sup>32</sup> Aitkin and Longford (1986) voiced their objection against aggregated analysis most forcefully: relying on aggregate analysis to analyze clustered data "is dangerous at best, and disastrous at worst" (p.42). Potential problems with aggregated analysis, according to Snijders and Bosker (1999), include shift of meaning, ecological fallacy (i.e., relationships between aggregated variables cannot be used to make assertions about the relationships between individual-level variables),

<sup>32</sup> An aggregated analysis would be appropriate if there is no within-cluster variation in the outcome (i.e., an ICC of 1), which, however, rarely occurs in the field of education.

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<sup>&</sup>lt;sup>31</sup> Another weakness of individual-level analysis is that it is unable to account for heterogeneity of regression slopes (e.g., the wider minority gap in achievement in some schools than in others) that is often of particular interest in educational research, especially research on school effects that have equity implications.

neglect of the original data structure, and inability to examine potential cross-level interaction effects. Snider and Bosker strongly recommend that multilevel statistical models be used to analyze clustered data, and many concur (e.g., Bloom, Bos, & Lee, 1999; Donner & Klar, 2000; Flay & Collins, 2005; Murray, 1998).<sup>33</sup>

Recent methodological advances in multilevel modeling have offered not only fresh insights into the nature of the unit of analysis problem, but also effective analytic tools (e.g., HLM and SAS Proc Mixed) for conducting multilevel analysis (Raudenbush & Bryk, 2002). Rather than focusing on one particular data level, multilevel analysis, as its name suggests, analyzes data at both the individual level and the cluster level simultaneously. While single-level analysis (either individual-level or cluster-level analysis) only recognizes one source of random variation and totally ignores variation from other sources, multilevel analysis recognizes multiple sources of variation embedded in the data (both between and within clusters), and explicitly takes into account the dependence among individuals within the same clusters in analyzing the data. It is thus able to overcome the problems with single-level analysis, and produce less-biased effect estimates.

## **Adjustment for Multiple Comparisons**

Another common source of inflated statistical significance is the failure to adjust for multiple comparisons or multiple hypothesis tests, which may arise when a study tests an intervention's effects on multiple outcomes, for multiple subgroups, or across multiple intervention conditions. As Williams, Johns, and Tukey (1999) observe:

Unless some correction is incorporated, the overall (simultaneous) Type I error rate—the probability that the decision for any one or more comparison will be in error—will exceed (often very substantially) the nominal  $\alpha$ . ... With multiplicity, it is appropriate—and usually essential—to adjust for the increased probability of simultaneous Types I error. (p. 43)

Indeed, as the number of comparisons increases, the overall or familywise Type I error rate increases exponentially, resulting in spurious significant findings.<sup>35</sup> If, for a single hypothesis test, the probability of erroneously rejecting the null hypothesis and claiming a significant effect is 5% (i.e., the typical level of statistical significance), then the probability of finding at least one spurious significant effect will be 10% with 2 independent hypothesis tests, 23% with 5 tests, and 40% with 10 tests, when the intervention actually has no true effects (i.e., all null hypotheses are true).

The problem of multiple comparisons has long been recognized, and a plethora of adjustment methods have been proposed (e.g., Bonferroni, 1935; Benjamini & Hochberg, 1995; Dunnett, 1955; Hochberg, 1988; Hochberg & Tamhane, 1987; Scheffe, 1953; Tukey, 1949). No single

<sup>&</sup>lt;sup>33</sup> So does the WWC—see <u>Tutorial on Mismatch Between Unit of Assignment and Unit of Analysis</u> (WWC, 2006b).

<sup>&</sup>lt;sup>34</sup> For simplicity, this discussion is based on a two-level framework (i.e., individuals nested with clusters). The idea can easily be extended to a three-level model (e.g., students nested with teachers and teachers nested within schools). <sup>35</sup> For g independent hypotheses, each tested at the significance level of  $\alpha$ , the overall Type I error rate is  $[1 - (1 - \alpha)^g]$  when all the null hypotheses are true (Cohen & Cohen, 1983; Bland & Altman, 1995).

method, however, is superior to all other methods under all circumstances. Reflecting the general tension between Type I and Type II errors, multiplicity adjustment methods typically guard against inflated Type I error rates at the cost of increased Type II error rates and, hence, reduced statistical power for detecting real intervention effects. Thus, it is not surprising that most studies of educational interventions reviewed during WWC Phase I ignored the multiple comparisons problem.

To address the multiple comparisons problem, the WWC reviewers conducted post hoc corrections of the statistical significance of study findings where necessary and feasible, using the Benjamini-Hochberg method, which, although not perfect, has been shown to be the preferred approach to the multiple comparisons problem in many practical situations (Benjamini, Hochberg, & Kling, 1993, 1997; Curran-Everett, 2000; Keselman, Cribbie, & Holland, 1999; Williams, Jones, & Tukey, 1999). Most importantly, the Benjamini-Hochberg method tends to have greater statistical power and is more robust to the number of comparisons involved than most alternative multiplicity-adjustment methods. A detailed explanation about how the method was applied to the WWC Phase I reviews can be found in the <u>Technical Details of WWC-Conducted Computations</u> document. The steps in making the Benjamini-Hochberg corrections are illustrated in the <u>BH\_Correction</u> workbook in the <u>WWC (Phase I) Computation Tools</u>.

In recognition of the prevalence of the multiple comparisons problem in studies of education interventions that surfaced from the WWC Phase I reviews, the Institute of Education Sciences (IES) commissioned its Methods Issues Working Group to develop guidelines for addressing the problem for researchers planning and conducting impact evaluations in education. Released in May 2008, the guidelines present the following basic principles for multiple testing (Schochet, 2008b, p.3–4):

- 1. The multiple comparisons problem should not be ignored.
- 2. Limiting the number of outcomes and subgroups forces a sharp focus and is one of the best ways to address the multiple comparisons problem.
- 3. The multiple comparisons problem should be addressed by first structuring the data. Furthermore, protocols for addressing the multiple comparisons problem should be made *before* data analysis is undertaken.

The IES guidelines also provide a set of specific recommendations for developing multiple testing strategies, including delineating separate outcome domains in the study protocols and defining confirmatory and exploratory analyses prior to data analysis, among others. In addition, the document also provides the relevant technical background for the recommended guidelines in several technical appendices, which discuss in detail the nature of the multiple comparisons problem, statistical solutions to the problem, and methods for constructing composite outcome measures that are central to the recommended guidelines. Educational researchers are encouraged to follow these guidelines, and take multiple comparisons into account in sampling design, data analysis, and report writing.

# Reporting

A study's value cannot be fully realized without a high-quality study report. As the primary means of dissemination of study findings, a study report not only documents study findings, but

also provides essential information about the study that would allow readers, including program officers from funding agencies and journal reviewers, to judge the quality of the study design and the credibility of the study findings. In this section, we first provide general reporting guidelines, and then highlight some of the most commonly missing information from reports of studies of educational interventions.

## **Full Reporting Guidelines**

As suggested throughout this paper, the methodological rigor of an impact study determines the credibility of study findings. It can be hard to determine how rigorous a study is—and therefore to judge how much to trust the findings—when critical information is not reported, or is incompletely reported. There has been a concerted effort over the past 10 years or so, paralleling the emphasis on more rigorous impact studies, to improve reporting practices. Many articles and guides describe the elements that should be reported in impact studies, and these guides tend to converge on which are most essential. In this section, we draw from these influential guides to summarize the elements that should be included in reports of impact studies.

Of the many guides that list the essential elements to be reported in impact studies, one of the most widely used is the *CONSORT Statement* (Altman et al., 2001; Moher, Schulz, & Altman, 2001). Although the *CONSORT Statement* was originally developed to guide the reporting of RCTs, many of its components also apply to other types of impact studies. The *CONSORT* Web site recorded an average of almost 50,000 page views and more than 8,000 visitors per month, from over 115 countries, in late 2007. In addition to its popularity, there is also evidence that the *CONSORT Statement* has indeed improved the reporting of RCTs. Plint, Moher, Schulz, Altman, & Morrison (2005), for example, reviewed eight evaluations of the impact of using the *CONSORT Statement*, and concluded that the use of the *CONSORT Statement* was associated with better reporting of RCTs.

As part of the first phase of the WWC, the Coalition for Evidence-Based Policy (2005) developed *Reporting the Results of Your Study: A User-friendly Guide for Evaluators of Educational Programs and Practices.* This guide built on the reporting guidelines of the *CONSORT Statement*, <sup>36</sup> but was specifically designed to reflect the standards of the WWC and the needs of the WWC users. For example, *Reporting the Results of Your Study* expanded the scope the *CONSORT Statement* by addressing QEDs as well as RCTs, as well designed QEDs were included in WWC reviews. In the remainder of this section, we summarize the essential components of the study report of an impact study, drawing on both the *CONSORT Statement* and *Reporting the Results of Your Study*.

Full reporting of an impact study should include at least the following sections: (1) title and abstract, (2) background and purpose, (3) methods, (4) results, and (5) discussion. As noted later, the WWC Phase I reviews revealed that certain sections were less likely to be fully reported than others in study reports. The title and abstract were seldom missing or incomplete. However, the methods and results sections often lacked key information. Therefore, important elements to be reported in the methods and results sections are described here in greater detail.

<sup>&</sup>lt;sup>36</sup> This guide also incorporates technical decisions from the WWC and Flay et al. (2005).

#### Title and Abstract

In addition to the obvious (title and authors), the abstract should state the purpose of the study and provide a basic description of the study design (i.e., RCT, QED, or other design) and other elements described more fully in the methods section (e.g., setting, sample, intervention description). It should also highlight the key findings from the study.

## **Background and Purpose**

This section should set the context for the study, including a brief description of the intervention and its history, the theory of action or conceptual framework guiding the study, a summary of the existing evidence base, and the need for the current study. This section should also clearly state the purpose of the study, as well as the research questions to be addressed or hypotheses to be tested.

#### Methods

The methods section should provide information about the setting, sample, intervention, assignment process, measures, data collection, and statistical methods. Information about the setting—geographical location, time period, type of environment (e.g., public elementary school)—and information on the sample—including eligibility criteria, sample size, participants' background characteristics, including pretest scores—can provide valuable guidance on where and to whom the study can be generalized.

The methods section should also describe the intervention and comparison conditions, both the conditions as planned and the conditions as implemented. A clear description of the intervention condition—including training and technical assistance, costs, personnel, and material resources—can provide the details necessary to replicate the intervention or the study. A clear description of the comparison condition, especially how it differed from the intervention condition, can help readers understand the precise nature of the comparison and properly interpret the substantive meaning of the impact estimates.

The process of allocating cases to different study conditions should be reported in detail in the methods section. If the study claims to use random assignment, the description should include the methods for generating the random assignment sequence (e.g., coin toss, random number generator), the persons who implemented the random assignment (e.g., blinded researchers, school staff), and the steps taken to protect against bias in the process. For QEDs with a comparison group, the description should include how the comparison group was formed, and matching methods and timing (before or after the intervention) if applicable. This information can help determine the degree to which the assignment process produces fair and comparable groups.

The methods section should describe the outcome constructs, the measures used in the study to capture these constructs, and how the data were collected.<sup>37</sup> Specifically, this section should

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<sup>&</sup>lt;sup>37</sup> See American Educational Research Association et al. (1999) for a discussion of construct validity and the ways in which outcome measures should map to the underlying constructs in the context of a specific study.

name each measure and provide evidence of adequate reliability and validity. This section can provide information on the administrators of the measures, and strategies taken to ensure the administrators do not compromise the integrity of the instruments. The timing of the assessments should be noted, especially in terms of the progress of the intervention. For example, an assessment given in the last month of a year-long intervention might have very different results from an assessment given as a follow-up two years later.

Finally, the methods section should describe the analytic methods used for addressing the research questions. Sufficient details should be provided to allow readers to understand how the statistical models were specified, what assumptions were made, whether study design features (e.g., clustering and blocking) were properly taken into account, and whether correction for multiple comparisons was needed and made, among others.

#### Results

The results section should go beyond simple reporting of analysis findings and include information about attrition, analytic sample sizes, and baseline equivalence of the analytic sample, among other issues. It is recommended that the results section provide information about the flow of participants through each stage of the study, attrition rates, and the final analytic sample sizes for the outcomes. It is especially important to clearly identify pre-intervention differences between the intervention and comparison groups in the analytic sample, not only for QEDs, but also for RCTs, because randomization does not always lead to equivalent groups, particularly in studies with small samples, and post-randomization attrition may also introduce baseline differences. If substantial baseline differences were detected, the study authors should explain whether and how the baseline differences were taken into account in the impact analyses.

When reporting findings, it is important to report all findings (not just positive, large, or statistically significant findings) and to report all the information necessary to replicate the findings. This may include analytic sample sizes, means, standard deviations, impact estimates with standard errors, test statistics (e.g., t or F-statistic, or chi-square) with associated p values and confidence intervals, and other information as appropriate. Study authors are also strongly encouraged to report the magnitude of the effects in terms of an appropriate effect size, and express findings in substantively meaningful, "real-world" terms such as grade-level gains or percentile increase in achievement, where possible. Subgroup and dosage analysis, if conducted, should describe the nature of the subgroup or dosage, the reasoning behind this analysis, and, again, complete reporting for all findings, not just statistically significant findings. If analyses of multiple outcomes or subgroups were conducted, the study authors should indicate how the multiple comparison problem was handled to avoid the risk of spurious significant findings.

#### Discussion

The discussion section should interpret the results and contributing factors, note the extent to which these results may be generalized, and explore the implications of these results for educators, policy makers, researchers, and others. In addition, the study authors should acknowledge any limitations of the study and may suggest directions for future research.

## **Common Missing Information From Reports of Education Interventions**

Having described what should be included in a study report, we discuss next the types of critical information that were most likely to be missing in study reports as revealed by our WWC Phase I reviews. In particular, we found that many study authors failed to provide sufficient details about the sampling design and the findings of their study.

## Missing Information About Sampling Design

The causal validity of an impact study depends most critically on its sampling design, particularly on how the comparison group is formed. While many studies provide details about sample characteristics, they typically include only sketchy descriptions of the sample allocation process. During our WWC Phase I reviews, we found that in most of the studies that involved random assignment, the authors merely stated that study participants were randomly assigned to different conditions without providing further details about the assignment process. It is thus difficult for readers to tell whether the randomization procedures were designed properly and implemented effectively.<sup>38</sup>

As well recognized among experienced researchers, designing and implementing an RCT is a highly complex and challenging task that is subject to a variety of practical problems (Gueron, 2002; Shadish et al., 2002). For example, one problem that occurred in some studies, as we mentioned earlier, is that certain participants opted out of the study after random assignment and were replaced by other participants. Such ad hoc sampling adjustments made after random assignment are likely to compromise the integrity of the original randomization because one could no longer be sure that the resulting study groups were equivalent. As another example, some researchers may not fully understand what random assignment entails and mistakenly label a haphazard assignment procedure as random assignment. Without information about how the assignment was actually carried out, readers would be led to believe that the study is a true RCT when it is essentially a QED.

Therefore, for studies designed to be an RCT, the researcher should report in sufficient detail how the study groups were formed and whether any problems were encountered in the sample allocation process, and if so, how the problems were handled. Such information will help readers make a fair judgment of both the strengths and the weaknesses of the study design and the credibility of the study findings.

The lack of specifics about the sample allocation process was common not only among RCTs, but also among QEDs that were reviewed by the WWC. Many QEDs that equated study groups through matching, for instance, offered little explanation about exactly how matching was done and how closely the study groups were matched. Given that exact match is often difficult to

the study authors, unless there is reason to believe otherwise.

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<sup>&</sup>lt;sup>38</sup> The <u>WWC Evidence Standards</u> require that for studies received by the WWC beginning January 1, 2007, for the sample allocation to be considered "random assignment," the study authors must report specifics about the randomization procedures, including details about the generation of the assignment sequence, the role of the person who generated the sequence, and the methods used to conceal the sequence before assignment. For studies received earlier, the WWC assumes that the random assignment was carried out properly even if no specifics were given by

achieve, particularly when the pool of potential comparison units is small and the number of characteristics to be matched is large, study authors should explain clearly the matching methods used and the baseline characteristics of the matched groups. This information will help readers to better understand the adequacy of matching in equating the study groups, which is particularly important for studies that rely on matching as the primary means to achieve group equivalence.

In addition to the sample allocation mechanism, another key aspect of sampling design is sample size determination. In designing an impact study, the researcher should perform a power analysis to ensure that the study has adequate sample size. Otherwise, the study may fail to yield statistically significant findings even if the intervention has a real impact. However, the WWC Phase I reviews showed that study authors rarely reported how they determined the sample size for their study or whether their study had adequate statistical power, which made it difficult to tell whether the nonsignificant findings in some studies were the result of an ineffective intervention or the result of insufficient power. Therefore, we strongly encourage researchers not only to routinely conduct a power analysis to inform the sampling design of their studies, but also to explain their power calculations, particularly the underlying assumptions (e.g., the desired power level, alpha, effect size, and ICC), in the study report.

With the availability of user-friendly power-analysis software programs (e.g., Optimal Design) and widely circulated primers on power analysis (particularly Schochet, 2008a) in recent years, more and more researchers have begun to pay attention to power analysis. This increased attention may also be attributable to the fact that power analysis has become a standard requirement of many funding agencies, including the U.S. Department of Education, for proposals that seek support for conducting impact studies. Therefore, we are hopeful that power analysis will be routinely performed and reported by researchers conducting impact studies in the future.

## Inadequate Reporting of Effect Sizes

Another area of reporting that limited studies reviewed by the WWC concerns study findings. While almost all studies reviewed by the WWC reported the statistical significance of intervention effects, few reported their findings in terms of effect sizes, and some did not provide enough data to allow effect size computation by the WWC (even though the data requirements to do so are minimal). Without information about effect sizes, it is difficult to judge the magnitude or the practical significance of study findings (Valentine & Cooper, 2003). As the American Psychological Association (APA) Publication Manual (2001, 5th edition) states:

For the reader to fully understand the importance of your findings, it is almost always necessary to include some index of effect size or strength of relationship in your Results section. ... The general principle to be followed ... is to provide the reader not only with information about statistical significance but also with enough information to assess the magnitude of the observed effect or relationship. (p. 25–26)

The APA manual asserts that "failure to report effect sizes" is a "defect in the design and reporting of research" (p. 5). The more recent American Educational Research Association (2006) reporting standards also emphasize the importance of reporting effect sizes, noting that

"interpretation of statistical analyses is enhanced by reporting magnitude of relations (e.g., effect sizes) and their uncertainty separately" (p. 37).

Effect sizes not only help readers understand the magnitude and the practical significance of effects estimated by individual studies, but also provide the primary means for combining findings across studies in research synthesis (Lipsey & Wilson, 2001). Therefore, the <u>WWC</u> <u>Evidence Standards</u> explicitly requires that a study report must provide the data necessary for computing the effect size for at least one relevant outcome in order to be considered eligible for WWC review. An RCT that assessed an intervention's effects using t-tests, for example, should report the means and standard deviations of each outcome, as well as the analytic sample size for each study group separately, to allow the computation of effect sizes. Effect sizes in this case can also be computed if the analytic sample size for each study group and the actual t-statistics from the impact analyses were reported.

Readers can refer to the <u>Technical Details of WWC-Conducted Computations</u> document for a detailed account of the types of data needed for effect size computation and the formulae for computing effect sizes under various scenarios. We have also created a set of Excel programs—the <u>WWC (Phase I) Computation Tools</u>—to assist researchers in conducting effect size computations. We highly recommend that researchers not only report effect sizes in their study report, but also explain how the effect sizes were computed and provide the necessary data (e.g., means, standard deviations, and sample sizes) for the effect size computation to allow readers and reviewers to replicate their effect size findings.

# **Concluding Remarks**

The process of developing evidence standards and reviewing studies during the first phase of the WWC generated a wealth of information that may be useful for designing and reporting future impact studies in education and related fields. The work undertaken during the first phase of the WWC also raised the awareness among many educational researchers of the need for more rigorous studies of educational interventions. Indeed, the paucity of rigorous studies of educational interventions was one of the most striking findings from the WWC Phase I reviews. Of the more than 1,500 studies that were reviewed during the first phase of the WWC, only 5% *Met Evidence Standards*, 5% *Met Evidence Standards With Reservations*, and 89% *Did Not Meet Evidence Screens*. Clearly, there is ample room for improvement in the rigor of empirical studies of educational interventions.

Drawing upon what we learned from the WWC and the literature on the design and analysis of impact studies, we have provided practical guidance on critical issues related to the design, implementation, analysis, and reporting of impact studies in education and related social science fields. We hope that the information presented in this paper will be useful for researchers as they plan and conduct their own studies, and for readers and reviewers as they judge the quality of the design and the credibility of the findings from studies conducted by other researchers. We also hope that as a result of the WWC and related work such as ours, an increasing number of studies will be able to meet the WWC standards and contribute to the scientific knowledge base about what works in education and to better-informed policies and practices that will have a positive impact on the achievement and well-being of schoolchildren.

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