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How Do Unobserved Confounding Mediators and Measurement Error Impact Estimated Mediation Effects and Corresponding Statistical Inferences? Introducing the R Package ConMed for Sensitivity Analysis

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Empirical studies often demonstrate multiple causal mechanisms potentially involving simultaneous or causally related mediators. However, researchers often use simple mediation models to understand the processes because they do not or cannot measure other theoretically relevant mediators. In such cases, another potentially relevant but unobserved mediator potentially confounds the observed mediator, thereby biasing the estimated direct and indirect effects associated with the observed mediator and threatening corresponding inferences. Additionally, researchers may not know the extent to which their measures are reliable, and accordingly, measurement error may bias estimated effects and mislead statistical inferences. Given these threats, we explore how the omission of an unobserved mediator and/or using variables with measurement error biases estimates and affects inferences associated with the observed mediator. Then, building off Frank's impact threshold for a confounding variable (ITCV), we propose a correlation-based sensitivity analysis. Lastly, we provide an R package ConMed to assess the robustness of mediation inferences given the omission of an unobserved, confounding mediator and/or measurement error.

Translational Abstract

Researchers across fields rely on mediation analyses to understand processes between the intervention and the outcome variable. Empirical studies regularly demonstrate the existence of multiple mediation pathways, such as through simultaneous or related mediators. However, many mediation analyses only include one mediator for various reasons and there are likely additional relevant mediators that could significantly bias estimates and inferences associated with the observed mediator. At the same time, valid statistical inferences also rely on the assumption that all the variables are measured without error, while researchers may not know the extent to which their measures are reliable. In practice, it is very likely that the omission of another confounding mediator and measurement error co-occurs. However, the extant literature on the combined effect of omitted confounders and measurement error does not evaluate cases where the confounder is a mediator; they focus on pretreatment confounders where the treatment has no impact on the omitted confounder. Therefore, we fill in the research gap by examining if/how omitting an alternative mediator and/or using variables with measurement error biases estimates and affects inferences associated with the observed mediator. We present analytical results as well as an illustrative example to demonstrate the potential consequences of omitting confounding mediator(s) given different reliability levels of observed variables. Additionally, we propose a correlation-based sensitivity analysis and provide an R package to help researchers assess the robustness of their mediation inferences given the omission of an unobserved, confounding mediator and/or measurement error.

Keywords: mediation model, posttreatment confounder, unobserved mediator, measurement error, sensitivity analysis, R package

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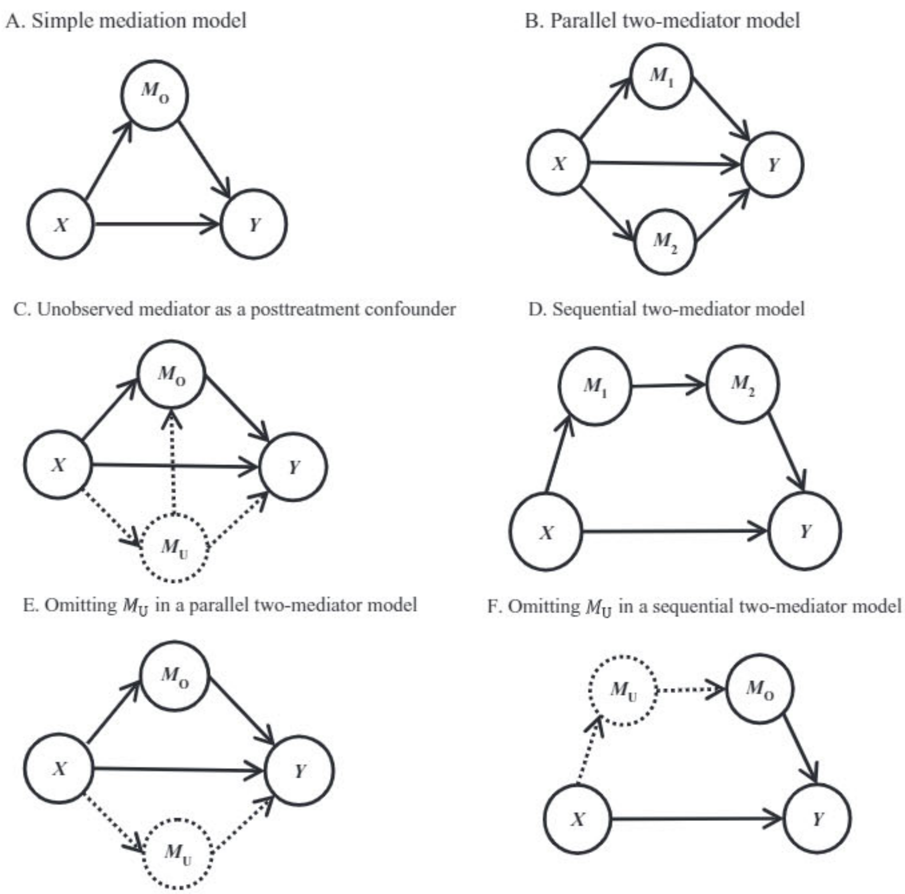
Researchers across fields rely on simple and complex mediation models to study processes (e.g., Cicchetti & Toth, 2006; O'Rourke & MacKinnon, 2019). If these analyses are misinformed or misspecified, researchers will have misguided interpretations, which can have severe consequences. This study informs researchers about such concerns by quantifying the implications of both omitted mediators and measurement error on estimated effects and their corresponding inferences.

In terms of a simple mediation model, a single mediator variable (M_O) represents one mechanism or process affected by the intervention (X) that, in turn, affects the outcome (Y) (Baron & Kenny, 1986; MacKinnon, 2008). In such a model, the product of the effects from X to M_O and from M_O to Y constitutes the indirect effect via M_O, also known as the product method. Figure 1A presents such a model.

Researchers, however, often consider more complex simultaneous mediator models (e.g., Bekman et al., 2010; Imai & Yamamoto, 2013; Singh et al., 2014). Figure 1B presents a parallel two-mediator model with two simultaneous mediation processes, one through each mediator connecting X to Y. Preacher and Hayes (2008) discussed ways to test hypotheses for individual mediators and contrast the magnitude of indirect effects in multiple mediation models, such as a parallel two-mediator model. Indeed, many researchers have noted the need to test multiple mediators in a single model to limit omitted variable bias (e.g., Hayes, 2018; Judd & Kenny, 2010; Preacher & Hayes, 2008). Nevertheless, researchers still frequently employ simple mediation models because they do not or cannot measure other theoretically relevant mediators. In such instances, M_U denotes the other potentially relevant, but unobserved, mediator. For example, if researchers expect two associated mediators—stigma and teacher mindset—to mediate the impact of educational tracking (X) on students' learning outcomes (Y), but only measure stigma, then stigma represents the observed mediator (M_O), and teacher mindset represents the unobserved mediator (M_U). In such a case, the researcher may obtain a biased estimate of the mediation effect via stigma, given the omission of teacher mindset.

In addition to unobserved mediators, measurement error likely affects mediation analyses. Based on Lord and Novick's (1968) classical test theory (CTT) framework, an observed score consists of a true score and measurement error unrelated to the true score or any other variables. In linear regression, measurement error in a *predictor* can bias both *standardized* and *unstandardized* coefficient estimates and mislead their corresponding statistical inference (Bloch, 1978; Lord & Novick, 1968). While measurement error in the *outcome* would not impact *unstandardized* coefficient estimates, it would bias the *standardized* estimates and increase the chance of obtaining a *non*significant result in linear regression (Charter, 1997; Cohen et al., 2003). In a simple mediation model, although (random) assignment to treatment may be measured without error (Judd &

Figure 1
Simple Mediation and Dual Mediator Designs



Kenny, 2010), measurement error may affect the mediator and/or the outcome (Fritz et al., 2016; Liu & Wang, 2021). In short, it is important to consider both M_U and potential measurement error within mediation analyses.

Collectively, both M_U and measurement error introduce bias and can affect statistical inferences. However, researchers often cannot (a) capture M_U or (b) know the reliability of their measures for observed variables. In response, sensitivity analyses can be especially useful, as they can inform researchers about the strength of the evidence undergirding their inferences (e.g., Frank et al., 2021; Rosenbaum, 2002; VanderWeele & Arah, 2011). More specifically, sensitivity analyses quantify conditions that would invalidate inferences, considering, for example, specific correlations (Frank, 2000), the percent of variance explained (Cinelli & Hazlett, 2020), or graphical representations like contour plots (Imbens, 2003). For instance, correlation-based sensitivity analyses indicate how strongly an omitted variable must be correlated with both the predictor and the outcome to change the inference regarding the effect of the treatment on the outcome (Frank, 2000).

Omitted Confounders and Measurement Error in Mediation Analyses

Confounders in Traditional and Modern Mediation Frameworks

In the past decade, many studies have investigated the influence of potential confounders on mediation inferences and provided different approaches for sensitivity analyses (e.g., Imai, Keele, & Tingley, 2010; Imai, Keele, & Yamamoto, 2010; Imai & Yamamoto, 2013; Liu & Wang, 2021; Park & Esterling, 2021; Tchetgen Tchetgen & Shpitser, 2012; VanderWeele, 2015). To better understand these different approaches to sensitivity analysis, we start with the relationship between modern causal mediation methods based on the potential outcomes framework (e.g., Hong et al., 2018; Imai & Yamamoto, 2013; VanderWeele, 2015) and traditional mediation analyses (e.g., Baron & Kenny, 1986). The potential outcomes framework emphasizes the estimation of causal quantities and stresses the assumptions required for causal conclusions (Mackinnon et al., 2020). Although some researchers prefer nonparametric analyses that compare expected values between treatment and control cases (e.g., Hong, 2010; Hong et al., 2015, 2018), many widely adopted modern causal mediation analyses are based on regression models (e.g., VanderWeele, 2015, Chapter 2.2; VanderWeele & Vansteelandt, 2009, 2010). In the absence of an *XM* interaction or any other nonlinear form in a single mediator model with a continuous mediator and outcome, both the potential outcomes framework (modern approach) and traditional mediation analyses estimate the same mediation effect (Mackinnon et al., 2020).

The comparison between the modern approach and traditional mediation analyses is more complicated in more complex mediation models since the mediation effect of interest could vary across different studies. Using the potential outcomes framework, Daniel et al. (2015) discussed 24 possible decompositions of the total treatment effect in a dual mediator model. As Daniel et al. (2015) explain, when researchers focus on M_O, they often decompose the total treatment effect into an indirect effect through pathways involving M_O and a direct effect not involving M_O. We refer to these two effects as M_O-oriented effects. In a dual mediator model (Figure 1C, with dotted line), the indirect M_O-oriented effect then includes both $X \rightarrow M_O \rightarrow Y$ and $X \rightarrow M_U \rightarrow M_O \rightarrow Y$, and the direct effect not involving M_O includes both $X \rightarrow Y$ and $X \rightarrow M_U \rightarrow Y$. Many modern causal mediation analyses adopt this approach of M_O-oriented effects to treat M_U in corresponding sensitivity analyses (e.g., Hong et al., 2018; Tchetgen Tchetgen & Shpitser, 2012; VanderWeele & Chiba, 2014).

Researchers using traditional mediation analysis handle multiple mediator models differently. Instead of starting from causal quantities based on potential outcomes, they specify linear models with stricter assumptions which allow them to estimate each path-specific effect. For example, Hayes (2018, p. 167) presents a "serial multiple mediator model" (Figure 1C, with dotted lines) assuming no interaction effects. Hayes then estimates all four *specific* linear pathways: the *specific* indirect effect of X on Y through M_O *only* ($X \rightarrow M_O \rightarrow Y$), the *specific* indirect effect of X on Y through M_U *only* ($X \rightarrow M_U \rightarrow Y$), the *specific* indirect effect of X on Y through both M_O and M_U ($X \rightarrow M_U \rightarrow M_O \rightarrow Y$), and the direct effect of X on Y ($X \rightarrow Y$). Similarly, adopting linear assumptions with no interaction effects, Preacher and Hayes (2008) present models with multiple mediators that do not causally affect one another and decompose the total treatment effect into the *specific* indirect effect via *each* mediator and the specific direct effect from X to Y.

Importantly, a *specific* indirect effect via M_O alone measures the effect of X on Y through M_O "while holding constant other mediators" (Hayes, 2018, p. 183). In contrast, the M_O-oriented indirect effect is a sum of all indirect effects via M_O. In both cases, however, M_U acts as a posttreatment confounder because X causes M_U, which, in turn, confounds the relationship from M_O to Y. In other words, omitting M_U may bias the statistical inference whether the researcher is interested in the M_O-oriented indirect effect or the *specific* indirect effect via M_O alone.

Co-Occurrence of Confounders and Measurement Error

Building on previous research on the impact of measurement error on linear regression and traditional mediation analyses (e.g., Cohen et al., 2003; Judd & Kenny, 2010; Kenny, 1979; Lord & Novick, 1968; Sengewald & Pohl, 2019), recent studies have started to consider the co-occurrence of confounding variables and measurement error. Fritz et al. (2016) discuss how the co-occurrence of omitted confounders and measurement error impacts the point estimation of the mediation effect. Liu and Wang (2021) extend Fritz et al.'s (2016) work by (a) discussing the combined impact of confounders and measurement error on the statistical inference of mediation effects and (b) proposing a sensitivity analysis. However, both Fritz et al. and Liu and Wang focus on *pretreatment* confounders; they do not evaluate cases where there is an association between the treatment and the confounder.

The Current Study

While recognizing the value of the modern potential outcomes framework, most existing psychological research relies on the traditional approach specified in terms of linear models. In this context, researchers, especially those conducting meta-analyses, need a tool to evaluate the robustness of their mediation inferences in linear models given the strong likelihood of potential omitted mediators and measurement error. Therefore, we focus on the traditional approach and assume both linearity and no interaction between the treatment and mediators.[1] With these assumptions, we identify and focus on the *specific* indirect effect via a single mediator *alone* and the direct effect from treatment to outcome in complex mediation models, and further propose a correlation-based sensitivity analysis that considers both an *unmeasured* confounding mediator and potential measurement error. In particular, building off previous research on pretreatment confounders (e.g., Fritz et al., 2016; Liu & Wang, 2021), we examine if/how (a) omitting an alternative mediator (as a posttreatment confounder) and (b) measurement error bias the estimated mediation effects from the *path-specific* linear perspective. We also propose a sensitivity analysis and provide an R package to assess the robustness of mediation inferences given the omission of an unobserved M_U and incorporating potential measurement error in observed M_O and Y.

To clarify, rather than decomposing the total treatment effect into two M_O-oriented effects (as mentioned in the last section), we focus on (a) the *specific* direct effect from X to Y ($X \rightarrow Y$), and (b) the *specific* indirect effect via M_O alone ($X \rightarrow M_O \rightarrow Y$), estimated as the product of the paths $X \rightarrow M_O$ and $M_O \rightarrow Y$ (Hayes, 2018, p. 170). For simplicity, we may refer to these two effects as simply indirect effect (or mediation effect) and direct effect in the following discussions. With the omission of M_U from the model (Figure 1C with dotted line), the indirect effect via M_U alone ($X \rightarrow M_U \rightarrow Y$) and the indirect effect via both mediators ($X \rightarrow M_U \rightarrow M_O \rightarrow Y$) are mistakenly reallocated to either the specific indirect effect via M_O alone or the direct effect from X to Y, leading to bias in the estimation of these two effects. This approach affords conceptual clarity and theory building for those familiar with the linear framework. Furthermore, it enables our analysis of measurement error and the development of a sensitivity analysis. While our sensitivity analysis approach is also applicable for *unobserved pretreatment* confounders, we assume no other confounding given *observed* covariates, the *unobserved* confounding mediator, and measurement error so that the effects of interest are well defined.

To follow, we first introduce dual-mediator designs that consider measurement error in M_O and Y as the true model. Then, we discuss bias when omitting unobserved mediators and/or measurement error in M_O and Y. We present the analytical findings along with an illustrative example to show how excluding a mediator and/or not accounting for measurement error affects parameter estimates and standard errors and, thus, mediation inferences. We conclude with implications for future research, specifically our proposed sensitivity analysis and its accompanying R package.

We present our findings in terms of both path coefficients and correlations. The path coefficient approach shows how different parameter levels in true models affect the direction and magnitude of bias, thereby allowing us to understand how the omission of an additional mediator generates bias (assuming the "truth" is known). Such approach is especially useful when interpreting analytical findings (Part I). The correlation approach, on the other hand, presents how path coefficient estimates vary by the magnitude of correlations among variables. Based on the left out variable error (L.O.V.E) framework (Cox et al., 2013; Mauro, 1990) and Frank's (2000) impact threshold for a confounding variable (ITCV), we proposed a sensitivity analysis method (Part II) using correlations as sensitivity parameters so that applied researchers could consider and evaluate such values more easily. Leveraging the joint significance test and the ITCV approach, the proposed sensitivity analysis method allows researchers to use one or two sensitivity parameters to understand how omitting M_U impacts statistical inference through influencing both the point estimate and the standard error. In short, the path coefficient framework and the correlation framework provide a comprehensive representation of the potential threat posed by confounding M_U and measurement error to mediation analyses.

Part I: Bias Due to Omitted Mediators and/or Measurement Error

Two Mediator Designs with Potential Measurement Error in M_O and Y

Hayes (2018) presented a serial multiple mediation model with two mediators (see Figure 1C), where one mediator (M_U) has a serial or sequential effect on the second mediator (M_O) on route to Y. The parallel and sequential mediation models (see Figure 1E and F, respectively) are likewise dual mediator models, but they are special cases. Thus, we focus on the more general serial mediation model to evaluate if/how omitting M_U biases the estimates of the direct effect from X to Y and the *specific* indirect effect via M_O alone, defined as the product of the paths $X \rightarrow M_O$ and $M_O \rightarrow Y$. Additionally, in line with previous literature (Fritz et al., 2016; Liu & Wang, 2021), we assume that in the true model, X is perfectly reliable and M_O and Y have potential measurement error. Equations (1)–(5) specify the true model with standardized coefficients,

$$M_O^* = k \cdot M_U + a_1 \cdot X + \varepsilon_{M_O^*} \tag{1}$$

$$M_U = a_2 \cdot X + \varepsilon_{M_U} \tag{2}$$

$$Y^* = b_1 \cdot M_O^* + b_2 \cdot M_U + c \cdot X + \varepsilon_{Y^*} \tag{3}$$

$$M_O = M_O^* + \varepsilon_{M_O} \tag{4}$$

$$Y = Y^* + \varepsilon_Y \tag{5}$$

where ε_{M_O} and ε_Y represent the measurement error in M_O and Y, respectively. The reliability levels of M_O and Y are $r_{MM} = \frac{\mathrm{Var}(M_O^*)}{\mathrm{Var}(M_O)}$ and $r_{YY} = \frac{\mathrm{Var}(Y^*)}{\mathrm{Var}(Y)}$. We also assume ε_{M_O} and ε_Y are independent to simplify the derivation. In contrast, Equations (6) and (7) specify the model excluding M_U and not considering measurement error. To simplify the discussion, we excluded any *observed* covariates in the analysis. However, the derived results still pertain when *observed* covariates Z are included in both the true and mis-specified models (Equations 1–7) if all quantities are expressed conditional on Z (i.e., we residualize the other variables with respect to Z). Additionally, the difference between Equations (1)–(5) and Equations (6)–(7) is restricted to the confounding

[1] For sensitivity analysis in the modern framework, in addition to existing approaches, users might want to consider the Robustness of Inference to Replacement (Frank et al., 2013, 2021) which is non-parametric and quantifies the robustness in terms of how many cases would have to be replaced with cases for which there was no effect to change inference (Lin & Frank, 2023).

mediator M_U and measurement error, meaning that there is no other confounding given observed covariates.

$$M_O = \tilde{a}_{1ME} \cdot X + \varepsilon_{M_O} \quad (6)$$

$$Y = \tilde{b}_{1ME} \cdot M_O + \tilde{c}_{ME} \cdot X + \varepsilon_Y. \quad (7)$$

Given our focus on the direct effect from X to Y and *specific* indirect effect via M_O alone, we are interested in estimating c and a_1b_1. Accordingly, the goal is to evaluate the differences between $\tilde{a}_{1ME}$, $\tilde{b}_{1ME}$, and $\tilde{c}_{ME}$ (the standardized parameter coefficients when excluding M_U and not accounting for measurement error) and a_1, b_1, and c (the standardized parameter coefficients when including M_U and accounting for measurement error). Toward this, we first assume zero measurement error and focus on the bias due to the omission of M_U. That is, we examine the implication of fitting model Figure 1A when the true model is Figure 1C. As shown in Figure 2, we denote the standardized parameter coefficients as $\tilde{a}_1$, $\tilde{b}_1$, and $\tilde{c}$ when excluding M_U (vs. $\tilde{a}_{1ME}$, $\tilde{b}_{1ME}$, and $\tilde{c}_{ME}$ when measurement error is *not* zero). Second, we discuss scenarios with multiple M_U in the true model with zero measurement error. Finally, we examine the combined effects of measurement error and the omission of M_U on estimated mediation effects.

Illustrating the Consequences of Omitting a Potential Confounding Mediator

We apply the example data Hayes (2018) used to demonstrate the potential consequences of omitting a potential confounding mediator in a serial two-mediator model, assuming zero measurement error. These data were originally drawn from Tal-Or et al.'s (2010) experimental study on how the media affects behavior. Specifically, this model tests if people's perceptions of how the media influences others (M_O) mediates the relationship between the media (X) and people's attitudes (Y). In other words, when a hypothetical character, Ashley, reads a media report, her perception of how other people will respond to the report may be affected by media and further influence her attitudes and behaviors. To test this hypothesis, participants were randomly assigned to two groups, both of which were asked to read a newspaper article about an economic crisis affecting the price and supply of sugar. Researchers told one group that this article came from the front page of a major newspaper, and they told the other group that it appeared on a supplemental page of the newspaper. Accordingly, participants were assigned to a condition variable (X, denoted by COND), indicating whether they were part of the front page (treatment) or the supplemental page (control) group. After participants finished reading the article, researchers asked them the extent to which they believed that other readers would be inclined to buy sugar. In our model, this presumed media influence (PMI) served as one mediator (M_O, denoted by PMI). Researchers also asked participants to rate the article's importance. Participants' perception of the importance of the article acted as the second mediator (M_U, denoted by IMPORT). Lastly, Tal-Or et al. (2010) asked all participants how soon they intended to buy sugar and how much they intended to purchase. Aggregating these responses, they generated the outcome variable (Y, denoted by REACTION), which served as a measure of participants' intention to purchase sugar.

As shown in Figure 3A, the first fitted model includes both mediators: PMI and IMPORT. For the mediation path via PMI, people are more likely affected by front-page news articles than those on supplemental pages. Meanwhile, for the mediation path via IMPORT, people infer the importance of the article by its placement in the newspaper and act according to the importance of said article. IMPORT also likely predicts PMI; the more important people believe the article is, the more likely they believe that it will influence others. Consequently, one would expect that people who read about this sugar crisis on the front page of a newspaper would view this economic situation as important and be more likely to purchase sugar before other readers do and, subsequently, drive up the price. Similarly, one would expect that people who read about this sugar situation in a supplemental article would assume this situation is less important and be less likely to quickly buy sugar, as they would be less concerned that others' purchasing behavior would drive up sugar prices.

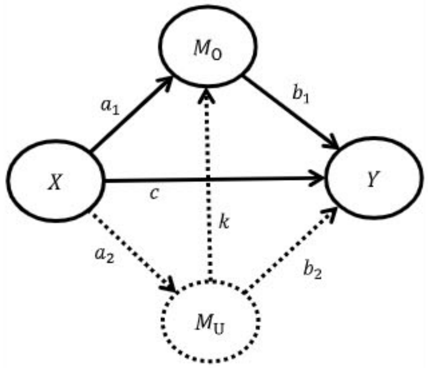
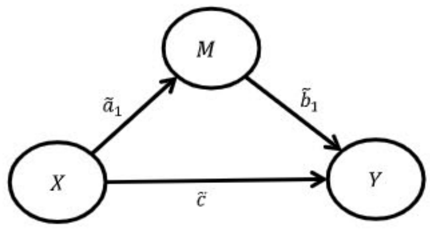
We fit Figure 3A with standardized data,[2] thereby creating standardized estimates for path coefficients and report both the joint test of significance approach (Fritz & MacKinnon, 2007; MacKinnon et al., 2002) and the 95% percentile bootstrap confidence intervals based on 5,000 samples (e.g., Falk, 2018; Fritz & MacKinnon, 2007). Both the effects from COND to IMPORT and from IMPORT to REACTION were significant and positive, with estimated effects of 0.181 ($SE = 0.086$, $p = .036$) and 0.363 ($SE = 0.074$, $p < .001$), respectively. The estimated specific indirect effect through IMPORT alone was positive and significant ($0.181 \times 0.363 \approx 0.066$, bootstrap CI [*0.001*, *0.150*]). In contrast, the estimated specific indirect effect via PMI alone was not significant ($0.134 \times 0.338 \approx 0.045$, [*−0.013*, *0.114*]). Only the effect from PMI to REACTION was positive and significant (0.338, $SE = 0.075$, $p < .001$), but the effect from COND to PMI was not significantly different from zero (0.134, $SE = 0.086$, $p = .119$). That is, presumed media influence does not appear to mediate the relationship between people's reactions and the article's location, when the perceived importance of the issue (IMPORT) is held constant. Additionally, the predictive relationship from IMPORT to PMI was significant and positive (0.258, $SE = 0.084$, $p = .002$), meaning the more important people perceive an issue to be, the more likely they believe that it will influence others' actions.

Now, we consider what would happen if we omitted IMPORT from the fitted model. Such a scenario could occur if this alternative, theoretically relevant mediator, was not measured or considered. Given the prevalence of published studies using single mediator models, such omissions are likely common because it is theoretically unlikely that any single mediator fully explains the association between X and Y (Maxwell et al., 2011). In the reduced model, PMI is the only observed mediator, and Figure 3B presents these results. When excluding IMPORT, the specific indirect effect via PMI was significant and positive ($0.181 \times 0.432 \approx 0.078$, bootstrap CI [*0.001*, *0.168*]), and both paths in the indirect effect were significantly positive. As such, one would erroneously conclude that the specific indirect effect via PMI is significantly larger than zero.

[2] We standardized all variables for analysis to be consistent with our later derivation, including the binary treatment variable. Therefore, the coefficients we present are different from those presented in Hayes (2018). However, this does not affect inferences based on statistical significance.

Figure 2

True Model with Two Mediators and the Model Omitting M_U (with Zero Measurement Error)

True Model (zero measurement error)	Model if omitting M_U
	
$M_O = k \cdot M_U + a_1 \cdot X + \varepsilon_{M_O}$ $M_U = a_2 \cdot X + \varepsilon_{M_U}$ $Y = b_1 \cdot M_O + b_2 \cdot M_U + c \cdot X + \varepsilon_Y$	$M_O = \tilde{a}_1 \cdot X + \varepsilon_{M_O}$ $Y = \tilde{b}_1 \cdot M_O + \tilde{c} \cdot X + \varepsilon_Y$

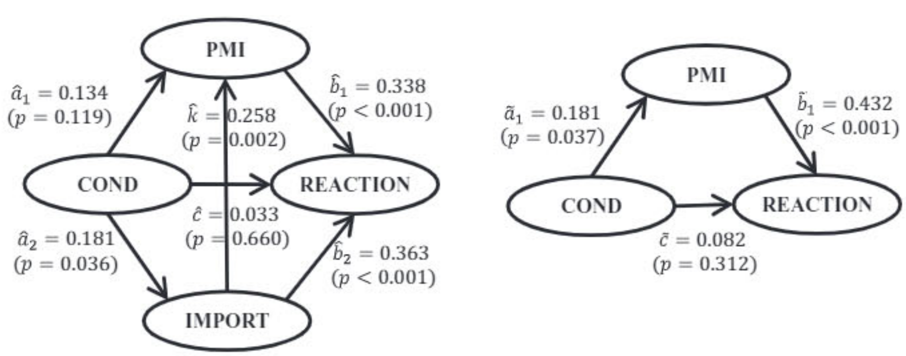
Specifically, when excluding the mediator IMPORT, the direct path from article location to PMI increased from 0.134 to 0.181, and the direct path from PMI to participants' reaction increased from 0.338 to 0.432. In short, when excluding IMPORT, the estimated effects of both paths for this indirect effect via PMI were greater.

As illustrated by the newspaper example, the omission of an alternative mediator produced an alternative conclusion or inference. Specifically, the indirect effect via PMI from COND to REACTION was significantly positive. In both models, the direct path from article location to participants' reaction was not significantly different from zero, but the point estimate increased from 0.033 to 0.082 with the exclusion of IMPORT. Thus, excluding an alternative mediator can affect both the estimated effects and their corresponding inferences. The differences in these results have deep implications. In social sciences, researchers base theoretical and real-life decisions on their inferences of such results, and decisions informed by inaccurate inferences may induce not only unintended, but profoundly adverse, consequences (e.g., Holland,

Figure 3

Illustrative Data Example of Presumed Media Influence

A The model that includes both PMI and IMPORT B The model that excludes IMPORT



1986). This is likely especially true in the case of mediation findings because preventive intervention efforts often target the mechanisms through which a risk process occurs (e.g., Cicchetti & Toth, 2006).

Asymptotic Bias When Omitting M_U

Now, we present analytical findings for asymptotic bias when omitting M_U. Recall we used Hayes' (2018) serial two-mediator model to assess the potential effects of omitted confounding mediators. Following the notations introduced earlier, we derived $\tilde{a}_1$, $\tilde{b}_1$, and $\tilde{c}$ (the standardized parameter coefficients when excluding M_U) and evaluate their differences with a_1, b_1, and c (the standardized parameter coefficients when including M_U), assuming zero measurement error (see Figure 2). For the derivation, we applied the Law of Iterated Expectation, which states that $E(Y|X) = E[E(Y|X, Z)|X]$, where X, Y, and Z are three variables, and $E(X)$ represents the conditional expectation (or conditional mean) of Y given X (Wooldridge, 2009). The following equations present the results (see online supplemental materials A for more detailed derivations and discussion):

$$\tilde{a}_1 = a_1 + k \cdot a_2 \tag{8}$$

$$\tilde{b}_1 = b_1 + b_2 \cdot k \cdot \frac{1 - a_2^2}{1 - (k \cdot a_2 + a_1)^2} \tag{9}$$

$$\begin{aligned}\tilde{c} &= c + b_2 \cdot \frac{a_2 - (k + a_1 \cdot a_2) \cdot (k \cdot a_2 + a_1)}{1 - (k \cdot a_2 + a_1)^2} \\ &= c + b_2 \cdot \frac{\rho_{X M_U} - \rho_{M_O M_U} \cdot \rho_{X M_O}}{1 - (k \cdot a_2 + a_1)^2}\end{aligned} \tag{10}$$

$$\tilde{a}_1 \tilde{b}_1 = a_1 b_1 + k \cdot a_2 \cdot b_1 + \frac{k \cdot b_2 \cdot (a_1 + k \cdot a_2) \cdot (1 - a_2^2)}{1 - (k \cdot a_2 + a_1)^2}. \tag{11}$$

As reflected in Equations (8)–(10), $\tilde{a}_1$, $\tilde{b}_1$, and $\tilde{c}$ are functions of true parameters.[3] More specifically, a_1 and b_1 represent the true effects via M_O, while a_2 and b_2 represent the true effects via M_U. In our earlier example, the product of a_1 and b_1 is the true indirect effect through the observed mediator PMI only, while the product of a_2 and b_2 is the true indirect effect through the omitted mediator IMPORT only.

First, only under stringent conditions are $\tilde{a}_1$, $\tilde{b}_1$, and $\tilde{c}$ equal to a_1, b_1, and c. Importantly, the conditions under which asymptotically unbiased *direct* and *indirect* effects occur are not the same, meaning one cannot simultaneously obtain both accurate direct and indirect effects. To obtain an asymptotically unbiased *indirect* effect via M_O alone when omitting M_U, M_U must have zero effect on M_O. This is equivalent to a parallel two-mediator model (i.e., Figure 1B). However, to obtain an asymptotically unbiased *direct* effect when omitting M_U, either one of the following conditions must be met: (a) $\rho_{X M_U} = \rho_{M_O M_U} \cdot \rho_{X M_O}$ or (b) $b_2 = 0$. The former condition occurs when X and M_U are uncorrelated, conditional on M_O. That is, when M_U contains no unique information about X (in terms of linear relationships) omitting M_U does not have an impact on the estimated direct effect from X to Y. The latter condition indicates that M_U has no effect on Y. In general, when the mediation effect via M_U is nonzero ($a_2 \neq 0$ and $b_2 \neq 0$), and M_U has a nonzero effect on M_O ($k \neq 0$), the estimates for a_1, b_1, and c are biased ($a_1 \neq \tilde{a}_1$, $b_1 \neq \tilde{b}_1$, $c \neq \tilde{c}$).

Second, the direction and magnitude of bias depend on the three M_U-related path coefficients (k, a_2, and b_2). From Equation (11), the indirect effect estimate via M_O alone is always positively biased when k, a_2, and b_2—the three M_U-related path coefficients—all take the same sign (see online supplemental materials A for detailed proof). The bias equals to: $k \cdot a_2 \cdot b_1 + \frac{k \cdot b_2 \cdot (a_1 + k \cdot a_2) \cdot (1 - a_2^2)}{1 - (k \cdot a_2 + a_1)^2}$. In our earlier example, the three path coefficients associated with IMPORT were all positive. Thus, when excluding IMPORT, the indirect effect through PMI increased from 0.045 to 0.078.

In terms of the direct effect $\tilde{c}$, the direction of bias depends on whether b_2 and $[a_2 - (k + a_1 \cdot a_2) \cdot (k \cdot a_2 + a_1)]$ have the same sign (in online supplemental materials A, we show that $a_2 - (k + a_1 \cdot a_2) \cdot (k \cdot a_2 + a_1) = \rho_{XM_U} - \rho_{XM_O} \cdot \rho_{M_O M_U}$). Returning to our example case, the path coefficient from IMPORT to the outcome REACTION (b_2) was positive. Additionally, the correlation between COND and IMPORT was greater than the product of the correlations between COND and PMI and between PMI and IMPORT ($\rho_{XM_U} > \rho_{XM_O} \cdot \rho_{M_O M_U}$). Accordingly, the direct effect increased from 0.033 to 0.082 upon omitting IMPORT.

Note that bias could also be written in terms of correlations only. Equations A5.1–A5.3 in online supplemental materials A present the result, which show that the bias is a function of three unknown correlations associated with M_U: ρ_{XM_U}, ρ_{YM_U}, and $\rho_{M_O M_U}$. Such a function is also consistent with our analytical results in Equations (8)–(11), where the three unknown parameters related to M_U (a_2, b_2, and k) determine the bias due to M_U. In our example, this means we can either consider bias in terms of unknown path coefficients related to IMPORT or the three unknown correlations associated with IMPORT. Later we will use the correlations as sensitivity parameters to evaluate how sensitive the estimated direct and specific indirect effects via PMI alone are to a potential posttreatment confounder M_U.

Asymptotic Bias When Omitting Multiple M_U

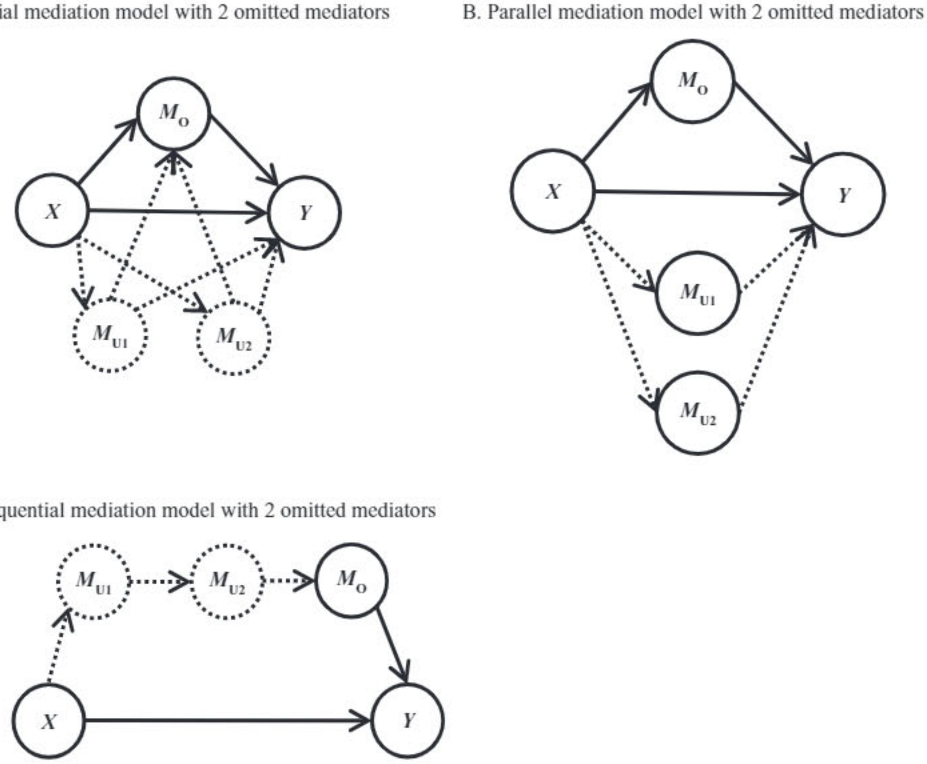
Above, we accounted for only one M_U in the true model. However, in practice, more than one omitted confounding mediator likely exists in the true underlying mediating process. In the online supplemental materials A, we provide analytical results for scenarios with N unobserved mediators $M_{U1} \ldots M_{UN}$. When these unobserved mediators are all independent of each other[4] (Figure 4A shows the case for $N = 2$), we show that the asymptotic bias due to omission of the N unobserved mediators is the sum of the asymptotic bias caused by each M_U. For example, when the two biases have the same direction (e.g., both positive), then the presence of a second M_U increases overall asymptotic bias. This is consistent with Fritz et al.'s (2016) discussion of pretreatment confounders and Clarke's (2005) conclusions that the bias can increase, decrease, or remain the same when excluding more than one confounder from the model. The assumption of independent omitted mediators

[3] We can also write $\tilde{a}_1$, $\tilde{b}_1$, and $\tilde{c}$ as functions of correlations among variables, see Equations SA5.1–SA5.3 in online supplemental material.

[4] But their correlations are not zero because they are all caused by the treatment X.

Figure 4

Omitting Two Mediators in Serial, Parallel, and Sequential Mediation Models



is a natural assumption for unobserved hypothetical variables. One could also conceptualize orthogonalizing the related mediators to establish independence (e.g., regressing each mediator on the previous mediators and using the residuals as the orthogonalized mediator) and then the presented results would pertain.

In the special scenario with N unobserved mediators in a parallel mediation model (Figure 4B shows such case for $N = 2$), the indirect effect via M_O alone is always asymptotically unbiased, irrespective of the total number of M_U in the true model. At the same time, the direct effect from X to Y is asymptotically biased unless the indirect effects via the other omitted mediators cancel each other out. In the special scenario with N unobserved mediators in a sequential mediation model (Figure 4C shows such a case for $N = 2$), the estimates for b_1 and c are asymptotically unbiased while the estimate of a_1 is always biased because the estimated effect of $X \rightarrow M_O$ picks up all the intermediated processes via those omitted mediators.

Measurement Error in M_O and Y

In addition to bias due to the omission of potential confounding mediators, it is also very likely that measurement error affects mediation analyses. In line with previous literature (e.g., Fritz et al., 2016; Liu & Wang, 2021), we assume there is only one omitted mediator and X is perfectly reliable, and there is measurement error in M_O and Y. Building on Fritz et al.'s (2016) work, we start with the scenario where there is measurement error in M_O and Y but no omitted M_U and illustrate the analytical findings using our earlier illustrative example.

As before, we focus on standardized coefficients. As shown by Kenny (1979) and Fritz et al. (2016), when X has no measurement error (i.e., the reliability of X is equal to 1; $r_{XX} = 1$), the standardized estimates of a, b, and c in a single mediator model equal:

$$a_{\mathrm{ME}} = a \cdot \sqrt{r_{MM}} \tag{12}$$

$$b_{\mathrm{ME}} = b \cdot \omega \cdot \frac{\sqrt{r_{YY}}}{\sqrt{r_{MM}}} \tag{13}$$

$$c_{\mathrm{ME}} = \sqrt{r_{YY}} \cdot [c + a \cdot b \cdot (1 - \omega)] \tag{14}$$

where ω is the reliability of M after partialling out X and equals $\frac{r_{MM} - r_{XM}^2}{1 - r_{XM}^2}$ (Fritz et al., 2016). a_{ME}, b_{ME}, and c_{ME} are the estimates that do *not* account for measurement error. r_{MM} and r_{YY} represent the reliability of M and Y, respectively.

When $r_{MM} < 1$, a_{ME} is always smaller than a, indicating the estimated effect of a is attenuated by measurement error in M. Also, ω is always less than 1 when $r_{MM} < 1$, indicating the estimated effect of b is also attenuated by measurement error when $r_{MM} = r_{YY}$ (i.e., $b_{\mathrm{ME}} < b$). To get sense of how measurement error affects c_{ME}, we regard the *standardized* estimate c_{ME} as a product of $\sqrt{r_{YY}}$ and $[c + a \cdot b \cdot (1 - \omega)]$, where the latter part is the *unstandardized* estimate of c. As Fritz et al. (2016) explain, when $a \cdot b$ and c have the same sign,[5] the *unstandardized* estimate of c is biased in the same direction of c, resulting in the overestimation of c. The overestimation, as reflected by $[a \cdot b \cdot (1 - \omega)]$,

[5] This is also known as consistent mediation. See MacKinnon et al. (2000).

shows a "complementing" of the attenuation in the estimated effect of b.[6] As such, in the standardized case of c_{ME}, the first part of $\sqrt{r_{YY}}$ shows attenuation due to measurement error in Y, while the second part $[c + a \cdot b \cdot (1 - \omega)]$ shows overestimation due to measurement error in M. The final impact on the *standardized* estimate c_{ME} then depends on the relative magnitude of the attenuation versus overestimation.

To illustrate, we revisit the example regarding presumed media influence (PMI). We generated two random errors independent from all other variables and used them as measurement error for the mediator PMI and outcome REACTION, respectively. We adjusted the variance of the two random errors so that the reliability levels for both are 0.7. Then, we fit the new data with a single mediator model for PMI (see Figure 5 for the results). Comparing Figure 5 with Figure 3B, the effect from COND to PMI (a path) is attenuated from 0.181 to 0.151, and the estimate is no longer significant. Also, the effect from PMI to REACTION (b path) is attenuated from 0.432 to 0.299. The effect from COND to REACTION increases from 0.082 to 0.089. That is, in this example, with a *consistent* mediation, the overestimation due to measurement error in PMI exceeds the attenuation due to measurement error in REACTION, leading to the overestimation of the final estimated effect of c (the direct effect from COND to REACTION). However, changing the reliability of PMI to 0.9 while leaving the reliability of REACTION at 0.7 (i.e., $r_{MM} = 0.9$ and $r_{YY} = 0.7$), the attenuation due to measurement error in REACTION exceeds the overestimation due to measurement error in PMI, leading to the underestimation of the final estimated effect of c (see Table 1).[7]

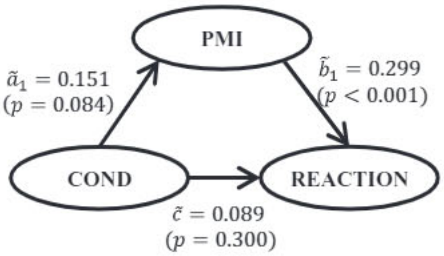
Combined Effect of Omitted M_{U} and Measurement Error in M_{O} and Y

Next, we examine the effect on the model upon omitting a single M_{U}, assuming there is measurement error in both M_{O} and Y. We first present analytical findings and then illustrate the results with the PMI example. Extending Fritz et al.'s (2016) work, we write the standardized point estimates of a_1, b_1, and c as follows (see online supplemental materials A for derivation details).

$$\tilde{a}_{1\mathrm{ME}} = a_1 \cdot \sqrt{r_{MM}} + k_{\mathrm{ME}} \cdot a_{2\mathrm{ME}} \tag{15}$$

Figure 5

Illustrative Data Example of Presumed Media Influence When $r_{MM} = r_{YY} = 0.7$



$$\tilde{b}_{1\mathrm{ME}} = b_1 \cdot \omega \cdot \frac{\sqrt{r_{\mathrm{YY}}}}{\sqrt{r_{\mathrm{MM}}}} + b_{2\mathrm{ME}} \cdot k_{\mathrm{ME}} \cdot \frac{1 - a_{2\mathrm{ME}}^2}{1 - (k_{\mathrm{ME}} \cdot a_{2\mathrm{ME}} + a_{1\mathrm{ME}})^2} \tag{16}$$

$$\tilde{c}_{\mathrm{ME}} = \sqrt{r_{YY}} \cdot [c + a_1 \cdot b_1 \cdot (1 - \omega)] + b_{2\mathrm{ME}} \cdot \frac{r_{X\,M_{\mathrm{U}}} - r_{M_{\mathrm{O}}\,M_{\mathrm{U}}} \cdot r_{X\,M_{\mathrm{O}}}}{1 - (k_{\mathrm{ME}} \cdot a_{2\mathrm{ME}} + a_{1\mathrm{ME}})^2} \tag{17}$$

where ω is the reliability of M_{O} after partialling out X and M_{U}. Specifically, it equals $\frac{r_{MM} + 2 \cdot r_{XM_{\mathrm{O}}} \cdot r_{M_{\mathrm{O}}M_{\mathrm{U}}} \cdot r_{XM_{\mathrm{U}}} - r_{MM} \cdot r_{XM_{\mathrm{U}}}^2 - r_{XM_{\mathrm{O}}}^2 - r_{M_{\mathrm{O}}M_{\mathrm{U}}}^2}{1 + 2 \cdot r_{XM_{\mathrm{O}}} \cdot r_{XM_{\mathrm{U}}} \cdot r_{M_{\mathrm{O}}M_{\mathrm{U}}} - r_{XM_{\mathrm{O}}}^2 - r_{XM_{\mathrm{U}}}^2 - r_{M_{\mathrm{O}}M_{\mathrm{U}}}^2}$. The terms k_{ME}, $a_{2\mathrm{ME}}$, and $b_{2\mathrm{ME}}$ are the path coefficients biased by measurement error, and $r_{X\,M_{\mathrm{U}}}$, $r_{M_{\mathrm{O}}\,M_{\mathrm{U}}}$, and $r_{X\,M_{\mathrm{O}}}$ are the observed correlations biased by measurement error.

Equations (15)–(17) demonstrate how measurement error biases the estimated point effects with the omitted M_{U}. When k_{ME}, $a_{2\mathrm{ME}}$, and $b_{2\mathrm{ME}}$ (the three M_{U}-related path coefficients) all take the same sign, measurement error and the omitted M_{U} have opposing effects on $\tilde{a}_{1\mathrm{ME}}$ and $\tilde{b}_{1\mathrm{ME}}$, assuming $r_{MM} = r_{YY}$. This is remarkably like Fritz et al.'s (2016) explanation of the combined effect of measurement error and a pretreatment confounder; the overall bias in $\tilde{a}_{1\mathrm{ME}}$ and $\tilde{b}_{1\mathrm{ME}}$ depend on whether measurement error or the omitted confounder has a stronger effect. If the measurement error has a stronger effect (smaller reliability), then the overall bias is negative ($\tilde{a}_{1\mathrm{ME}} < a_1$ and $\tilde{b}_{1\mathrm{ME}} < b_1$). If the omitted confounder has a stronger effect (such as larger k_{ME}), then the overall bias is positive ($\tilde{a}_{1\mathrm{ME}} > a_1$ and $\tilde{b}_{1\mathrm{ME}} > b_1$). Although it is mathematically possible to get unbiased estimates (i.e., if the two effects cancel each other), it is exceedingly rare in practice for $\tilde{a}_{1\mathrm{ME}} = a_1$ and $\tilde{b}_{1\mathrm{ME}} = b_1$.

When we examine the effect of measurement error and M_{U} separately, we conclude that, in both cases, the estimated effect of c could be positively biased, negatively biased, or unbiased depending on either the magnitude of path coefficients in the true model or the reliability levels of M_{U} and Y. Equation (17) makes it clear that the effect on the bias is even more complicated when we allow simultaneous existence of measurement error and M_{U}. The effect of omitting M_{U} depends on whether $r_{X\,M_{\mathrm{U}}}$ is larger than $r_{M_{\mathrm{O}}\,M_{\mathrm{U}}} \cdot r_{X\,M_{\mathrm{O}}}$. Meanwhile, the effect of measurement error depends on whether $\sqrt{r_{YY}}$ yields a stronger attenuation effect or if $[c + a \cdot b \cdot (1 - \omega)]$ shows a stronger overestimation effect due to measurement error in M_{O}. The overall bias of $\tilde{c}_{\mathrm{ME}}$ depends on the relative magnitude of all these effects.

Now, we illustrate the combined effects of measurement error and M_{U} with the PMI example (Table 1). In the example, the three path coefficients related to IMPORT (M_{U}) were all positive. Thus, excluding IMPORT generates positive bias for the coefficients of both a_1 and b_1. As reliability levels change, the corresponding

[6] Note that the *unstandardized* estimate of a is not affected by measurement error in M_{O}; only the *unstandardized* estimated effect of b is biased and attenuated.

[7] Note that the total effect (in terms of *standardized* coefficients) from COND to REACTION in Figure 5 is attenuated as well compared to Figure 3B because the correlation between COND and REACTION becomes smaller due to measurement error in REACTION.

Table 1

Standardized Point Estimates and Statistical Inferences When M_O and Y Have Unattended Measurement Error in the Illustrative Example Regarding Presumed Media Influence

	Reliability		Standardized point estimates and statistical inferences					
	r_{MM}	r_{YY}	Estimate of a_1	Inference of a_1	Estimate of b_1	Inference of b_1	Estimate of c	Inference of c
Exclude M_U (i.e., IMPORT)	1	1	.181	Sig.	.432	Sig.	.082	Not Sig.
	.9	.9	.171	Not Sig.	.387	Sig.	.086	Not Sig.
	.9	.7	.171	Not Sig.	.341	Sig.	.076	Not Sig.
	.7	.9	.151	Not Sig.	.339	Sig.	.101	Not Sig.
	.7	.7	.151	Not Sig.	.299	Sig.	.089	Not Sig.
Include M_U (i.e., IMPORT)	1	1	.134	Not Sig.	.338	Sig.	.033	Not Sig.

Note. a_1 = direct effect of $X \rightarrow M_O$ (i.e., COND → PMI); b_1 = direct effect of $M_O \rightarrow Y$ (i.e., PMI → REACTION); c = direct effect of $X \rightarrow Y$ (i.e., COND → REACTION).

attenuation also changes. When $r_{MM} = r_{YY} = 0.9$, the effect of measurement error is weaker than the effect of excluding IMPORT. Accordingly, both the estimated effect from COND to PMI and from PMI to REACTION increase with the co-occurrence of measurement error and the exclusion of IMPORT, leading the indirect effect through PMI to increase from 0.045 to 0.066. Note that 0.066 is smaller than 0.078, which is the estimate of the indirect effect when we only exclude IMPORT but have zero measurement error. This reflects what we previously described as opposing effects of measurement error and M_U.

As the reliability drops to 0.7 ($r_{MM} = r_{YY} = 0.7$), the attenuation effect of measurement error becomes even stronger that it counters the positive bias caused by omitting M_U. In that case, the estimated effect from COND to PMI drops to 0.151, and the estimated effect from PMI to REACTION drops to 0.299, generating an estimated indirect effect of 0.045 via PMI. The indirect effect via PMI is no longer statistically significant. That is, even if we exclude the mediator IMPORT, the inference regarding the indirect effect via PMI alone does not change because of the attenuation effect of measurement error on PMI and REACTION. From this perspective, the measurement error is useful as it counters the bias due to M_U. Practically, this also means it is more conservative to consider M_U and assume everything is perfectly measured.

In terms of the direct effect from COND to REACTION, it increased from 0.033 to 0.082 with the exclusion of IMPORT, assuming no measurement error. When PMI and REACTION are measured with different reliability levels, the estimated direct effect varies between 0.076 and 0.101 (Table 1). The largest estimated effect—0.101—occurs when the attenuation associated with REACTION's measurement error is weak, but the overestimation associated with PMI's measurement error is strong ($r_{YY} = 0.9$ and $r_{MM} = 0.7$). The inference, however, stays the same; the effect is not statistically significant from zero.

To further illustrate the magnitude of bias with the co-occurrence of M_U and measurement error, we calculate the severity of bias relative to the true effect (i.e., relative bias) under different scenarios. Specifically, like other studies on bias in mediation models (e.g., Maxwell & Cole, 2007; Maxwell et al., 2011; Mitchell & Maxwell, 2013), we determine the severity of bias under varying magnitudes of a_2, b_2, and k (i.e., 0.1 and 0.4) and reliability levels of M_O and Y (i.e., 0.7 and 1). Starting with the serial dual mediator design, we solve for the asymptotic bias of the direct effect of X on Y and the indirect effect via M_O alone (see Table 2 and Figure 1C). We replicate these calculations for a parallel mediation model ($k = 0$; see Table 3 and Figure 1E) and for a sequential mediation model ($a_1 = b_2 = 0$; see Table 4 and Figure 1F). In all models (Tables 2–4), $a_1 = 0.2$, $b_1 = 0.15$, $a_1b_1 = 0.03$, and $c = 0.1$, except in the case of the sequential mediation model, where $a_1 = 0$. The rows in each table display the estimated level of relative bias given different values of a_2, b_2, k, r_{YY}, and r_{MM}.

Magnitude of Asymptotic Bias in Serial Dual Mediator Models

For simplicity, we continue to assume all pathway coefficients were positive (results for negative pathways can be obtained by symmetry). When the measurement error is zero, the estimated indirect effect via M_O ($X \rightarrow M_O \rightarrow Y$) is always positively biased (see Table 2). Except for two minor cases, the direct effect from X to Y is also positively biased. Meanwhile, the magnitude of bias for the estimated indirect effect via M_O varies among cases. Based on our numerical computation of the analytical results, the largest level of (or worst) relative bias—a staggering 265.29%—occurred when we assumed a_2, b_2, and k were all 0.4. The smallest level of (or best) relative bias at 12.25% occurred when we assumed a_2, b_2, and k were all 0.1. Indeed, through additional analysis, we show that as k increases, the asymptotic bias (and relative bias) of $\tilde{a}_1\tilde{b}_1$ increases, while the asymptotic bias of $\tilde{c}$ decreases (see online supplemental materials A for more detailed discussion). The magnitude of asymptotic bias for the estimated direct effect ($\tilde{c}$) also varied substantially by case, with the most severe relative bias reaching an immense 151.44%. When the reliability levels of M_O and Y decreased from 1 to 0.7, measurement error then demonstrated the opposite effect of M_U, generating either a smaller positive bias or even a negative bias, except for one minor case for the direct effect from X to Y. The attenuation effect from measurement error is especially strong for the *indirect* effect, with the largest level of (or worst) relative bias drops from 265.29% to 104.79% due to measurement error ($a_2 = b_2 = k = 0.4$).

Magnitude of Asymptotic Bias in Parallel and Sequential Mediation Models

Assuming zero measurement error, all cases of parallel mediation model yield positively biased direct effects from X to Y, but unbiased indirect effects via M_O alone (Table 3). In contrast, all cases of the sequential mediation model yield positively biased indirect effects via M_O alone but unbiased direct effects from X to Y (Table 4). Equations (11) and (10) likewise suggest these patterns, where $k = 0$ produces an asymptotically unbiased estimated effect for a_1b_1 in the

Table 2
Bias in the Estimated Direct Effect of X on Y and Estimated Indirect Effect via M_O Alone

Parameters[a]			Reliability		Relative Bias (%)			
a_2	b_2	k	r_{MM}	r_{YY}	$(\tilde{a}_{1ME} - a_1)/a_1$	$(\tilde{b}_{1ME} - b_1)/b_1$	$(\tilde{c}_{ME} - c)/c$	$(\tilde{a}_{1ME}\tilde{b}_{1ME} - a_1b_1)/a_1b_1$
.4	.4	.1	1	1	20.00	23.77	151.44	48.52
.4	.4	.4	1	1	80.00	102.94	104.41	265.29
.4	.1	.1	1	1	20.00	5.94	37.86	27.13
.4	.1	.4	1	1	80.00	25.74	26.10	126.32
.1	.4	.1	1	1	5.00	27.62	31.30	34.00
.1	.4	.4	1	1	20.00	112.05	−0.34	154.47
.1	.1	.1	1	1	5.00	6.90	7.83	12.25
.1	.1	.4	1	1	20.00	28.01	−0.08	53.62
.4	.4	.1	.7	.7	0.40	−14.92	122.03	−14.58
.4	.4	.4	.7	.7	50.60	35.98	101.27	104.79
.4	.1	.1	.7	.7	0.40	−27.18	25.31	−26.89
.4	.1	.4	.7	.7	50.60	−15.75	24.25	26.88
.1	.4	.1	.7	.7	−12.15	−11.89	20.27	−22.59
.1	.4	.4	.7	.7	0.40	45.77	3.35	46.35
.1	.1	.1	.7	.7	−12.15	−26.19	−1.07	−35.16
.1	.1	.4	.7	.7	0.40	−12.00	−4.35	−11.65

Note. a_2 = direct effect of $X \to M_U$; b_2 = direct effect of $M_U \to Y$; k = direct effect of $M_U \to M_O$; r_{MM} = reliability of M_O; r_{YY} = reliability of Y; a_1 = direct effect of $X \to M_O$; b_1 = direct effect of $M_O \to Y$; c = direct effect of $X \to Y$; $\tilde{a}_{1ME}$ = direct effect of $X \to M_O$ with the omission of M_U and not accounting for measurement error; $\tilde{b}_{1ME}$ = direct effect of $M_O \to Y$ with the omission of M_U and not accounting for measurement error; $\tilde{c}_{ME}$ = direct effect of $X \to Y$ with the omission of M_U and not accounting for measurement error.
[a] Hypothetical path coefficients for the model depicted in Figure 1C.

parallel model, and $b_2 = 0$ produces an unbiased estimated effect for c in the sequential model. Additionally, both the bias of estimated *direct* effect in the parallel mediation model and the bias of the estimated *indirect* effect in the sequential mediation model increase as M_U-related path coefficients (k, a_2, and b_2) increase. In the parallel mediation model, the relative bias of the estimated direct effect increases from 10% to 160%, as a_2 and b_2 increase from 0.1 to 0.4. More importantly, the actual indirect effect in the sequential model is zero (since $a_1 = 0$), but the omission of M_U can give the impression of a considerable indirect effect: as a_2 and k increase from 0.1 to 0.4, the asymptotic bias of the estimated indirect effect increases from 0.0015 to 0.024, while the true value of a_1b_1 is zero.

The effect on the estimated indirect and directs effects changes when we assume non-zero measurement error in M_O and Y. In the parallel mediation model, although the omitted M_U does not cause bias in the indirect effect, the presence of measurement error leads to its underestimation, specifically a negative relative bias of 42.16% (Table 3). Measurement error also attenuated the positive bias in the direct effect; the largest (worst) relative bias drops to 125.28% (Table 3). Similarly, the direct effect $X \to Y$ in the sequential model is no longer unbiased with non-zero measurement error. Instead, it is negatively biased, with a relative negative bias of around 15%. Measurement error also dilutes the positive bias caused by the omitted M_U in the indirect effect via M_O alone, reducing the largest (worst) bias from 0.0240 to 0.0139.

Through these various investigations, we demonstrate how omitting potential mediators/posttreatment confounders can bias the estimate of the direct effect and the specific indirect effect via M_O alone. For example, the relative bias in the estimation of the indirect effect can exceed 200% when a_2, b_2, and k are relatively large. We also show how the co-occurrence of measurement error and M_U may further complicate

Table 3
Bias in the Estimated Direct Effect of X on Y and Estimated Indirect Effect Via M_O Alone in a Parallel Mediation Model

Parameters[a]			Reliability		Relative bias (%)			
a_2	b_2	k	r_{MM}	r_{YY}	$(\tilde{a}_{1ME} - a_1)/a_1$	$(\tilde{b}_{1ME} - b_1)/b_1$	$(\tilde{c}_{ME} - c)/c$	$(\tilde{a}_{1ME}\tilde{b}_{1ME} - a_1b_1)/a_1b_1$
.1	.1	0	1	1	0.00	0.00	10.00	0.00
.1	.4	0	1	1	0.00	0.00	40.00	0.00
.4	.1	0	1	1	0.00	0.00	40.00	0.00
.4	.4	0	1	1	0.00	0.00	160.00	0.00
.1	.1	0	.7	.7	−16.33	−30.86	−0.22	−42.16
.1	.4	0	.7	.7	−16.33	−30.86	24.88	−42.16
.4	.1	0	.7	.7	−16.33	−30.86	24.88	−42.16
.4	.4	0	.7	.7	−16.33	−30.86	125.28	−42.16

Note. a_2 = direct effect of $X \to M_U$; b_2 = direct effect of $M_U \to Y$; k = direct effect of $M_U \to M_O$; r_{MM} = reliability of M_O; r_{YY} = reliability of Y; a_1 = direct effect of $X \to M_O$; b_1 = direct effect of $M_O \to Y$; c = direct effect of $X \to Y$; $\tilde{a}_{1ME}$ = direct effect of $X \to M_O$ with the omission of M_U and not accounting for measurement error; $\tilde{b}_{1ME}$ = direct effect of $M_O \to Y$ with the omission of M_U and not accounting for measurement error; $\tilde{c}_{ME}$ = direct effect of $X \to Y$ with the omission of M_U and not accounting for measurement error.
[a] Hypothetical path coefficients for the model depicted in Figure 1E.

Table 4

Bias in the Estimated Direct Effect of X on Y and Estimated Indirect Effect via M_O Alone in a Sequential Mediation Model

Parameters[a]			Reliability		Bias				Relative bias (%)			
a_2	b_2	k	r_{MM}	r_{YY}	$\tilde{a}_{1ME} - a_1$	$\tilde{b}_{1ME} - b_1$	$\tilde{c}_{ME} - c$	$\tilde{a}_{1ME}\tilde{b}_{1ME} - a_1b_1$	$(\tilde{a}_{1ME} - a_1)/a_1$	$(\tilde{b}_{1ME} - b_1)/b_1$	$(\tilde{c}_{ME} - c)/c$	$(\tilde{a}_{1ME}\tilde{b}_{1ME} - a_1b_1)/a_1b_1$
.1	0	.1	1	1	.01	0.00	0.00	.0015	NA	0.00	0.00	NA
.1	0	.4	1	1	.04	0.00	0.00	.0060	NA	0.00	0.00	NA
.4	0	.1	1	1	.04	0.00	0.00	.0060	NA	0.00	0.00	NA
.4	0	.4	1	1	.16	0.00	0.00	.0240	NA	0.00	0.00	NA
.1	0	.1	.7	.7	.008	−.045	−.016	.0009	NA	−30.00	−15.96	NA
.1	0	.4	.7	.7	.033	−.045	−.015	.0035	NA	−30.03	−14.83	NA
.4	0	.1	.7	.7	.033	−.045	−.015	.0035	NA	−30.03	−14.83	NA
.4	0	.4	.7	.7	.134	−.046	−.010	.0139	NA	−30.55	−10.20	NA

Note. a_2 = direct effect of $X \rightarrow M_U$; b_2 = direct effect of $M_U \rightarrow Y$; k = direct effect of $M_U \rightarrow M_O$; r_{MM} = reliability of M_O; r_{YY} = reliability of Y; a_1 = direct effect of $X \rightarrow M_O$; b_1 = direct effect of $M_O \rightarrow Y$; c = direct effect of $X \rightarrow Y$; $\tilde{a}_{1ME}$ = direct effect of $X \rightarrow M_O$ with the omission of M_U and not accounting for measurement error; $\tilde{b}_{1ME}$ = direct effect of $M_O \rightarrow Y$ with the omission of M_U and not accounting for measurement error; $\tilde{c}_{ME}$ = direct effect of $X \rightarrow Y$ with the omission of M_U and not accounting for measurement error.

[a] Hypothetical path coefficients for the model depicted in Figure 1F.

the scenarios. However, in practice, researchers rarely, if ever, know the actual parameters of underlying mediation models, which brings us to our proposed sensitivity analysis.

Part II: Sensitivity Analysis

As mentioned in the introduction, sensitivity analyses gauge the strength of inferences by quantifying conditions that would alter said inference. In this section, we quantify the robustness of inferences regarding M_O by evaluating how sensitive the estimated direct and specific indirect effects via M_O alone are to a potential posttreatment confounder M_U for given reliability levels of M_O and Y. Specifically, we quantify the sensitivity of estimates and robustness of inferences as functions of correlations between M_U and other observed variables —X, Y, and M_O. We use correlations as sensitivity parameters because these quantities are easier for applied researchers to consider and use to gauge the robustness of their inferences. Additionally, such correlation-based approach, by extending Frank's (2000) ITCV, allows us to consider how omitting M_U may impact the statistical inference through affecting both the point estimate and the standard error.

We use the joint significance test (MacKinnon et al., 2002) in this sensitivity analysis.[8] Using the joint significance test, researchers claim evidence for statistically significant mediation effects when both paths ($\hat{a}$ and $\hat{b}$) are jointly significantly different from zero. As such, the statistical inference of a mediation effect essentially depends on the statistical inference regarding the a and b pathways in their respective linear regression models. Leveraging the joint significance test and extending Frank's (2000) ITCV, we propose a sensitivity approach where the researchers only need to consider one or two sensitivity parameters to evaluate the robustness of inference regarding the specific indirect effect via the mediator of interest. Below, we first introduce the ITCV in the context of linear models. Then, we present how to extend the ITCV approach to a mediation model, incorporating potential measurement error. Lastly, we introduce an R package to conduct such sensitivity analysis, using the illustrate example regarding presumed media influence.

Impact Threshold for a Confounding Variable (ITCV)

Extending Mauro's (1990) L.O.V.E framework, Frank (2000) developed an index to quantify the properties of an omitted variable necessary to change an inference regarding one key predictor of interest in a linear regression model. In particular, Frank quantified the conditions in terms of the Impact Threshold for a Confounding Variable (ITCV), where *impact* refers to the smallest product of $r_{X,CV} \cdot r_{Y,CV}$ needed to change the statistical inference regarding X on Y from statistically significant to not significant. The two correlations—$r_{X,CV}$ and $r_{Y,CV}$—refer to the two arms of a confounder (CV) as the confounder must correlate with both X and Y. Specifically, Frank derives the smallest possible *impact* that changes the inference which occurs when $|r_{YCV}| = |r_{XCV}| = \sqrt{\text{impact}}$ and $r_{Y,CV} \cdot r_{X,CV} > 0$. Other combinations of $r_{Y,CV}$ and $r_{X,CV}$ could also alter the inference, but their product would need to be larger than the impact threshold. As such, Frank (2000) refers this smallest *impact* as the Impact Threshold for a Confounding Variable (ITCV). Note that the derivation of ITCV deals with statistical inference by focusing on the t value, taking into account not only the bias in the point estimate, but also the change in the standard error.[9] See online supplemental materials A and Frank (2000) for more derivation details.

We can use Frank's (2000) ITCV approach to quantify how strong a confounder would need to be to change a statistical inference. The larger the ITCV, the more robust the inference is, as the confounder must show stronger correlations with X and Y to change the inference. We can extend the calculation to multivariate scenarios, in which cases *impact* refers to the product of two partial correlations conditional on all the other covariates in the linear model. For example, for a model with two covariates Z_1 and Z_2, such that $Y = \beta_0 + \beta_1 X + \beta_2 Z_1 + \beta_3 Z_2 + \varepsilon$, the impact threshold, or ITCV, needed to alter the inference regarding X represents the product of (a) the

[8] We use the joint significance test for the following reasons. Although bootstrap tests can deal with multiple sources of bias more holistically than other approaches, they assume users have access to complete datasets, which is often not the case, particularly when social scientists conduct meta-analyses. In such cases, researchers likely only have access to the information reported in the result tables, such as estimated coefficients, standard errors, and the final statistical inference.

[9] The ITCV does not assume invariant standard errors across different confounding amounts. In other words, the ITCV accounts for changes in the standard error due to the confounding variable which can reduce or increase the standard error depending on its correlations with the predictor and the outcome in a given model (see Equation 2 in Frank, 2000).

partial correlation between Y and CV conditional on both Z_1 and Z_2 ($r_{YCV|(Z_1\ Z_2)}$) and (b) the partial correlation between X and CV conditional on both Z_1 and Z_2 ($r_{XCV|(Z_1\ Z_2)}$). See Frank (2000) and Xu et al. (2019) for more derivation details.

Now, we extend the ITCV to a mediation model, where the regression $M = \beta_{01} + aX + \theta_1 Z_1 + \varepsilon$ estimates the a pathway, and the regression $Y = \beta_{02} + bM + cX + \theta_2 Z_2 + \varepsilon$ estimates the b and c pathways. Z_1 and Z_2 are observed covariates. Because the ITCV approach allows for any number of covariates, we can apply this sensitivity technique to mediation models with any number of covariates Z, including observed pretreatment confounders and interaction terms of any covariates. Assessing the robustness of the inference regarding the c pathway is a direct application of the ITCV approach, meaning the impact threshold needed to change the inferences, or ITCV, refers to the smallest product of $r_{YCV|(M\ Z_2)}$ and $r_{XCV|(M\ Z_2)}$.

However, in terms of the inference of the specific indirect effect via M, there could be two distinct impact thresholds for the a and b pathways. These two ITCV values require researchers to consider multiple correlations simultaneously: $r_{MCV|Z_1}$, $r_{XCV|Z_1}$, $r_{YCV|(X\ Z_2)}$, and $r_{MCV|(X\ Z_2)}$, which essentially reflects the fact that the exact point estimates and standard errors of the a and b pathways depend on three unknown correlations: $r_{X,CV}$, $r_{Y,CV}$, and $r_{M,CV}$.[10]

Researchers may sometimes have ideas about a particular omitted confounder and know which pathway (either a or b pathway) might be impacted more, in which case ITCV could be applied directly to the specific pathway (see Figure SB2 and R code in the online supplemental materials). When the researcher knows little about the omitted confounder, which is likely the case in practice, it is difficult for researchers to consider multiple unknown parameters simultaneously. To simplify the sensitivity analysis in this case, we leverage the joint significance test and focus on the pathway where the inference is "easier" to invalidate. That is, considering $\hat{a}$ and $\hat{b}$, we select the one with the least robust inference because once one pathway becomes *non*-significant, the mediation path is broken. Specifically, we compare the ITCV for $\hat{a}$ and $\hat{b}$ respectively and focus on the path with the smaller ITCV.[11] We then use this smaller ITCV to assess the robustness of the inference regarding the specific indirect effect. For example, if ITCV for $\hat{a}$ is smaller than the ITCV for $\hat{b}$, we consider the inference regarding the a pathway less robust and easier to invalidate.[12] In this case, the ITCV quantifies the smallest product of $r_{MCV|Z_1}$ and $r_{XCV|Z_1}$ to change $\hat{a}$ from statistically significant to not significantly from zero. A larger ITCV indicates a more robust inference. If the ITCV for $\hat{b}$ is smaller, then we consider the inference regarding the b pathway is less robust. In this case, the ITCV quantifies the smallest product of $r_{YCV|(XZ_2)}$, and $r_{MCV|(XZ_2)}$ to overturn our conclusion regarding b and thus the indirect effect as well. Like the ITCV approach where we assume $r_{X,CV} = r_{Y,CV}$ to maximize the *impact* of a confounder (Frank, 2000), we take a conservative standpoint here by favoring the challenger/skeptic of the inference and picking one from $\hat{a}$ and $\hat{b}$ that is easier to alter the statistical inference of a mediation effect.

Incorporating Measurement Error in Sensitivity Analysis

Now, we extend the sensitivity analysis to incorporate potential measurement error. To simplify the discussion, we start with a regression model $Y = \beta_0 + \beta_1 X + \varepsilon$ where we consider how a potential CV affects our inference regarding X, along with potential measurement error in the predictor (X) and in the outcome (Y). As before, we first calculate the correlation between X and Y, but now, the correlation is potentially biased by measurement error in X and Y ($r_{(\mathrm{ME})Y,X}$). Thus, we correct for measurement error first, using the following formulate: $r_{YX} = \frac{r_{(\mathrm{ME})YX}}{\sqrt{r_{XX} r_{YY}}}$. Then, we use the corrected correlation to calculate ITCV. Online supplemental materials A also shows how we correct for measurement error when there are covariates in the model.

Note that $r_{(\mathrm{ME})Y,X}$ is always smaller than the true $r_{Y,X}$ because measurement error in X and Y attenuates the correlation.[13] From a conservative standpoint, it is *not* necessary to consider measurement error in sensitivity analyses such as this one because correcting for it would only make a significant inference more robust. That is, if we considered measurement error, the resulting ITCV would become larger, suggesting a more robust inference. However, we present this approach here in case researchers have some knowledge of the reliability level of their measures and want to explore the potential impact on their inferences due to measurement error.

Following the same approach, we can also consider measurement error in M and Y for a mediation model in the sensitivity analysis. Specifically, we first correct for measurement error in the estimated $r_{(\mathrm{ME})XM|Z_1}$ and $r_{(\mathrm{ME})YM|(XZ_2)}$ for given reliability levels of M and Y. After solving for $r_{XM|Z_1}$ and $r_{YM|(XZ_2)}$, we follow the same procedure explained before to find the least robust pathway and evaluate the sensitivity using the corresponding ITCV.[14]

Illustration of Sensitivity Analysis Using R Package ConMed

To demonstrate this sensitivity analysis, we return to our earlier illustrative example regarding the presumed media influence (PMI). If we fit the model with only one mediator (PMI), the estimated specific indirect effect via PMI was 0.078 and significantly

[10] To highlight the connection between our bias formula and ITCV, take the a pathway as an example. Equation SA5.1 in online supplemental material shows how ρ_{XM_U} and $\rho_{M_O M_U}$ determine the bias when estimating the a pathway. In the context of ITCV, M_U is the confounder CV and thus, the key unknown correlations are exactly $r_{X,CV}$ and $r_{M,CV}$. Additionally, the derivation of ITCV deals with statistical inference by focusing on the t value, taking into account not only the bias in the point estimate, but also the change in the standard error (see Equation 2 in Frank, 2000). Such a correlational framework also allows a straightforward extension to scenarios with any number of observed covariates (see Equations 10 and 11, in Frank, 2000).

[11] One can also draw on Frank (2000) Equation (18) to express the ITCV unconditional on covariates allowing for a more direct comparison between the ITCV for $\hat{a}$ and the ITCV for $\hat{b}$. These calculations require extra quantities that may not be available or directly interpretable in all settings (e.g., R^2 for each regression model). Therefore, we will add this option in future versions of the software.

[12] An alternative approach is to compare the robustness of inferences regarding $\hat{a}$ and $\hat{b}$ using the percent of bias necessary to invalidate the inference (Frank et al., 2013). See http://konfound-it.com (Rosenberg et al., 2020).

[13] This is because $r_{(ME)YX} = r_{YX} \cdot \sqrt{r_{XX} r_{YY}}$, where r_{XX} and r_{YY} are the reliability levels of X and Y, respectively.

[14] The proposed approach does not work if the interest is the inference regarding the direct effect from X to Y while the concern is measurement error in the observed mediator M. In this case, one may consider using Equations (20) and (21) in Frank (2000) that address the question: how small must be the reliability of the confounding variable such that the observed relationship between X and Y can be attributed to the unreliability of the measure of the confounding variable. This was intended to address potential measurement error in *observed* covariates. In other words, here we are asking: how small must be the reliability of M such that the observed relationship between X and Y can be attributed to the unreliability of M? Note that we are not considering another omitted M_U in this case.

positive. Next, we consider how sensitive the inference about this indirect effect is to an unobserved posttreatment confounding mediator. Specifically, although we recognize IMPORT as a potential confounding mediator, we did not, for any number of reasons, measure this variable. Focusing on the indirect effect via PMI, we walk through how to use and interpret the results of our R package, ConMed (short for "Confounding Mediator").

Use the function `conmed_ind` in the ConMed R package to conduct the sensitivity analysis. The first four arguments—`est_eff_a`, `std_err_a`, `est_eff_b`, and `std_err_b`—specify the estimated effects and standard errors for the a_1 pathway (from X to M_O) and b_1 pathway (from M_O to Y), respectively. In our illustrative example, we estimated that the path coefficient from COND to PMI was 0.181, with a standard error of 0.087. We also estimated that the path coefficient from PMI to REACTION was 0.432, with a standard error of 0.074. The fifth argument, `nobs`, specifies the sample size, which in our example was 123. The sixth and seventh arguments, `n_covariates_a` and `n_covariates_b`, specify the number of covariates in the linear regression model for estimating the a_1 pathway and b_1 pathway, respectively. In this case, these values were 0 and 1. The last two arguments, `alpha` and `tails`, specify the significance level for inference and whether it is a one-tail or two-tail test, with `alpha` set by default to 0.05 and `tails` set by default to 2. As such, we call the function `conmed_ind` by filling in all the arguments: `conmed_ind(est_eff_a = 0.181, std_err_a = 0.087, est_eff_b = 0.432, std_err_b = 0.074, n_obs = 123, n_covariates_a = 0, n_covariates_b = 1, alpha = 0.05, tails = 2)`. Figure 6 presents the output generated by ConMed.

Based on the R output, the mediation effect would become *non*-significant if the correlation between COND and M_U and the correlation between PMI and M_U are above the impact curve, as shown in Figure 6. The smallest impact (ITCV = 0.011) occurs when both correlations equal to 0.103 (the point in Figure 6 where the impact curve intersects with the 45-degree angle line). From Figure 6, one can tell that it is highly likely to have such confounder M_U where the correlation between COND and M_U and the correlation between PMI and M_U are above the impact curve. Thus, we conclude that the inference regarding the specific mediation effect via PMI is not robust to a potential confounder M_U.

To further illustrate this sensitivity analysis technique, we also applied the approach to indirect effects for different effect sizes, as shown in Figure 7. In particular, each plot represents the sensitivity analysis result for particular indirect effect size.[15] From Figure 7A–F, $\hat{a}$ ranges from 0.2 to 0.7, while $\hat{b}$ is fixed at 0.432. The standard errors for both $\hat{a}$ and $\hat{b}$ are also fixed across all plots ($SE(\hat{a}) = 0.087$; $SE(\hat{b}) = 0.074$). As such, all plots in Figure 7 generate the same inference that the specific indirect effect via M is statistically different from zero; but the inference in each plot has different levels of robustness. Figure 7A has the smallest indirect effect estimate (0.086) with the smallest ITCV ($0.183 \times 0.183 = 0.033$): a confounder CV would invalidate the inference if the correlation between X and CV and the correlation between M and CV are above the impact curve in Figure 7A. As $\hat{a}$ increases to 0.5 (Figure 7D), the estimated indirect effect increases to 0.216. Accordingly, the ITCV also increases to 0.349 (0.591×0.591), indicating a more robust inference. Comparing Figure 7D with 7A, the impact curve moves toward the upper right corner: the correlation between X and CV and the correlation between M and CV needs to be much stronger to invalidate the inference in Figure 7D. We focus on $\hat{a}$ across Figure 7A–D as $\hat{a}$ is less robust than $\hat{b}$. However, as $\hat{a}$ further increases to 0.6 (Figure 7E) and 0.7 (Figure 7F), we turn to invalidate $\hat{b}$ as $\hat{b}$ is considered as easier to invalidate than $\hat{a}$. As such, even though $\hat{a}$ keeps increasing, the same ITCV is calculated based upon the unchanged $\hat{b}$ that relates to $r_{Y,CV|X}$, and $r_{M,CV|X}$ (i.e., ITCV are the same in Figure 7E and F).[16]

The function, `conmed_ind`, is especially designed for confounders like M_U that could impact the a pathway and b pathway simultaneously. For those concerned about an unobserved pretreatment confounder that biases one specific pathway of interest (i.e., $\hat{a}$, $\hat{b}$, or $\hat{c}$), we recommend using the konfound R package (J. M. Rosenberg et al., 2020) that provides the ITCV approach in a general linear regression framework. For instance, one can use the function `pkonfound` to evaluate the robustness of inference regarding $\hat{a}$ if they are concerned about any omitted pretreatment confounder that correlates with X and M but not Y. This function also works well with any observed covariates as the user only needs to specify $\hat{a}$ and its standard error when the observed covariate Z is included in the regression model. Assume $\hat{a} = 0.181$, $SE(\hat{a}) = 0.087$ and there is one observed covariate Z included in the regression model, then we call `pkonfound(est_eff = 0.181, std_err = 0.087, n_obs = 123, n_covariates = 1, alpha = 0.05, tails = 2, index = "IT")`. In such case, ITCV is the smallest product of $r_{X,CV|Z}$ and $r_{M,CV|Z}$. See online supplemental materials B for more detailed documentation and an example for the function `pkonfound`. See Figure SB2 in the online supplemental materials for guidance regarding what R function to use in different cases and the corresponding interpretation of ITCV.

For concerns about measurement error in the mediator and the outcome, users can also use the function, `conmed_ind_ME`, to specify reliability levels. Most of this function's arguments are the same as those in `conmed_ind`. However, `conmed_ind_ME` includes a few additional arguments, requiring users to, for example, specify reliability levels, the standard deviations of observed variables, and R squared information for linear models. Nevertheless, as noted earlier, it is more conservative to *not* account for measurement error in M and Y when considering a potential confounder on the mediation effect. Also, as mentioned before, although measurement error affects standardized and unstandardized point coefficients differently, the way measurement error impacts the statistical inference is the same.

[15] The effect sizes across each plot are comparable as the only change across plots is the value of $\hat{a}$. Since we standardized all variables, the indirect effect specified in the plots can be interpreted as either "partially standardized effect size" or "completely standardized effect" (Hayes, 2018, pp. 133–136).

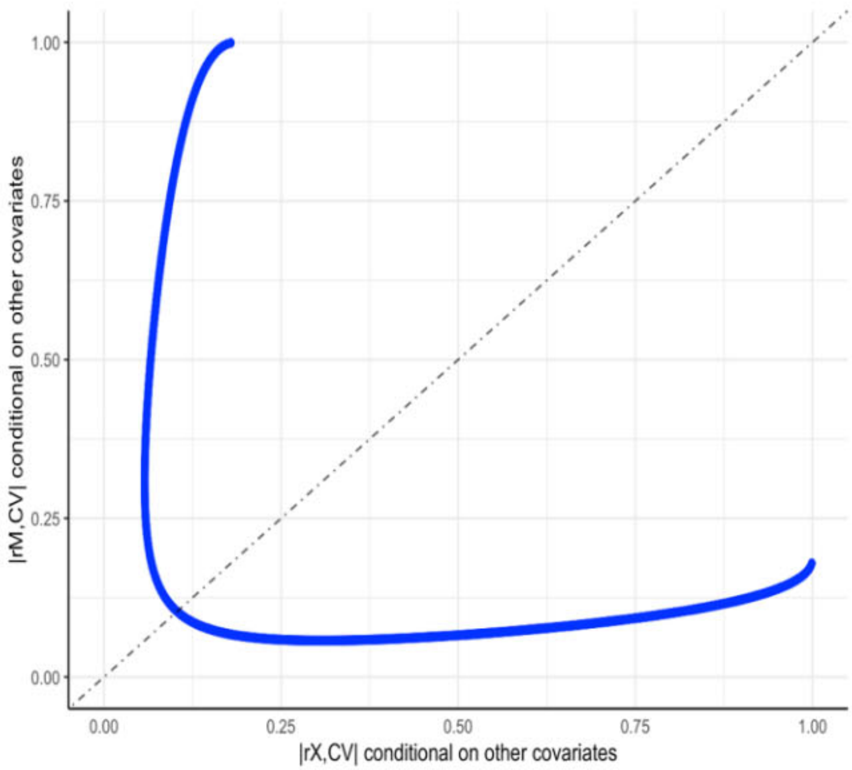
[16] We resist the temptation to provide absolute thresholds for the ITCV because doing so would invite a spiraling conversation about how close a calculated ITCV is to a threshold. Instead, we seek more generally to inform inferences regarding concerns about potentially unobserved mediators by quantifying the conditions necessary to invalidate an inference. We also encourage researchers to consider these conditions within contexts of specific fields and research focuses. One approach could be benchmarking with other observed control variables (e.g., an observed pretreatment confounder Z) included in the model. For example, researchers can examine the *impact* of any given control variable Z to determine whether it seems plausible an omitted M_U could influence the parameter estimate of $\hat{a}$ by an amount that exceeds the *impact* of Z.

Figure 6

R Output for the Sensitivity Analysis for Unobserved Post-Treatment Confounder Using ConMed

```
conmed_ind(est_eff_a = 0.181, std_err_a = 0.087, est_eff_b = 0.432, std_err_b= 0.074,
           n_obs = 123, n_covariates_a = 0, n_covariates_b = 1, alpha = 0.05, tails = 2)
```

```
## The original estimated mediation effect is 0.078 and it is statistically significant.To invalidate an inferenc
e of a significant mediation effect, we consider an omitted confounder CV to change the inference regarding the a
pathway (from the treatment to the mediator).The minimum impact as defined by Frank 2000 (the product of rX,CV an
d rM,CV) would be 0.011 to invalidate an inference for a null hypothesis of 0 pathway.This is generated by a scen
ario that generates the smallest impact necessary to invalidate the inference where |rX,CV| = |rM,CV| =  0.103 (c
onditioning on observed covariates). The correlation is also based on a threshold of 0.178 for statistical signif
icance (alpha = 0.05).
## NOTE: the two correlations would have to have same signs (rX,CV * rM,CV > 0) because the initial estimate of t
he pathway is positive. Accordingly, the mediation effect via M is not significant anymore, based on a joint sign
ificance test.Other combinations of rX,CV and rM,CV with impacts greater than 0.011 can change the inference. The
se are shown on the impact curve below for which combinations of correlations on or above the curved line would i
nvalidate the inference regarding the a pathway (from the treatment to the mediator).
```

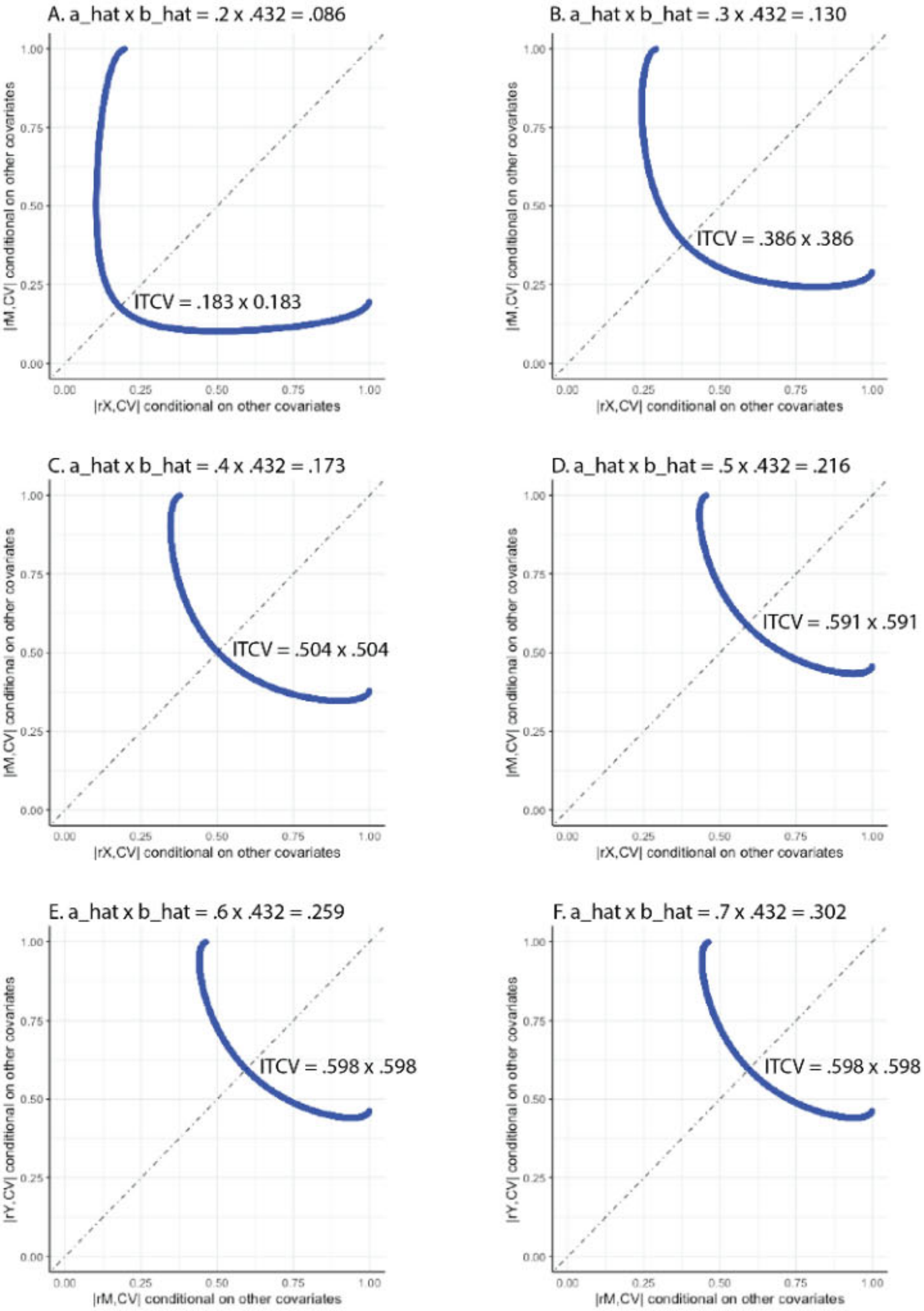


Discussion

Our analysis shows that omitting a mediator will typically generate biased estimates for the specific indirect effect via M_O alone and the direct effect from X to Y. Additionally, our simulation results show the magnitude of bias can be substantial. In the case of our illustrative example, the exclusion of an alternative mediator (IMPORT) yields a different conclusion, one that suggests that the indirect effect via PMI (M_O) alone is significantly positive, rather than not statistically significant. Indeed, when including IMPORT (M_U) in the model, the indirect effect via PMI was not significantly different from zero, decreasing from 0.078 to 0.045. Finally, although the inference about the direct path from article location (X) to participants' reaction (Y) does not change with the inclusion or exclusion of IMPORT, the point estimate decreases from 0.082 to 0.033 with the inclusion of IMPORT in the model. When there is measurement error in PMI (M_O) and participants' reaction (Y), the exclusion of an alternative mediator (IMPORT) may or may not yield a statistically significant indirect effect via PMI because of the counterbalancing effect of excluding the mediator (IMPORT) and measurement error. The overall impact of excluding IMPORT and measurement error on the estimated direct effect from article location (X) to participants' reaction (Y) also varies by the measures' reliability levels.

Figure 7

How ITCV Quantifies the Robustness of Inference for Estimated Specific Indirect Effect with Different Effect Sizes



Patterns of Asymptotic Bias

A critical finding from this study is that the exact pattern of asymptotic bias depends on the specific underlying mediation process. In the parallel two-mediator model (Figure 1E) in which M_U is independent of M_O, the estimate of the specific indirect effect via M_O is asymptotically unbiased. However, the estimate of the direct effect from X to Y can be either positively or negatively biased, depending on the specific indirect effect via M_U. If the specific indirect effect via M_U is positive, then the direct effect from X to Y is overestimated. That is, some explanatory power via the direct effect from X to Y is likely attributed to M_U as a mediator. If the specific indirect effect via

M_U is negative, then the direct effect from *X* to *Y* is underestimated. The magnitude of the asymptotic bias in the estimate of *c* is also the true specific indirect effect via M_U.

We encounter similar findings when excluding more than one M_U in a parallel mediation model. In such cases, the specific indirect effect via M_O is always asymptotically unbiased, irrespective of the total number of omitted mediators in the true model. However, the direct effect from *X* to *Y* is asymptotically biased unless the indirect effects via the other omitted mediators cancel each other out. In fact, the indirect effects through all other omitted M_U are mistakenly attributed to the direct effect from *X* to *Y*.

In the sequential two-mediator model, the estimate of the direct effect from *X* to *Y* is asymptotically unbiased, but the estimate of the specific indirect effect via M_O can be either positively or negatively biased, depending on the M_U-related path coefficients. Specifically, the estimated effect attributed to $X \rightarrow M_O$ should be attributed to $X \rightarrow M_U \rightarrow M_O$. If the effect $X \rightarrow M_U \rightarrow M_O$ is positive, then the effect from *X* to M_O is overestimated. That is, some explanatory power via the direct effect from *X* to M_O is likely attributed to M_U as a mediator. The magnitude of the asymptotic bias in the estimation of *X* to M_O is also the true effect of the following path: $X \rightarrow M_U \rightarrow M_O$. Note that the estimated effect from M_O to *Y* is unbiased, so the bias for the specific indirect effect via M_O comes from the estimation of *X* to M_O alone. In other words, the true effect of the path—$X \rightarrow M_U \rightarrow M_O$—directly determines the direction and magnitude of the asymptotic bias in the estimation of the specific indirect effect via M_O. If this path's true effect is negative, then the specific indirect effect via M_O is negatively biased, and the magnitude of the asymptotic bias equals the true effect of this path ($X \rightarrow M_U \rightarrow M_O$) multiplied by the effect of M_O to *Y*.

Similar conclusions can be drawn of such models excluding more than one M_U. One can always obtain asymptotically unbiased estimates for the direct effect from *X* to *Y*, while the estimate of the specific indirect effect via M_O can be either positively or negatively biased because the estimated effect of *X* to M_O includes all the intermediated effects via those omitted mediators. However, unlike the parallel mediation model, these different omitted mediators cannot cancel each other's bias.

If the underlying mediating process represents a serial two-mediator model where all path coefficients are positive, then the indirect effect via M_O alone is overestimated, and the magnitude of bias can vary substantially. In fact, the specific indirect effect via M_O is always positively biased if all three M_U-related path coefficients take the same sign. The estimate of the direct effect from *X* to *Y* can be either positively or negatively biased. When the path coefficient from M_U to M_O is relatively small (approaches zero), researchers *overestimate* the direct effect from *X* to *Y*. In contrast, when the effect from M_U to M_O approaches one, researchers *underestimate* the direct effect from *X* to *Y* (see Figure SA1 in the online supplemental materials). To understand this more intuitively, consider a flow starting from following path: $X \rightarrow M_U$. When the path coefficient from M_U to M_O is relatively small, most of the flow follows $X \rightarrow M_U \rightarrow Y$, contributing to the asymptotic bias of the direct effect from *X* to *Y*. In contrast, when the path coefficient from M_U to M_O is relatively large, more flow goes through $X \rightarrow M_U \rightarrow M_O \rightarrow Y$, contributing to the asymptotic bias of the indirect effect via M_O.[17] As such, the larger the path coefficient from M_U to M_O (indicating a stronger correlation between M_O and M_U), the larger the positive asymptotic bias in the estimation of the indirect effect via M_O, the smaller the positive bias or even negative bias in the estimation of the direct effect from *X* to *Y*. We also find when omitting multiple independent mediators, that the overall asymptotic bias equals to the sum of the asymptotic bias caused by each M_U. Thus, depending on the direction and magnitude of bias due to each M_U, the overall bias can increase, decrease, or remain the same compared to that with one single M_U.

A second critical finding is that different conditions are required to obtain asymptotically unbiased direct and indirect estimates when omitting M_U, meaning that researchers may not be able to accurately estimate direct and indirect effects at the same time. In the case of our illustrative example, IMPORT (M_U) must have no effect on PMI (M_O) to obtain an asymptotically unbiased indirect effect via PMI with the exclusion of IMPORT. In other words, if IMPORT and PMI are two parallel mediators, then one can accurately obtain the indirect effect via PMI and the estimates for both the path coefficients from article location (*X*) to PMI (M_O) and from PMI (M_O) to participants' reaction (*Y*). However, to attain an asymptotically unbiased direct effect from article location (*X*) to participants' reaction (*Y*) when omitting IMPORT (M_U), one of the following two conditions must be met. Either IMPORT must have no effect on participants' reaction, or article location and IMPORT must be uncorrelated conditional on PMI ($\rho_{\text{article location,IMPORT}} = \rho_{\text{PMI,IMPORT}} \cdot \rho_{\text{article location,PMI}}$). That is, IMPORT cannot contain any unique or extra information about article location in addition to PMI (in terms of linear relationships). To note, the illustrative example meets neither of these conditions. In sum, asymptotically unbiased direct and indirect effects occur under different conditions.

A third critical finding is that measurement error in M_O and *Y* may affect overall bias when it co-occurs with an omitted confounding M_U. When the three M_U-related path coefficients all take the same sign, measurement error and the omitted M_U have opposing effects on the estimated indirect effect via M_O. Specifically, measurement error in M_O and *Y* attenuates the estimated indirect effect via M_O, while omitting M_U overestimates the estimated indirect effect via M_O. In the illustrative example, excluding IMPORT increases the estimated indirect effect via PMI from 0.045 to 0.078. As measurement error in PMI and REACTION increases (reliability levels decrease from 1 to 0.7), the attenuation effect due to measurement error becomes stronger, and the estimated indirect effect via PMI drops to 0.045. In other words, measurement error in PMI and REACTION counteracts the effect of excluding the other mediator (IMPORT), ultimately generating the same inference regarding the mediation effect via PMI. In terms of the estimated direct effect from COND to REACTION, however, measurement error in PMI and REACTION may have the same or opposing effect as excluding IMPORT. Specifically, the direct effect from COND to REACTION increases from 0.033 to 0.082 with the exclusion of IMPORT. Different reliability levels of PMI and REACTION may further increase the estimate from 0.082 to 0.101 or decrease the estimate from 0.082 to 0.076. To sum, the combined effect of measurement error and omitted M_U depends on the specific reliability levels of M_O and *Y*.

[17] See Lin (2019) for a more detailed explanation.

Sensitivity Analysis

Omitting an alternative confounding mediator may have extreme consequences for hypothesis tests involving M_O. Therefore, we propose a sensitivity analysis where M_U-related correlations serve as sensitivity parameters. We also offer an R package for researchers to examine how an alternative omitted mediator may affect the robustness of their inference regarding the specific indirect effect via M_O alone or the direct effect from X to Y. We present one way to apply our R package to assess the robustness of an inference regarding a significant indirect effect by considering if the estimated effect from X to M_O or from M_O to Y is less robust and, thus, easier to invalidate. Extending Frank's (2000) ITCV, the R package reports how large the correlation between both the unmeasured M_U and X and the correlation between the unmeasured M_U and M_O need to be to alter the inference regarding the estimated effect from X to M_O. It also indicates how large the partial correlation between the unmeasured M_U and Y and the correlation between the unmeasured M_U and the M_O (conditional on X) need to be to alter the inference regarding the effect from M_O to Y. In particular, the proposed R package defines the product of the two unknown correlations in each case as *impact* and reports the minimum impact needed to change the inference (or ITCV). Using the joint significance test, once either path estimate becomes not significant, the mediation effect is broken and no longer significant. Based on these reported correlations and ITCV values, researchers can evaluate the robustness of their inference regarding the specific mediation effect via M_O.

To conservatively assess the robustness of their inferences, we recommend researchers use our sensitivity analysis approach, assuming they know little about M_U. Alternatively, researchers can use the R package to assess the robustness of inference regarding any specific direct effect, meaning they can evaluate the robustness of inferences regarding $X \rightarrow M_O$, $M_O \rightarrow Y$ or both. This could be useful when researchers have some knowledge of a specific M_U. For example, the researcher may have reason to suspect that a specific unobserved M_U is more strongly related to Y than X ($r_{YM_U} > r_{XM_U}$). In such a case, even though the reported ITCV for the estimated a pathway is smaller than that for the estimated b pathway, it is more likely to achieve the second ITCV because $r_{YM_U} > r_{XM_U}$.

Our sensitivity analysis is flexible. The ability to focus on any specific pathway and any combination of correlations that exceed the ITCV (anywhere above the impact curve in Figure 6) is especially helpful when researchers suspect a relationship between an alternative M_U and X, Y, or M_O. Without such knowledge, however, our sensitivity analysis takes a conservative standpoint and provides one impact threshold (ITCV) to help facilitate evaluating the robustness of inferences. Importantly, because the ITCV approach was originally developed for the linear regression framework, it can account for any number of observed covariates in mediation models. The approach can also directly quantify the robustness of an inference for the treatment effect to concerns about an omitted pretreatment confounder (see online supplemental materials B for R code). For concerns about co-occurrence of omitting pretreatment and posttreatment confounding along with measurement error, we recommend considering one confounder at a time using approaches we outline here (see Figure SB2 in the online supplemental materials) or considering what pathways are of the greatest concern with respect to confounders and calculate the corresponding ITCV for that particular pathway. In the latter case the ITCV could be considered as the combined effect of multiple confounders.

Implementation

Our analysis can be generally applied to any set of path coefficients, regardless of their sign. To simplify the discussion, we focus on the interpretation of scenarios where all path coefficients in the true model are positive; however, these path coefficients could all plausibly be negative too. Our derivations and analytical results apply to such a scenario as well as others. Indeed, researchers can input any path coefficient into Equations (8)–(11) to examine asymptotic biases. In short, although we discuss one scenario, the contributions of the present work can be applied more broadly.

Sensitivity analyses only serve as a post-hoc procedure, which alerts researchers to the robustness of their inferences. As such, sensitivity analyses do not resolve underlying issues within the mediation model in question. Considering potentially biased estimates and changes in inferences due to M_U, we recommend that researchers carefully consider potential alternative mediators when designing their studies to better approximate the true underlying mediating process. However, we also acknowledge that various reasons can lead to the omission of an alternative mediator, such as data collection limitations, particularly the challenge of measuring certain constructs (e.g., teacher mindset), and secondary data analyses unanticipated in the original design. Therefore, our R package is a useful resource that enables researchers to assess the robustness of their mediation inferences given the omission of M_U. If the results suggest a weak inference, researchers should consider returning to theory, refining their measures, and/or rethinking their modeling decisions. In contrast, if the results suggest a robust inference, researchers may more confidently claim and share their findings, as well as use the inference to guide practical decision-making (Frank et al., 2013).

Even when our sensitivity analyses suggest robust inferences, some researchers may still challenge the findings, positing that likely more than one omitted confounding mediator affects this mediation inference. However, as discussed, the overall bias associated with multiple omitted confounding mediators can increase, decrease, or even remain the same compared to that with one omitted confounder. Nevertheless, to assess the strength of the evidence undergirding an inference, we argue that it is likely sufficient to consider the effect of one confounding mediator that captures all sources of bias similarly affecting said inference. Accordingly, using our sensitivity analysis, one may understand M_U as a *latent* variable, representing a weighted sum of all potential omitted mediators related to X, M_O, and Y, which may bias the inference. Ultimately, our proposed approach is appropriate when researchers are unsure about the true underlying mediating process.

Limitations and Avenues for Future Research

A few limitations of the present work suggest avenues for additional research. First, we made assumptions about model specifications such as no mediator–outcome interaction. Future research should assess how the omission of M_U may affect inferences under more complex scenarios. However, our sensitivity analysis approach accommodates any number of observed covariates, including interaction effects. Second, for ease of use, we applied the joint significance test in our proposed sensitivity analysis and corresponding R package. However, this approach does not generate a confidence interval for the mediation effect, which may be desirable under some scenarios. In response, future researchers can expand our R package to estimate sampling variability using different approaches, such as bootstrap methods (e.g., Shrout & Bolger, 2002; Williams & MacKinnon, 2008) or other approaches to approximate the sampling distribution of the mediation effect when the original dataset is not available (e.g., MacKinnon et al., 2004; Pan & Frank, 2004). Third, we examined the cross-sectional, dual-mediator model. Scholars have also suggested using longitudinal designs to test mediation effects because cross-sectional models can generate biased estimates (e.g., Maxwell & Cole, 2007; Maxwell et al., 2011; Mitchell & Maxwell, 2013). Accordingly, future studies should consider whether omitting another confounding mediator can bias estimates in longitudinal designs (Lin, 2019).

Conclusion

As theorized, our study provides evidence that omitting an alternative confounding mediator typically generates asymptotically biased estimates for the specific indirect effect via M_O alone and the direct effect from X to Y. While the direction and magnitude of the asymptotic bias depend on the true underlying mediating process, the omission of M_U can sometimes profoundly affect researchers' inferences. We also discuss how measurement error in the M_O and Y may have the opposite or same direction of effect as the omitted M_U. Hence, we recommend that researchers carefully consider alternative mediators when designing studies and pay close attention to their data collection methods. Since various circumstances result in the omission of an alternative M_U, we offer an R package that assesses the robustness of mediation inferences given the omission of an unobserved, confounding mediator and/or measurement error.

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