Scientific Methods for Prevention Intervention Research

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NIDA Research Monograph 139
1994

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
National Institutes of Health

National Institute on Drug Abuse
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Rockville, MD 20857

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Analysis of Mediating Variables in Prevention and Intervention Research

David P. MacKinnon

This chapter describes mediation analysis in prevention and intervention studies. First, the links between theory and the mediators targeted in prevention and intervention programs are emphasized, and reasons for conducting mediation analysis are listed. Second, the statistical procedures in mediation analysis are given and applied to a drug prevention example. Finally, guidelines for mediational analyses in prevention and intervention grant applications are described.

INTRODUCTION

Everyone has ideas about how to prevent health problems:

- "If we change social norms regarding drug use, we will prevent drug abuse."
- "If women know the importance of detecting cancer early, they will get screened for breast cancer."
- "If athletes know that there are effective nutrition and training alternatives to anabolic steroids, they will not put themselves at risk by using steroids."
- "If pregnant women are warned about fetal alcohol syndrome, they will not drink alcohol while pregnant."

Ideas like these suggest that health problems can be prevented by first changing intermediate behavioral, biological, psychological, or social constructs.

These intermediate constructs thought to prevent health problems are called mediating variables or mediators. Prevention programs are designed to change these mediators. A variable functions as a mediator of a prevention program if the mediator accounts for the relation between exposure to the prevention program and the outcome measure (Baron and Kenny 1986). It is assumed that the prevention program influenced the mediator, which consequently affected the outcome measure (Sobel 1990).

Figure 1 summarizes prevention programs in many substantive areas. In this general scheme, a prevention program is designed to change mediating variables that are hypothesized to be causally related to the outcome. If the mediating variables are causally related to the outcome, a prevention program that changes the mediating variables will change the outcome.

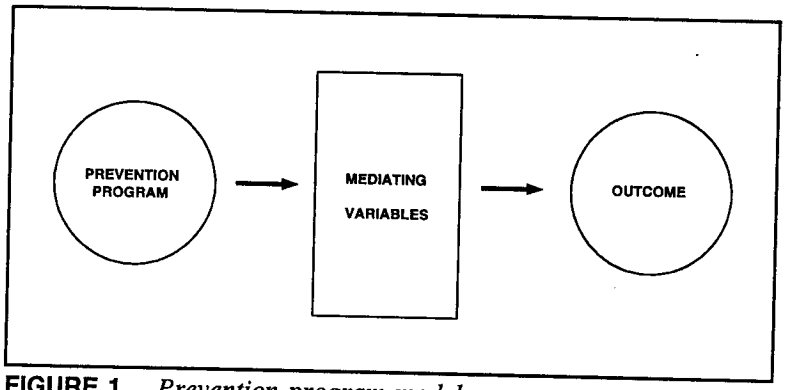

FIGURE 1. *Prevention program model*

A wide range of constructs serve as potential mediators. Mediating constructs can be biological (e.g., blood pressure), psychological (e.g., attitudes), or behavioral (e.g., exercise). Programs to prevent coronary heart disease often target such behaviors as smoking and such biological factors as cholesterol and blood pressure (The Multiple Risk Factor Intervention Trial Research Group 1990). Social influence-based drug prevention programs are designed to increase skills to resist drug offers and establish norms less tolerant of drug use (Flay 1985). Most acquired immunodeficiency syndrome (AIDS) and sexually

transmitted disease (STD) prevention programs are designed to increase safer sex practices and abstinence to reduce infection (Mays et al. 1989).

Figure 1 summarizes secondary and tertiary prevention programs as well. Secondary prevention campaigns to increase screening rates for serious illness, such as mammography and breast cancer, attempt to increase knowledge about early detection of disease, reduce barriers to screening, and change norms regarding screening (Murray et al. 1986; Shapiro 1976). Tertiary prevention in substance abuse treatment programs target mediators like communication and support to prevent relapse (Prochaska et al. 1992). Examples of the mediators targeted in other prevention research studies are shown in table 1.

Mediator analysis is the statistical analysis of: (1) the effect of an independent variable, such as exposure, to a prevention program on mediating variables and (2) the link between program effects on mediators with program effects on outcomes. Mediator analysis also is called process analysis (Baron and Kenny 1986; Judd and Kenny 1981*a*) and effect decomposition (Alwin and Hauser 1975; Hayduk 1987). The term "process analysis" reflects that the chain from the prevention program to the mediator to the outcome is the hypothesized process by which the prevention program is effective. The term "mediator analysis" is used in this chapter, rather than process analysis, because process analysis also refers to the monitoring of treatment implementation (Coyle et al. 1991; Isaac and Michael 1989). "Effect decomposition" is the term most commonly used in nonexperimental studies where the total effect of an independent variable is separated into the direct effect of the independent variable on the outcome variable and the indirect effect of the independent variable on the outcome through changes in one or more mediators (Alwin and Hauser 1975). The terms "mediated effect" and "indirect effect" are used synonymously in this chapter.

The success of prevention programs is determined appropriately by effects on outcome variables, such as death, disease, or drug use. If researchers measure mediating constructs as well as outcome measures, they gain more information about the prevention program and about theories of health behavior. Despite the information gained from

TABLE 1. *Examples of mediators and outcomes for prevention studies*

REFERENCE	TWO MEDIATORS	OUTCOMES
Symptomatology in Children of Divorce (Sandler et al. 1988)	Quality of Parent-Child Relationship Child's Active Coping	Conduct Problems Anxiety Depression
Drug Abuse (Hansen 1992)	Social Norms Resistance Skills	Cigarette Use Alcohol Use Marijuana Use
Learning Disorders (Silver and Hagin 1989)	General Social Competency Skills Specific to Learning	School Achievement Standardized Test Scores
Symptomatology After Disasters (Pynoos and Nader 1989)	Affirm Family Support Facilitate Through Grief Stages	Depression Anxiety Fear
Suicide (Shaffer et al. 1989)	Awareness of Hotline Services Referrals to General Psychiatric Care	Suicide Intention Deaths Due to Suicide
Delinquency (Dryfoos 1990)	Educational Achievement Parental Support and Guidance	Arrest Records
Teenage Pregnancy (Dryfoos 1990)	Educational Achievement Parent-Child Communication	Unintentional Pregnancy Unprotected Intercourse
AIDS/HIV Sexually Transmitted Diseases (Coyle et al. 1991)	Safer Sex Practices Abstinence	Unprotected Sexual Relations Sexually Transmitted Diseases
Adolescent Anabolic Steroid Use (Goldberg et al. 1991)	Alternatives Social Norms	Anabolic Steroid Use
Mental Illness (Heller et al. 1984)	Positive Coping With Stress Social Competency	Adjustment DSM III Diagnosis

mediational analyses (Baron and Kenny 1986; Judd and Kenny 1981*a*; McCaul and Glasgow 1985), few prevention studies have reported program effects on mediating variables, and fewer have tested the link between effects on mediating variables and effects on outcome variables (MacKinnon et al. 1988).

THEORY AND SELECTION OF MEDIATORS

Theory provides a framework for understanding health behavior across situations and populations (Flay and Petraitis 1991; Hansen, this volume; Kellam, this volume; Lorion et al. 1989). Theories of health behavior guide the selection of mediating constructs in most intervention and prevention programs. By using theory to design programs, researchers benefit from previous research and synthesis. A prevention program based on established theory may be more likely to change the outcome measure, and the results would provide scientific evidence for the refutation or acceptance of the theory.

Social Learning Theory (Bandura 1977), Problem Behavior Theory (Jessor and Jessor 1977, 1980), and the Theory of Reasoned Action (Ajzen and Fishbein 1980), for example, provide much of the background for drug prevention approaches. These theories suggest that social norms, social skills, and beliefs play important roles in the initiation and progression of drug use. Drug prevention programs attempt to change mediators with one or more of the following twelve program components: information, decisionmaking, pledges, values clarification, goal-setting, stress management, self-esteem, resistance skills, life skills, norm-setting, assistance, and alternatives (Hansen 1992).

Theory is used to target mediators that can be changed. Both theoretical and practical considerations limit the mediators that realistically can be changed in a prevention study. More effort probably will be needed to change personality characteristics like risk-taking behavior than to change knowledge of the risks of drug use, for example.

In many studies, it is not possible to include measures of each step in the hypothetical chain of mediation leading to the outcome measure. For example, it may be impractical to measure each of the six constructs in a theoretical chain from exposure to a program component, comprehension of the component, retention of the component's message, short-term attitude change, long-term attitude change, and long-term refusal to use drugs because of attitude change. In this case, a researcher may measure only an overall attitude mediator rather than all mediators in the chain. Cook and Campbell (1979) make this distinction between molar mediation, where some steps in a theoretical chain are not measured, and micromediation, where each link in a chain is measured. Researchers must decide how many steps in a mediational chain will be measured. Theory can provide a rationale to identify the most important mediator in the chain.

A related choice must be made about outcome measures. The outcome measure in many studies actually is a mediator in a longer mediational chain; for example, cholesterol level may be the studied outcome, but death due to coronary heart disease is the ultimate outcome. In prevention studies without the ultimate outcome variable, theory or past research must link the outcome studied with the ultimate outcome.

REASONS FOR ANALYSIS OF MEDIATING VARIABLES

Below are seven related benefits of conducting mediation analysis in prevention and intervention studies (Judd and Kenny 1981*a*; MacKinnon et al. 1991*a*; McCaul and Glasgow 1985). The discussion of the reasons for mediator analysis assumes that the program was implemented well and that the mediator and outcome measures are sufficiently valid (Pedhazur and Pedhazur-Schmekin 1991; Crocker and Algina 1986).

Manipulation Check

Mediation analysis provides a check on whether the program changed the intervening variables it was supposed to change. If the program did not change the mediator hypothesized to prevent the problem behavior, it is unlikely to change the outcome variable. A program to

increase knowledge about the importance of early cancer detection, for example, should yield program effects on knowledge measures.

Program Improvement

Mediation analysis identifies successful and unsuccessful program components. One interpretation of a lack of program effect on a mediating variable is that a program component failed. If a program component did not change the mediator, then the component must be improved. If no program effects on skills to resist drug-use offers are found, for example, the program may need to improve resistance skills training. A program component ineffective in several studies should be removed or replaced by another component, unless there is evidence that it has an important relationship with other more successful components.

Measurement Improvement

Lack of a program effect on a mediating variable also can suggest that the measures of the mediator were not reliable or valid enough to detect changes. If no program effects are found on skills to resist drug-use offers, for example, the program may need to improve measurement of resistance skill. In an ideal situation, the psychometric properties of mediating variables are resolved prior to the study.

Delayed Effects

Program effects on mediating variables but not outcome measures may suggest that program effects on outcomes will emerge later. For example, the ultimate effects of an elementary-school drug prevention program on drug abuse may not be evident until the students are older.

Testing of the Process of Mediation

Mediation analysis provides information on how the prevention program achieved its effects. Such information increases understanding of the mechanisms underlying changes in the outcome. For example, if prevention program effects on drug use are found, it is possible to study whether the changes in mediators like social norms or resistance skills or another mediator were responsible for the reduction

in drug abuse. In the drug prevention study described below, there was evidence that change in norms was an important mediator of program effects.

Theoretical Implications

One of the greatest strengths of mediation analysis is the ability to test the theories upon which prevention programs are based. Many theories are based on results of cross-sectional studies with little or no experimental verification. In this respect, mediation analysis in the randomized design often used in prevention intervention research is the ideal environment for testing theories. Competing theories of the onset of drug abuse, for example, may suggest alternative mediators that can be tested in an experimental design.

Practical Implications

Prevention programs will cost less and provide greater benefits if effective and ineffective components can be identified. Outcome measures in prevention research usually have clear, practical importance, such as daily smoking or early cancer diagnosis.

STATISTICAL ANALYSIS OF MEDIATING VARIABLES

Important mediators may be identified when the level of a mediating variable can be randomly assigned to subjects. For example, Hansen and Graham (1991) experimentally compared two major social-influence components—one to establish conservative norms, the other to increase resistance skills. They found greater evidence for the mediational pathway through social norms rather than resistance skills. Although randomization of subjects to levels of the mediator is ideal, it often is difficult to accomplish in prevention research. Programs include multiple components targeting many mediators, and it may not be feasible to test the effects of each mediator or subgroup of mediators in separate studies. Even when randomization of subjects to the level of mediators is possible, the link between the program effect on the mediator and the outcome should be tested using the procedures described below.

Mediation Analysis

The parameter estimates and standard errors in three regression equations provide the necessary information for three tests to establish mediation for the case of one mediator and one outcome variable (Judd and Kenny 1981*a*, 1981*b*). The author adds a fourth test.

Conclusion 1: $Y_O = \tau X_P + \epsilon_1$
Conclusion 2: $X_M = \alpha X_P + \epsilon_3$
Conclusion 3: $Y_O = \tau' X_P + \beta X_M + \epsilon_2$

The symbols in the equations are the following: Y_O is the outcome variable; X_P is the independent variable (prevention program); X_M is the mediator; τ codes the relationship between the program and the outcome; τ' is the coefficient relating the program to the outcome, adjusted for the effects of the mediator; α is the coefficient relating the program to the mediator; β is the coefficient relating the mediator to the outcome variable, adjusted for the program; ϵ_1, ϵ_2, and ϵ_3 code unexplained variability; and the intercept is assumed to be zero, so scores are in deviation form. It is assumed that the relationship (β) between the mediator (X_M) and the outcome (X_P) in the program and control groups differs only in sampling variability.

Conclusion 1: The Prevention Program Causes the Outcome Variable. The test of the statistical significance of the program effect (τ) is conducted in all prevention studies. Judd and Kenny (1981*a*) advise that, if there is not a program effect, the mediation analysis should stop as there is no effect to mediate. Later, Judd and Kenny (1981*b*, p. 207) note it is possible for there to be mediation even when the program effect is insignificant. If some mediators reduce the problem behavior and others increase the problem behavior (a suppressor effect), there may be a nonsignificant overall program effect when mediation actually exists. Prevention programs are designed to have a beneficial effect on one or more outcome variables, and mediators then are chosen to lead to this goal. It is possible that a program component may backfire or not work as planned and actually produce disadvantageous results. In such a case, mediational analyses may uncover such patterns. Models that include positive and negative mediation (suppression) effects are called inconsistent models (Blalock 1969; Davis 1985).

Conclusion 2: The Prevention Program Causes the Potential Mediator. This test determines whether there is a statistically significant program effect on the mediator (α). Program effects on mediators are reported infrequently in research articles, even though such results identify the mediators that the prevention program successfully changed (McCaul and Glasgow 1985).

Conclusion 3: The Mediator Must Cause the Outcome Variable Controlling for Exposure to the Prevention Program. The effect of the mediator on the outcome variable (β) must be statistically significant when controlling for the effect of the prevention program variable (τ'). If the treatment effect is zero when adjusted for the mediator, there is evidence for mediation (Judd and Kenny 1981*a*, 1981*b*). Baron and Kenny (1986) further refine Conclusion 3 to ensure that the effect is a mediator and not a suppressor by requiring that the program effect (τ) for Conclusion 1 be larger than the program effect (τ') for Conclusion 3.

Conclusion 4: The Mediated Effect Is Statistically Significant. It is unlikely that a single mediator would completely explain prevention program effects (Baron and Kenny 1986). A method to determine the confidence limits of the mediated effect for partial as well as complete mediated effects is needed.

The mediated effect is calculated in two ways. The value of the mediated or indirect effect equals the difference in the program effect with and without the mediator (τ-τ') (McCaul and Glasgow 1985). If the independent variable coefficient (τ') is zero when the mediator is included in the model, the effect of the independent variable is mediated entirely by the mediating variable as mentioned in Conclusion 3.

A second method that yields identical mediated-effect estimates is based on path analysis. The mediated effect is equal to the product of the α and β parameters. The coefficient relating the independent variable to the outcome adjusted for the mediator (τ') is the nonmediated or direct effect. As shown in figure 2, the rationale behind this method is that mediation depends on the extent to which the independent variable changes the mediator (α) and the extent to which the

mediator affects the outcome variable (β). The following formulas summarize the effects:

Total Effect = $\alpha\beta + \tau'$
Mediated Effect = Indirect Effect = $\alpha\beta = \tau - \tau'$
Direct Effect = τ'
Proportion Mediated = $\alpha\beta/\tau = \alpha\beta/(\alpha\beta + \tau')$.

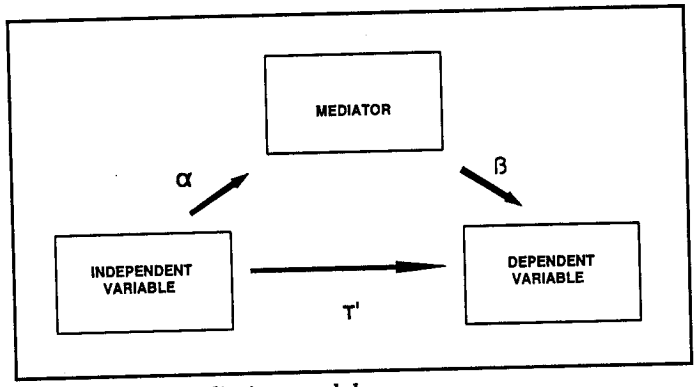

FIGURE 2. *Mediation model*

Standard Error of the Mediated Effect

The large sample variance of the indirect or mediated effect derived by the multivariate delta method (Folmer 1981; Sobel 1982, 1986) is equal to $\sigma_{\alpha\beta} = \sqrt{\alpha^2\sigma_\beta^2 + \beta^2\sigma_\alpha^2}$. The formula is not exact because it does not include a $\sigma_\alpha^2\sigma_\beta^2$ term, but this term is typically small (Goodman 1960; Mood et al. 1974; Rice 1988). Simulation studies (MacKinnon et al. 1991*b*, 1992; Stone and Sobel 1990) indicate that this standard error based on large-sample theory appears to be satisfactory even at small sample sizes under multivariate normality. For the simple mediation model described above and multivariate normal data, the true and estimated standard errors are very similar when the sample size is larger than 50. In a more complicated model studied by Stone and Sobel (1990), the standard error formula performed well at sample sizes of 200 or larger. The standard error

formula also is accurate when the independent variable is binary, as in most prevention and intervention studies (MacKinnon et al. 1991*b*). The large-sample theory standard error may not be as accurate in the presence of nonnormal data and outliers, however (Bollen and Stine 1990). At smaller sample sizes and positive mediated effects, there is a tendency for the confidence interval determined by the sample point and interval estimates to be to the left of the true value too often.

Mediation When the Dependent Variable Is Categorical

The procedure to estimate the mediated effect and its standard error described above does not apply directly in logistic or probit regression because error variances are not fixed in these analyses (Winship and Mare 1983). One solution is to standardize logistic and probit regression estimates and standard errors and then calculate mediated effects as described above (MacKinnon and Dwyer 1993; MacKinnon et al. 1992). By standardizing the estimates and standard errors, the scale is made equivalent across equations (Winship and Mare 1983). The standard error of the mediated effect using this procedure for standardized probit and logistic regression estimates may be conservative, however (MacKinnon and Dwyer 1993).

Measures of the Relative Magnitude of Mediation

The mediated effect ($\alpha\beta$) and its standard error provide a method to test the statistical significance of mediation. The $\alpha\beta$ measure does not provide information on the relative magnitude of mediation, however. One measure of the extent of mediation is the percent of the total effect that is mediated ($\alpha\beta/(\alpha\beta+\tau')$). For example, with this measure, a researcher could state that 67 percent of the effect of the prevention program on cigarette smoking was mediated by program effects on social norms. A second measure is the ratio of the indirect to the direct effect ($\alpha\beta/\tau'$). A researcher could state, for example, that the mediated effect was about two-thirds as large as the direct effect. Simulation studies indicate that the ratio measure is accurate only when sample size is greater than 3,000, even for the simplest mediation model (MacKinnon et al. 1991*b*). The proportion-mediated measure stabilizes at a sample size of 500. The accuracy of the ratio and proportion measures are a function of parameter values, however. Large direct effects are associated with more accurate proportion and

ratio estimates. Both these measures of the magnitude of mediation should be used only with relatively large sample sizes.

Statistical Power

The statistical power of the test of the mediated effect is less than a test of regression coefficients for several reasons. First, since the program variable is causally related to the mediator variable, multicollinearity may inflate the standard errors in the model for Conclusion 3 (Judd and Kenny 1981*a*). Second, most mediators are measured with error, generally leading to reduced power in the regression estimates used to calculate the mediated effect. Third, the formula for the standard error combines the unreliability in both the α and β parameters. One solution is to increase the reliability of measures by constructing measurement models using multiple indicators of each variable and other techniques (Aiken and West 1991; Fuller 1987).

Longitudinal Models

Figures 3 and 4 display possible longitudinal mediation models for one mediator and one outcome variable measured on two and three occasions, respectively. In these models, the total indirect effect is the effect of all mediation pathways between an independent variable and an outcome variable. In figure 4, for example, the total indirect effect of the program on the outcome at Time 3 equals the sum of b_3b_1, b_4b_6, $b_4b_5b_1$, and $b_4b_2b_5$. Specific indirect effects refer to individual indirect effects. More detailed information on types of indirect effects can be found in Bollen (1987), who makes the distinction between exclusive specific effects, which refer to an individual pathway, and incremental specific effects, which may include a subset of the pathways in the total indirect effect.

The parameters, standard errors, and goodness-of-fit of longitudinal models can be estimated using several computer programs for covariance structure models (Bentler 1980; Bollen 1989; James et al. 1982) such as EQS (Bentler 1989), CALIS (SAS Institute 1990), LISREL (Jöreskog and Sorbom 1988) or LINCS (Schoenberg and Arminger 1990).

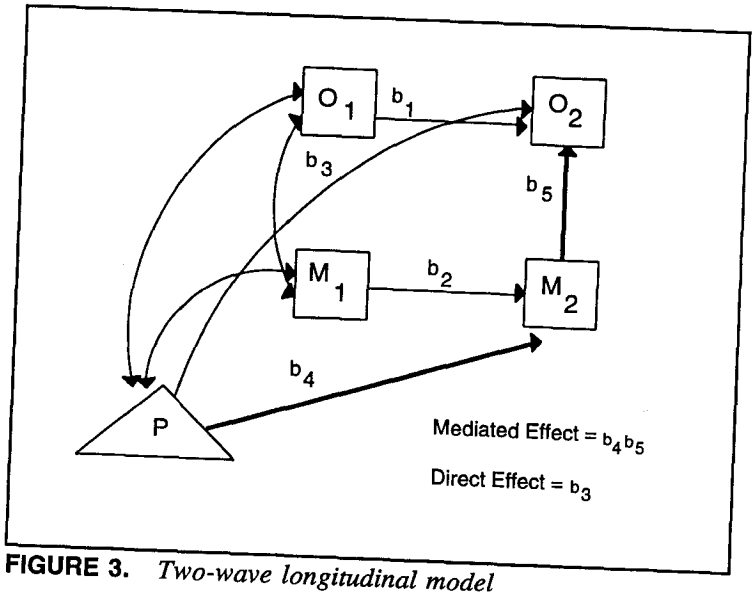

FIGURE 3. *Two-wave longitudinal model*

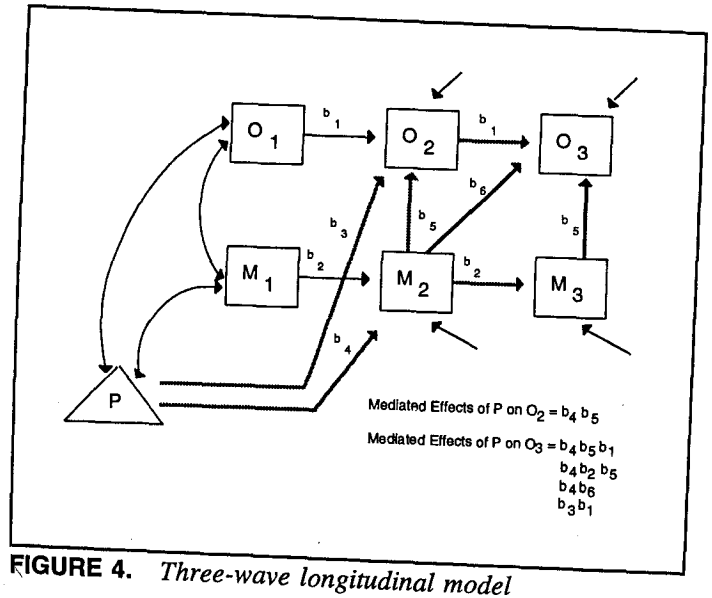

FIGURE 4. *Three-wave longitudinal model*

All four programs compute total direct and indirect effects. Some of the programs (e.g., EQS and LISREL) compute the standard errors of the indirect effects.

Multiple Mediators and Outcomes

The methods described above focused on one mediator and one outcome. The same methods can be extended for multiple mediators and multiple outcomes. A model for an anabolic steroid prevention study where eight mediators are targeted is shown in figure 5. The parameters of the model in figure 5 could be estimated by extending the regression equations described above or with covariance structure modeling. The covariance structure modeling approach is preferable because it can be used to estimate a wide variety of models with one or more mediators and one or more outcome variables (Bentler 1980, 1989; Bollen 1989; Jöreskog and Sorbom 1988).

EXAMPLE OF MEDIATION EFFECTS IN A DRUG PREVENTION STUDY

The mediation analysis described above has been applied to the results of a large community- and school-based prevention project (MacKinnon et al. 1991*a*). The prevention program, implemented since 1984, was aimed at delaying the onset of "gateway" drug use (alcohol, tobacco, and marijuana) through use of school, parent, community organization, mass media, and health-policy program components (Pentz et al. 1986, 1989). The program targeted mediators primarily are based on social learning and problem behavior theories. The school program was designed to change mediating variables of psychosocial consequences of drug use; normative expectations regarding drug-use prevalence; recognition and counteraction of adult, media, and community influences; peer and environmental resistance skills; assertiveness in practicing pressure resistance; problem-solving for difficult situations involving drug use; and public commitment to avoid drug use. Students in 42 middle and junior high schools in Kansas City, KS, and Kansas City, MO, were measured in the fall of 1984 ($\underline{N}$ = 5,065) and again a year later ($\underline{N}$ = 5,008) after 24 of the schools received the program.

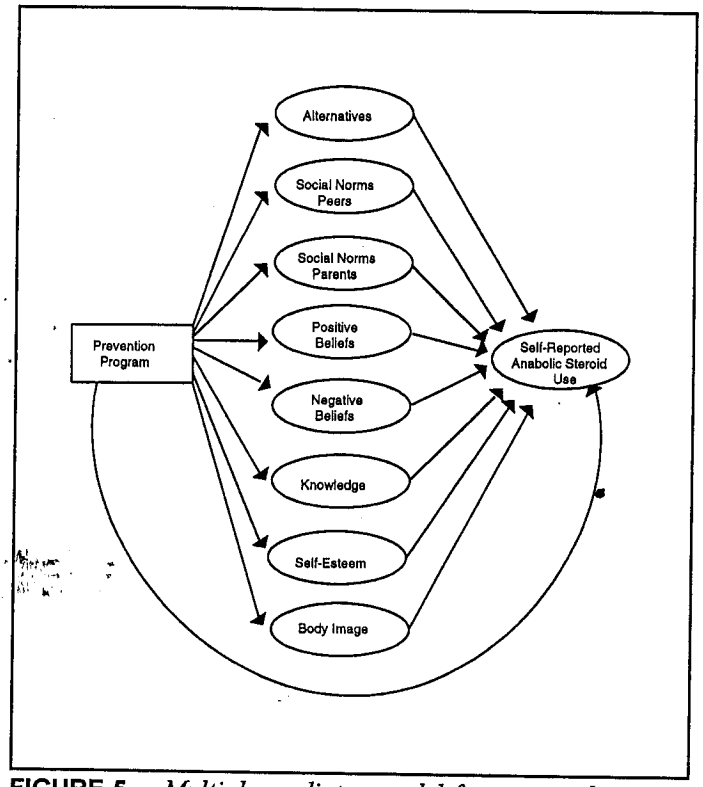

FIGURE 5. *Multiple mediator model for a steroid prevention project*

The mediation of prevention program effects on cigarette use by friends' reactions to drug use is used to illustrate mediation analysis. The dependent variable was the difference in the logit of the proportion of cigarette users between 1984 and 1985 in each of the 42 schools. The mediator was the difference in a summary index of several items measuring friends' reactions to drug use. The regression estimates and standard errors (in parentheses) for the three models are presented on the following page.

$$\text{Model 1:}\quad Y_0 = \underset{(.047)}{.137}\ X_P + \varepsilon_1$$

$$\text{Model 2:}\quad Y_0 = \underset{(.043)}{.045}\ X_P \underset{(.009)}{-.041}\ X_M + \epsilon_2$$

$$\text{Model 3:}\quad X_M = \underset{(.685)}{-2.23}\ X_P + \epsilon_3$$

Students in schools that received the program (X_P) reported less cigarette use than students in control schools, providing evidence for Conclusion 1. Evidence for Conclusion 2 was obtained with a statistically significant program effect on the friends' reaction mediator (X_M). The effect of the friends' reaction-to-drug-use mediator was statistically significant (β) even when controlling for program exposure, providing evidence for Conclusion 3. The mediated effect was $\alpha\beta = \tau\text{-}\tau' = .092$, $\sigma_{ab} = .035$, with 95 percent confidence limits of .023 and .161, suggesting that the program effect was mediated by friends' reactions to use.

INTERPRETATION OF THE RESULTS OF A MEDIATION ANALYSIS

Program Effects on the Mediator but Not the Outcome

A prevention study may affect the mediator but not the outcome variable. This pattern of results is open to several possible interpretations: (1) The program changed the mediator as intended, but the mediator is not causally related to the outcome measure; (2) the sample size was not large enough or the measures of the outcome measure were not sufficiently valid or reliable enough to detect effects; (3) the effects of the mediator on the outcome may emerge later; or (4) the program effect on the outcome may be nonsignificant due to the presence of both mediation and suppression effects.

Program Effects on the Outcome but Not the Mediator

Effects on the outcome but not the mediator suggest that the mediator is not causally related to the outcome measure. It also is possible that

the measures of the mediator were not reliable or valid enough or the study may not have had sufficient statistical power to detect program effects on the mediator.

No Program Effects on the Outcome or the Mediator

Possible explanations here include: (1) lack of statistical power due to sample size or poor measurement of the mediator and the outcome and (2) an ineffective prevention program. As in any study where the null hypothesis is not rejected, these results do not prove that the theory or the mediators targeted by the program are wrong. The results do raise questions about the theory, intervention approach, and implementation of the program.

Program Effects on the Mediator and the Outcome but Nonsignificant Mediation

It is possible that there are program effects on mediators and outcomes but that the results from the statistical test of mediated effects are nonsignificant. There is some evidence for mediation because the relationship between program exposure and the mediator and the relationship between the mediator and the outcome are statistically significant. In this case, separate null hypotheses that $\alpha = 0$ and $\beta = 0$ are both rejected, which suggests that the program caused the mediator and that the mediator caused the outcome, although the latter relationship was not determined experimentally. Another interpretation of these results, however, is that the prevention program is not causally related to the outcome through the mediator because the confidence limits used to test this process hypothesis (H_o: $\alpha\beta = 0$) included a value of zero. Other interpretations are lack of sufficient statistical power, model misspecification such as reciprocal effects, and potential suppressor effects that may be remedied in another study.

Program Effects on the Mediator and the Outcome and Statistically Significant Mediation

A successful intervention or prevention program will yield statistically significant mediation effects along with effects on mediators and the outcome. In this case, the prevention program changed relevant mediators, and the change in these mediators changed the outcome

measure. The results suggest that the mediator is important and should be emphasized in later prevention programs. Evidence for the theoretical basis of the program is obtained. Other similar outcome measures may be affected by changing the same mediator.

Like any other study where the null hypothesis is rejected, such results must be treated with some caution. First, if the sample size is large, the mediated effect may be small (i.e., not clinically significant), even though it is statistically significant. Second, it is possible that an omitted mediator is the actual mechanism by which the program had its effect.

MEDIATION ANALYSIS IN GRANT APPLICATIONS

Eight aspects of mediation analyses should be described in proposed research:

1. *Link theory and the mediators targeted by the program.* An important aspect of mediation analysis is that it forces the researcher to consider the theoretical basis for how the prevention program leads to changes in an outcome measure. Experimental comparison of mediators suggested by competing theories provides an ideal test of the theories. As described above, such a prevention study will provide information on how to prevent a problem behavior as well as information on competing theories.

2. *Link prevention program components with targeted mediators.* A table with the specific program components and the mediators targeted by each component clarifies the link.

3. *Select mediators that can be changed.* Build an argument for the importance of the mediators based on prior research on the proposed outcome and related outcomes. If personality mediators or other mediators that may not be easily modifiable are included, justify their role as mediators and how the program will be intense enough to change them.

4. *Select mediators that are related to the outcome measure.* Prior research should suggest that the mediator is causally related to the outcome measure.

5. *Describe a program of research.* The identification of putative mediators requires a program of study beginning with the identification of the mediators that are related to the outcome, the development of a prevention program to change the mediators, and the evaluation of the prevention program (West et al. 1991). Replication of previous research results and experimental studies provides the most convincing evidence for putative mediators.

6. *Include information on the psychometric properties of mediators and outcome measures.* The information may include internal consistency, test-retest, and alternative-forms reliability of proposed measures (Carmines and Zellner 1979). Measurement models for the mediators and outcome measures indicate that unreliability of measures is not likely to reduce the statistical power of the tests of mediated effects. The corroboration between biological and self-report measures and multimethod-multitrait analyses further show that the investigators emphasize measurement issues in their proposed work (Campbell and Fiske 1959; Widaman 1985). The match between the content of the measures and the targeted construct should be described.

7. *Include persons in the research team who have experience with mediational analyses and with the strengths and limitations of covariance structure models* (Berk 1988). The three conclusions described by Judd and Kenny (1981*a*, 1981*b*) and methods to determine the standard error of the mediated effect and its confidence limits for Conclusion 4 (Baron and Kenny 1986; MacKinnon and Dwyer 1993; Sobel 1982, 1986) should be described.

8. *Ensure that the proposed research has promise of generating new and important scientific information.* A grant that proposes to test the value of the coefficients (Meehl 1967) in a mediational model, for example, is likely to interest reviewers. To propose such a model requires an existing line of research and very specific theory regarding the actual value of the quantitative relationships among constructs.

Mediation effects also may occur when a prevention program changes the relationship between a correlate and an outcome variable (Judd and Kenny 1981*a*). For example, a drug prevention program may remove the effect of norms on alcohol use, such that normative influences predict alcohol use in the control group, but not in the treatment group. A grant application with detailed hypotheses regarding this and other types of mediation (James and Brett 1984) is important because it would be one of the first to test such hypotheses.

SUMMARY

Mediational analysis is one way to test specific hypotheses derived from theory. Although this analysis has been suggested in the prevention literature, mediation analysis rarely is conducted. As the field of prevention matures, more questions about how prevention programs work (or fail to work) will emerge. Studies of mediation can address these questions, thereby reducing the cost and enhancing the impact of prevention programs.

The methods outlined here can be applied in the evaluation of primary, secondary, and tertiary prevention programs. Since most prevention studies include measurement of some mediating constructs, mediation effects can be assessed on many existing data sets. Mediation analysis can be used to test ideas about prevention.

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ACKNOWLEDGMENT

This chapter was supported in part by PHS Grants DA06211 and DA03976 from the National Institute on Drug Abuse.

Special thanks to Steve West and Linn Goldberg for comments on the chapter.

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