Mediator and Moderator Analysis in Program Development

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This chapter explores how mediator and moderator analysis can be used to help develop efficacious health behavior programs. Mediation analysis is most fruitfully employed in the analysis of previous main trial data and at the pilot-testing phase of program development, when multiple program components have been placed together into the same program and immediate-outcome mediator measures of these sets of components can be refined and tested with a relatively large sample. Thus, this chapter is placed toward the end of the text. Certainly, however, several of the lessons provided herein (in particular, a visual conceptual framework of main effects, mediator, and moderator models) are relevant to earlier stages of program development, including the advancement of theory development (Chapter 4, this volume), pooling programming (Chapter 7), and development of immediate-outcomes measures in perceived efficacy and component studies (Chapters 9, 11, and 13). Program conceptual frameworks hypothesizing mediator and moderator relationships among variables, in combination with empirical
feedback, are used to guide program development. This approach promises to identify (a) which program components are most effective, (b) the mediating causal processes through which they work, and (c) the characteristics of the participants, service providers, settings, and the like that moderate the relationships between a program and its outcomes. Examples from the health behavior literature are used to illustrate the value of conceptualizing and analyzing mediator and moderator relationships in health behavior program development and evaluation.

Social programming in general—and, more specifically, health behavior intervention research—has a history filled with illustrations of “black-box,” “input/output,” or outcome-focused investigations. For example, Lipsey and Wilson (1993) meta-analyzed 111 meta-analyses of intervention studies across a wide range of program domains (representing evaluations of more than 10,000 programs) and reported that most of this literature is based on only crude outcome research with little attention to potential mediating and moderating factors. They suggested that the proper agenda for the next generation of program evaluation should focus on which program components are most effective, the mediating causal processes through which they work, and the characteristics of the participants, service providers, settings, and the like that moderate the relationships between a program and its outcomes.

It is argued in this chapter that this agenda should be broadened to aid in the development of better programs as well as their eventual evaluation. A basic premise is that health behavior interventions are much more likely to be successful if they are developed using a theory-driven, empirically based program development approach (see Chen, 1990; Donaldson, 1995a, 1995b; Sussman, 1991; Sussman, Dent, Burton, Stacy, & Flay, 1995; Sussman, Petosa, & Clarke, 1996). This approach rests on using empirical feedback to guide program development. Succinctly stated, first the process through which program components are presumed to affect outcomes and the conditions under which these processes are believed to operate are conceptualized. For example, a mediator is a variable that is affected by the program, which in turn affects the outcome of interest. In contrast, a moderator variable affects the direction or strength of the relationships between the program and a mediator or a mediator and an outcome. Next, hypothesized mediator and moderator relationships are examined by piloting the program or components of the program and conducting rather small-scale data collection efforts (see Chapters 13 and 16, this volume). Data about the program are used to refine the conceptual framework, and the data collection process is repeated until the program developer decides the program is worthy of full-scale implementation and evaluation (see Figure 19.1). The definitions and use of mediator and moderator variables in program development are described in more detail in this chapter.
DEVELOPING CONCEPTUAL FRAMEWORKS

Many health behavior programs represent practitioners' best guesses or opinions about how to improve desired outcomes. Although practitioners' perspectives are certainly important, they often can be made much more potent when they are used as a starting point in a systematic program development process (see Chapter 1, this volume). Using a theory-based evaluation framework (Chen, 1990), the first task of systematic program development is to develop a conceptual framework of how the program intends to achieve its objectives. In some cases, this may be purely the program designers' view of the program. Often, this view is implicit, and the task is to make this view or program theory explicit and testable. However, it is often possible and highly desirable to base this conceptual framework on multiple sources of information such as (a) prior theory and research in the program domain (see Chapters 4-6), (b) implicit theories held by those clos-
est to the operation of the program (program personnel such as health educators or other human service providers), (c) observations of the program in action, and, in some cases, (d) exploratory research to test critical assumptions about the nature of the program (see Donaldson, 1995a, 1995b; Lipsey & Pollard, 1989; Weiss, 1997).

Programs can be conceptualized to take on many theory forms (Lipsey & Pollard, 1989). However, in the health behavior domain, variable-oriented models are the standard. Variable-oriented theory forms depict a causal process presumed to work in terms of variables and the covariation among those variables. For example, a health education program might be postulated to improve dietary knowledge, which is presumed to improve dietary behavior. This simple model asserts that the program is related to both dietary knowledge and dietary behavior and that they are related to each other. Of course, it is easy to conceptualize some programs to include a large number of variables and various types of relationships among variables. Part of the task of developing a conceptual framework during the program development phase is to find a parsimonious model that is likely to account for a large percentage of the variance in the desired outcome variables. That is, a model is needed that explains why participants who receive the program would do better on the desired outcomes than those who receive a control or comparison program.

Although some program conceptual frameworks can be complex and contain a large number of variables within the framework, relationships among variables are typically described as one of three basic types: (a) direct or main effects, (b) indirect or mediator relationships, or (c) moderator relationships. That is, program conceptualization in health behavior programming usually breaks down into direct, mediator, and moderator relationships between variables. Below, I describe how each type of relationship is used to represent health behavior programs.

**DIRECT EFFECT**

In the past, the standard and most common conceptualization of a health behavior program was known as a direct effect. That is, a program was typically conceived to affect an outcome or outcomes (see Figure 19.2). Health behavior programs were focused on outcomes such as increased physical activity, improving eating habits, weight loss, smoking cessation, and the like. The focus of most program developers was to include as many activities as possible in the program in an effort to make sure outcomes were in fact improved. The task of the evaluation researcher was to demonstrate whether a program did improve desired outcomes. Reviews of the program evaluation literature over the past two decades have found that, in most studies, programs are conceptualized as undifferenti-
ated "black-box" treatment packages and only report information about direct effects (Lipsey, 1988; Lipsey, Crosse, Dunkel, Pollard, & Stobart, 1985; Lipsey & Wilson, 1993).

One main limitation of the direct-effect conceptualization and evaluation is that little is learned when there is no overall program effect. For example, the researcher is not able to disentangle the success or failure of program implementation from the validity of the conceptual model on which the program is based (Chen, 1990; Donaldson, 1995a, 1995b). Similarly, there is no way to sort out which components of a program are efficacious and which are ineffective or actually harmful. Another serious problem with the direct-effect conceptualization is that, arguably, behavioral interventions have only indirect effects. Hansen and McNeal (1996) call this the law of indirect effect:

This law dictates that direct effects of a program on behavior are not possible. The expression or suppression of a behavior is controlled by neural and situational processes over which the interventionist has no direct control. To achieve their effects, programs must alter processes that have the potential to indirectly influence the behavior of interest. Simply stated, programs do not attempt to change behavior directly. Instead they attempt to change the way people think about the behavior, the way they perceive the social environment that influences the behavior, the skills they bring to bear on situations that augment risk for the occurrence of the behavior, or the structure of the environment in which the behavior will eventually emerge or be suppressed. The essence of health education is changing predisposing and enabling factors that lead to behavior, not the behavior itself. (p. 503)

Another way to restate this law is to say that a program affects immediate-outcome variables directly (which may include changes in attitudes or results of behavioral skills training) and long-term outcome variables indirectly (the targeted health behavior). Therefore, the direct-effect conceptualization alone adds
little value to the process of theory-driven, empirically based program development.

**MEDIATION MODELS**

In contrast, using an indirect-effect conceptualization of a program can dramatically improve understanding about a program's functioning. I will illustrate this point first by modestly adding only one additional variable to the direct-effect conceptualization shown in Figure 19.2. Figure 19.3 illustrates a basic two-step mediation model. This model shows that the program affects the mediator (Path a), which in turn affects the behavioral outcome (Path b). Path c represents the residual direct effect. Theoretically, if Path c is zero, the mediator variable is the sole cause of the outcome. If Path c is nonzero, there are believed to be additional mediators (as yet unexplained) that explain the link between the program and the outcome. It is important to note that with just this additional variable, a researcher is now in a position to determine (a) whether the program was effective enough to alter its target (i.e., success or failure of program implementation) and (b) whether the program is aimed at the right target (the validity of the conceptual model; i.e., does the mediator variable in fact improve the outcome variable?).

Most health behavior programs are considered to be multiple-component interventions, which are more accurately conceptualized to contain multiple-mediator variables (e.g., see Figure 19.4). In the practice of program development, it is probably most often the case that program components reflect the program developer's view of how to optimize the chances of obtaining desired outcomes, rather than a combination of components shown to be effective (cf. Hansen, 1993). West and Aiken (1997) described fundamental tensions between
program developers and evaluation researchers associated with the development of multicomponent programs. Put simply, although program developers are primarily concerned with maximizing the efficacy of the entire program, evaluation researchers have become increasingly concerned with how each component affects targeted mediators or risk factors and which, in turn, produce their effects on the desired outcomes.

I submit that more complex multiple-mediator model conceptualizations of health behavior programs are usually necessary to accurately reflect the multicomponent nature of programs. These conceptualizations can enhance the program development process by more precisely identifying the program characteristics that are presumed to influence each target mediator. Pilot empirical work can then be conducted to estimate whether it is likely that each individual program component will have a large enough effect on the targeted mediators to have an effect on desired outcomes when the program is actually implemented. Carefully selecting mediators to explain and maximize the effects of the program should be the common goal of program developers and evaluators.
Another important benefit of conceptualizing a program in this way is that it exposes often implicit theoretical program mechanisms. That is, the paths going from the mediators to the outcomes represent the conceptual foundation of the program. In some cases, the link between the assumed risk factor (mediator) and outcome has been well established in prior research. In other cases, there is considerable ambiguity about the links. It is not uncommon for program developers who use this approach to modify the program dramatically because the original conceptual links appear very unrealistic once they are exposed. It is important to keep in mind that the magnitude of change in a behavioral outcome that a program can produce is directly limited by the strength of the relationships that exist between mediators and outcomes, according to Hansen and McNeal (1996). Hansen and McNeal describe this as the law of maximum expected potential effect:

The magnitude of change in a behavioral outcome that a program can produce is directly limited by the strength of relationships that exist between mediators and targeted behaviors. The existence of this law is based on the mathematical formulae used in estimating the strength of mediating variable relationships, not from empirical observation, although we believe that empirical observations will generally corroborate its existence. An understanding of this law should allow intervention researchers a mathematical grounding in the selection of mediating processes for intervention. An added benefit may ultimately be the ability to predict with some accuracy the a priori maximum potential of programs to have an effect on targeted behavioral outcomes, although this may be beyond the current state-of-the-science to achieve. (p. 502)

This does not mean that a program might not achieve strong effects without knowledge of all its mediators of effects. However, better control over programming would be achieved by such knowledge. Furthermore, this does not mean that composite, diffuse mediators such as perceived program quality are not adequate for some program development purposes. Certainly, perceived program quality is affected by the impact of the program, and it predicts later behavior change. However, knowledge of specific mechanisms of change provides better prediction of ultimate, behavioral program effects. Therefore, it is critical to make sure that the program is aiming at the right targets (mediators) if it is going to have any chance of achieving outcomes.

PATH MODERATORS

In general, a moderator is a qualitative (e.g., gender, ethnicity, socioeconomic status, intelligence) or quantitative (e.g., program attendance, integrity of the program) variable that affects the direction or strength of the relationships
between the program and mediator or mediator and the outcome (see Baron & Kenny, 1986). Figure 19.5 illustrates that Moderator 1 conditions or influences the path between the program and the mediator. This means that the strength or the direction of the relationship between the program and the mediator is significantly affected by the moderator variable. This type of moderator relationship is of primary importance in program development. Program developers can benefit greatly from considering if potential moderator variables such as participant characteristics, provider characteristics, characteristics of the setting of program implementation, strength of the programs, and program fidelity significantly influence the program's ability to affect target mediators.

Figure 19.6 illustrates that Moderator 2 conditions the path between the mediator and outcome. This type of relationship addresses the generalizability of the presumed program mechanism. For example, is the relationship between the mediator and the outcome the same for (a) females versus males, (b) inner-city children versus children living in the suburbs, or (c) Latinos, African Americans, Asian Americans, and European Americans? Although it is most often the case that the relationships between the mediators and program are presumed to generalize across all participants, in some cases it is possible that participant characteristics condition the relationships between the mediators and outcomes. Assessing this type of moderator relationship is usually not feasible during the program development phase. Nevertheless, it is important to identify significant moderators of all paths when conceptualizing how a program is presumed to
work. These relationships may be critical to understand the program effects, or the lack thereof, later on when the program is being evaluated.

**ALTERNATIVE CONCEPTUALIZATIONS**

This chapter is focused on analyzing mediator and moderator relationships during program development. However, it is worth mentioning that there are alternative ways programs may be conceptualized. First, Lipsey and Pollard (1989) pointed out that although variable-oriented thinking is ubiquitous in the social sciences, much of what is of interest in program development and evaluation is not the status of variables but the status of persons (e.g., are they healthier?). They illustrate person-oriented conceptual frameworks by describing stage state models, including a concrete example provided by Runyan (1980). Furthermore, Collins, Graham, Rouscump, et al. (1994) have introduced a relatively new methodology, latent transition analysis, which allows for the examination of stage-sequential development of persons. Examples of stage-sequential program models are presented in Collins, Graham, Rouscump, and Hansen (1997) and Collins, Graham, Long, and Hansen (1994). Although person-oriented models represent a promising alternative for conceptualizing programs, this approach is still relatively new, and its value in program development is yet to be demonstrated.

Others have discussed how to develop more complex logic models to graphically represent management objectives, actual project operations, and the logi-
cal structure of the program (e.g., see Smith, 1989). Most of these approaches share the ultimate goal of developing a conceptualization of the program in which measurements could be taken to test assumptions and verify mediation and moderator relationships. Finally, the discussion above is limited to cases of one wave (set) of mediators. More complex conceptualizations might involve two or more waves of mediators. Although these models may be valuable in certain program evaluation situations, it is important to note that testing a model such as this typically requires a very large and complex longitudinal data set. Testing multiwave mediation models is beyond the scope of most theory-driven, empirically based program development efforts.

VALUE OF STARTING WITH A CONCEPTUAL FRAMEWORK: A SUMMARY

The purpose of this chapter is to show the value of conceptualizing and assessing mediator and moderator relationships during program development. I argue that there is great value in thinking through the logic or rationale for the various program activities prior to implementation and evaluation. This conceptual framework or program theory, often a refined set of mediator and moderator relationships, ultimately can be used

1. to disentangle the success or failure of program implementation (action theory) from the validity of program theory (conceptual theory);
2. as a basis for informed choices about evaluation methods;
3. to identify pertinent variables and how, when (e.g., dose-response and intervention-decay functions), and on whom they should be measured;
4. to carefully define and operationalize the independent (program) variables;
5. to identify and control for extraneous sources of variance;
6. to alert the program developer and evaluator to potentially important or intrusive interactions (e.g., differential participant response to the intervention);
7. to dictate the proper analytical or statistical model for data analysis and the tenability of the assumptions required in that model; and
8. to make a thoughtful and probing analysis of the validity of program evaluation in a specific context and provide feedback that can be used to improve the program under investigation while developing a cumulative wisdom about how programs work and when they work (cf. Baranowski,
So far, I have described only the first step of conceptualizing the program under investigation, which is shown as constructing program theory in Figure 19.1. Once we have done our best initial thinking about the program, it is time to test some of the assumptions of the framework. That is, the next challenge is to obtain empirical data to assess if initial mediator or moderator relationships match the reality of the participant experiences. As illustrated in Figure 19.1, empirical feedback (data) is used to refine program theory in an iterative fashion. That is, small-scale studies are conducted during program development in an effort to confirm or refine program theory and to strengthen the program.

Others have discussed in some depth systematic strategies (West & Aiken, 1997) and models (Sussman, 1991; Sussman et al., 1995, 1996) for empirically testing hypothesized program mediators and moderators during program development. For example, Sussman (1991) proposed a four-step empirical curriculum development model that consists of (a) adopting and extending a theoretical knowledge base on prior research in the program domain; (b) pooling curriculum activities from similar programs shown to be effective, as well as developing new activities to target potential mediators (risk factors) not previously addressed; (c) testing individual activities using focus groups, theme studies, and experimental and quasi-experimental component studies; and (d) combining activities and lessons to produce a full curriculum to be tested using feasibility and pilot studies. Results from a model such as Sussman’s can provide valuable information for refining program theory and for strengthening a program before it is fully implemented. (An updated “chain model” is presented in Chapter 1, this volume.)

**PROGRAM-MEDIATOR RELATIONSHIPS**

When using empirical data to refine or confirm the program conceptualization during program development, one must focus on the program-mediator relationships. That is, the emphasis is on assessing whether the program is able to change target mediators. For example, Figure 19.7 illustrates a multicomponent (three-component) program designed to affect three mediators. Note that although program Components 1 and 2 are presumed to affect one specific media-
Component 3 is theorized to affect both Mediators 2 and 3. This is meant to illustrate that program activities may be designed to affect more than one mediator, and one mediator may be targeted by more than one program component. As described by Sussman (1991) and West and Aiken (1997), quantitative or qualitative methods can be employed to give some indication of how well the program appears to be affecting the mediators by using a small sample of participants receiving a component, some combination of program components, or the entire program curriculum. However, it is important to note that one of the greatest challenges of empirical confirmation or disconfirmation during program development is to obtain trustworthy empirical information. The risks and concerns about data quality are discussed below.

MODERATORS

Investigating the extent to which program-mediator relationships are affected by key moderator variables also can yield important information during program development. For example, participant characteristics such as gender, ethnicity, socioeconomic status, relevant experience, and the like may affect how well the program is received and consequently the program’s ability to change target mediators in some subgroups. In Figure 19.7, it can be seen that program Component 1 may significantly affect Mediator 1 among female participants but not among male participants. This would suggest that adjustments in program content are necessary if the goal is to change the behavior (outcome) of both female and male participants.

Service provider characteristics, characteristics of the setting of program implementation, strength of the program, and program fidelity are other common moderators that can be examined during program development. Identifying the optimal strength of a program or dose-response function can be a critical issue to examine in program development (Lipsy, 1990). The dose-response function describes the relationship between the dose of the program delivered to participants (e.g., weak dose, moderate dose, strong dose) and the targeted mediators. It is not uncommon for a relatively strong dose of a program (e.g., 8-week curriculum) to affect mediators significantly more than a relatively weak version of the program (e.g., 1-day workshop). This would indicate that the strength of the program is a significant moderator variable. However, in other cases, a relatively weak dose may have the same effect on mediator variables as stronger doses, indicating that the additional time and resources needed to provide the higher dose of the program are not needed or cost-effective. Obviously, finding the optimal dosage of a program during program development can dramatically increase the chances that the program eventually will be shown to be effective.
MEDIATOR-OUTCOME RELATIONSHIPS

It is typically much more difficult to test mediator-outcome relationships using empirical evidence collected during program development than it is to examine program-mediator relationships. In many situations, mediators are measured immediately following the program, whereas outcomes are measured at later points. That is, once a program has changed its targeted mediating variables, it usually takes some time before the mediators produce changes in health behavior. Although there certainly are exceptions, it is usually more fruitful to review prior research establishing the strength of the relationships between a program's target mediators and target outcomes (see also Chapter 7, this volume). If previous studies on the whole suggest weak or nonexistent relationships, it is important to think carefully about how likely previous findings generalize to the program under development. If it seems highly likely that negative findings could generalize, it might be worth abandoning those target mediators that are unlikely to affect outcomes. In addition, evidence showing strong moderator relationships between target mediators and outcomes may suggest the conditions under which the program should be implemented. Again, due to time and re-
source constraints, it is usually not feasible to gather quality data to adequately test mediator-outcome relationships while the program is being developed.

DATA QUALITY

I have been careful not to advocate a specific method or methods of data collection that should be used during program development. Rather, I have emphasized the development of a strong conceptual framework to guide program development activities. The purpose of data collection during program development is to examine, as rigorously as possible given the practical constraints of the program development context, the likelihood that the components of the framework will hold up when the program is fully implemented and evaluated. The inherent dilemma is that program developers most often must rely on data that could have serious limitations by common evaluation research standards. Nevertheless, by using focus groups, theme studies, interviews, surveys, experimental and quasi-experimental component studies, and the like to gather some data to examine mediator and moderator relationships, one can shed light on the feasibility of program assumptions and ultimately help program developers strengthen the program (see Sussman, 1991).

In my experience, data collection efforts during program development are particularly useful for uncovering serious program flaws. For example, if a program is implemented to a sample of people with similar characteristics to the target population, and pilot data suggest that program activities are not affecting specific mediators, this alerts the program developer to areas where program activities may need to be strengthened or changed. However, it is also possible that null findings are simply due to research design sensitivity problems (Lipsey, 1990). Similarly, positive findings that appear to confirm the model can be in error due to threats to internal, construct, or external validity (see Cook & Campbell, 1979; Donaldson, 1995a, 1995b). The challenge of empirical program development is to probe and consider these issues in an effort to make empirically informed decisions about improving the program. Again, the underlying premise is that it is more likely to develop a strong program with limited data than with no data at all.

ANALYTIC TECHNIQUES

There has been significant advancement in statistical techniques for testing mediation in intervention research over the past two decades (Folmer, 1981; MacKinnon & Dwyer, 1993; Sobel, 1982). Common structural equation modeling statistical packages such as EQS (Bentler, 1995) and LISREL (Jöreskog &
Sörbom, 1993) can now be used to test complex mediation models when rather large and complex databases are available. Moreover, mediation also can be established using a series of simple regression equations (Baron & Kenny, 1986; MacKinnon, 1994; West & Aiken, 1997). Although it is often unrealistic to imagine conducting full-scale mediation analyses during program development, the logic behind these statistical tests is worth reviewing in anticipation of what a program must eventually achieve to be considered effective.

There are five steps or tests commonly used to assess mediation (Baron & Kenny, 1986; Judd & Kenny, 1981a, 1981b; MacKinnon, 1994). To establish mediation, the following relationships (tests) typically are examined:

1. The program causes the outcome (regressing the outcome variable on the program variable).
2. The program causes the mediator (regressing the mediator variable on the program variable).
3. The mediator causes the outcome variable (regressing the outcome variable on the mediator variable) (Baron & Kenny, 1986).
4. The mediator causes the outcome variable controlling for exposure to the program (regressing the outcome variable on both the program and mediator variable).
5. The mediated effect is significant (see MacKinnon, 1994).

It is important to point out that subtle nuances must be considered when testing for mediation. For example, it is possible that mediation still exists even if Test 1 is not positive (program causes mediator) because a suppressor effect could be present (e.g., one mediator variable is effective, and another is counterproductive, leaving the appearance of no effect of the program on the outcome). Furthermore, Test 5 is particularly important when there are multiple mediators of program effects (MacKinnon, 1994; West & Aiken, 1997). Fortunately, there have been some very good full-length treatments in recent years of how to use statistical approaches to test for mediation in intervention research (see MacKinnon, 1994; MacKinnon & Dwyer, 1993; West & Aiken, 1997).

Statistical approaches for testing moderators in intervention research are also well established (Aiken & West, 1991; Baron & Kenny, 1986). Again, a moderator variable is a third variable that affects the strength and direction of the statistical relationship (e.g., zero-order correlation) between two other variables (e.g., program and mediator variable). Figure 19.8 illustrates how to test whether dosage level moderates the relationship between the program and its target mediator. Path a represents the effect of the program on the mediator. Path b represents the relationship between dosage level (moderator) and the target mediator. Path c represents the products of Paths a and b (known as the interaction). In this
example, dosage level moderates the relationship between the program and the mediator if the interaction term is statistically significant (Path c). Paths a and b are superfluous to the test of moderation. However, it is easier to interpret the interaction term when the moderator is not related to the program or mediator variables (Baron & Kenny, 1986). For in-depth discussions on using statistical approaches for testing moderator models and statistical interactions, see Aiken and West (1991) and Baron and Kenny (1986).

In all but the rare situation, program developers are forced to analyze mediator and moderator relationships with limited empirical data. For example, if we assume a medium effect size (ES = .40) and set alpha at .05 and power at .80, we would need to implement our program to at least 200 participants (e.g., 100 randomly assigned to treatment and 100 randomly assigned to a comparison group) to have confidence in statistical tests such as the ones described earlier (see Lipsey, 1990). It is unlikely that this level of time and resources is available for data collection during program development. Of course, when it is, the statistical approaches described earlier can be used to confirm or modify the program’s conceptual framework (see Chapter 16, this volume).
However, it is more likely that trends in a more limited set of data collected from fewer participants will have to be used to estimate the likelihood that program components will have their desired effects when the program is fully implemented. Under these conditions, quantitative or qualitative data from participants who experience all or some aspect of the program can be used to assess trends between (a) the program and the target mediators and (b) the potential moderators of those trends (e.g., did the program appear to work better for certain subgroups?). Again, these analyses can be used to modify aspects of the program in an effort to strengthen its impact on target mediators, which should ultimately lead to more robust program effects.

LIMITATIONS

An accurate conceptual framework can go a long way toward improving the chances of program success. Most program frameworks can be reduced down to a series of mediator and moderator relationships. Empirical confirmation or disconfirmation of these relationships and the framework as a whole are often essential for building effective program theory and, consequently, effective health behavior programs. Unfortunately, the process of good program theory development is often rather long term and ongoing. Although assessing mediators and moderators during program development can be useful, it also carries the risk of misleading program developers. I have argued that this risk is due largely to the dangers associated with making decisions about the program based on limited data. But acknowledging and understanding these limitations can improve decisions about program modification in response to the limited data collected. In the best-case scenario, one can assess mediators and moderators in program development by using some version of an empirical curriculum or program development model, which promises to dramatically improve the overall quality of program development in health behavior research and practice (Sussman, 1991; Sussman et al., 1996).

SOME HEALTH BEHAVIOR EXAMPLES
That is, a health behavior program increases knowledge (e.g., of the benefits of regular physical activity, nutrition, safe sex, or cancer screening), more knowledge leads to changes in attitudes (e.g., about exercise, diet, condom use, or preventive health services), and changes in attitudes lead to changed health behavior. However, the literature is now replete with examples that deviate from this popular basic framework.

MacKinnon (1994) provides a table illustrating a wide variety of mediators of health behavior outcomes found across a diversity of prevention studies. For example, educational achievement and parent-child communication are listed as mediators of unintentional pregnancy and unprotected intercourse in teenage pregnancy prevention (Dryfoos, 1990), safer-sex practices mediate the prevalence of sexually transmitted diseases in AIDS/HIV prevention programming (Coyle, Boruch, & Turner, 1991), the quality of parent-child relationships and active coping skills mediate outcomes of conduct and mental health problems in divorce prevention research (Sandler, Wolchik, & Braver, 1988), awareness of hotline services and referrals to general psychiatric care mediate outcomes of reduced suicide ideation and deaths due to suicide in suicide prevention research (Shaffer, Philips, Garland, & Bacon, 1989), and social norms mediate anabolic steroid use in adolescent steroid use prevention (Goldberg, Bents, Bosworth, Trevisan, & Elliot, 1991). Furthermore, an application of mediation analysis with a multicomponent health behavior program targeting multiple mediators recently has been described in some detail by West and Aiken (1997). Using data from a breast cancer screening trial based on the health belief model (Aiken, West, Woodward, Reno, & Reynolds, 1994), the benefits of screening mammography, the severity of breast cancer, a woman’s perceptions of her susceptibility to breast cancer, and the barriers to screening mammography are hypothesized to influence a woman’s intention to get a screening mammography. West and Aiken (1997) concluded that perceptions of susceptibility and knowledge about benefits were the key mediators of intentions to get screening, and they show the reader in detail how they arrived at that conclusion through mediation analysis. Below, I will further illustrate mediator and moderator relationships in health behavior research by highlighting examples from the exercise, occupational mental health promotion, and adolescent drug abuse prevention literatures.

**PHYSICAL ACTIVITY**

The direct benefits of regular physical activity and fitness are well documented. Regular physical activity can increase life expectancy and prevent obesity, coronary heart disease, hypertension, diabetes, osteoporosis, colon cancer, stroke, and depression (U.S. Department of Health and Human Services, 1991). What is probably less well known is that physical activity appears to also buffer or
moderate the relationship between stress and illness. Research conducted by Brown (1991) illustrates this moderator relationship clearly. In summary, under periods of high stress, people who are not physically fit report significantly more health center visits (illness) than those who are physically fit (see Figure 19.9). However, fitness itself was not significantly related to health center visits, illus-
trating the importance of conceptualizing and testing for interactions or moderators in health behavior program development and research (see Brown, 1991; Brown & Siegel, 1988).

**OCCUPATIONAL MENTAL HEALTH PROMOTION**

The nature of one’s work (e.g., the presence or absence of work, conditions of work) is often a substantial determinant of health status, well-being, and overall quality of life (Donaldson, Gooler, & Weiss, 1998). A decade of reengineering, downsizing, or “right-sizing” has caused many loyal workers to lose stable, well-paying jobs (Donaldson & Weiss, 1998). Many displaced workers remain unemployed for long periods, suffering a variety of psychosocial and physical health consequences. Preventive interventions for the recently unemployed have been shown to enable unemployed workers to avoid depression, anxiety, and adverse health behaviors while seeking reemployment (Price, van Ryn, & Vinokur, 1992; Vinokur, Price, Caplan, van Ryn, & Curran, 1995; Vinokur, van Ryn, Gramlich, & Price, 1991). Another illustrative example of mediators and moderators of health behavior programs comes from the occupational health promotion literature and is shown in Figure 19.10. Figure 19.10 illustrates that the JOBS Program affects the target mediators of job search self-efficacy, self-mastery, and inoculation against setbacks, and that these mediators lead to better reemployment and mental health outcomes. However, it also was discovered that mental health status at pretest moderated the relationships between the mediators and outcomes. That is, the program worked much better for people who were not depressed or showing signs of other mental illnesses before receiving the program. This is a good example of mediators and a moderator operating together in one prevention program, and the findings suggest that different types of programs are needed for those already depressed or experiencing mental illness symptoms.

**DRUG ABUSE PREVENTION**

One health behavior domain in which mediation analyses have received much attention in recent years is adolescent drug abuse prevention programming (Donaldson et al., 1996). Hawkins, Catalano, and Miller (1992) conducted a thorough review of this literature and presented 17 risk factors (potential mediators of prevention program effects) with corresponding prevention findings. These risk factors included laws and norms, availability, extreme economic deprivation, neighborhood disorganization, physiological factors, family drug behavior, family management practices, family conflict, low bonding to family, early and persistent problem behaviors, academic failure, low commitment to school,
peer rejection in elementary grades, association with drug-using peers, alienation and rebelliousness, attitudes favorable toward drug use, and early onset of drug use. Interventions designed to prevent these risk factors are presumed to lower rates of adolescent drug abuse (see also Chapter 6, this volume).

Hansen (1993) summarized the 12 most popular drug abuse prevention strategies (and their presumed theoretical program or mediating mechanisms):

1. normative education (decreases perceptions about prevalence and acceptability beliefs, establishes conservative norms),
2. refusal assertion training (increases the perception that one can deal effectively with pressure to use drugs if they are offered, increases self-efficacy),
3. information about consequences of use (increases perceptions of personal vulnerability to common consequences of drug use),
4. personal commitment pledges (increases personal commitment and intentions not to use drugs),
5. values (increases perception that drug use is incongruent with lifestyle),
6. alternatives (increases awareness of ways to engage in enjoyment without using drugs),
7. goal-setting skills (increases ability to set and achieve goals, increases achievement orientation),
8. decision-making skills (increases ability to make reasoned decisions),
9. self-esteem (increases feeling of self-worth and valued personal identity),
10. stress skills (increases perceptions of coping skills, reduces reported level of stress),
11. assistance skills (increases availability of help), and
12. life skills (increases ability to maintain positive social relations).

Although most drug abuse prevention programs still reflect the program developers’ view of how to optimize prevention effects rather than a combination of strategies proven to work (Hansen, 1993), mediation analyses suggest that social influences-based prevention programming is one of the most effective approaches for preventing drug abuse among young adolescents from general populations (Donaldson et al., 1996).

For example, MacKinnon et al. (1991) found that social norms, especially among friends, and beliefs about the positive consequences of drug use appeared to be important mediators of program effects in project STAR (Students Taught Awareness and Resistance). The program did not appear to have effects through resistance skills (refusal training). The notion that social norms are a potent aspect of prevention programming was subsequently tested in a randomized prevention trial known as the Adolescent Alcohol Prevention Trial (AAPT) (Donaldson, Graham, & Hansen, 1994; Donaldson, Graham, Piccinin, & Hansen, 1995; Hansen & Graham, 1991). Figure 19.11 represents a summary of the findings from project AAPT and shows the following:

(a) Normative education lowered beliefs about drug use acceptability and prevalence estimates (in seventh grade), which predicted cigarette, marijuana, and cigarette use (in eighth grade). This pattern of results was virtually the same across potential moderators of gender, ethnicity, context (public vs. private school), drugs, and levels of risk and was durable across time (Donaldson et al., 1994). MacKinnon, Weber, and Pentz (1988) also failed to find strong moderator relationships across drug abuse prevention programs using gender, ethnicity, grade, socioeconomic status, and urbanization.

(b) Resistance skills training did improve refusal skills, but refusal skills did not predict subsequent drug use (Donaldson et al., 1994).
(c) Those who received only resistance skills in public schools actually had higher prevalence estimates (a harmful effect; type of school is shown as the moderator) (Donaldson et al., 1995).

(d) Refusal skills did predict lower alcohol use for those students who had negative intentions to drink alcohol (negative intention to drink is the moderator) (Donaldson et al., 1995).

This example is meant to illustrate that some health behavior programs are quite complex, and mediator and moderator analyses conducted over a series of studies are sometimes needed to aid understanding of program effects.

**CONCLUSION**

Many health behavior interventions involve rather complex relationships among program, mediator, moderator, and outcome variables. Throughout this chapter,
I have provided a range of examples of mediator and moderator relationships found in the health behavior intervention research literature. It now should be clear that traditional black-box program conceptualizations and evaluations fail to capture the complexity of most health behavior programs.

It has been argued in this chapter that using conceptual frameworks consisting of hypothesized mediator and moderator relationships during program development, in combination with empirical feedback, promises to improve our ability to develop efficacious programs. Although limited data collection efforts conducted during program development are particularly useful for uncovering serious program flaws, design sensitivity and threats to validity problems must be carefully considered when using an empirical program development approach. Nevertheless, analyzing mediator and moderator relationships using limited data, in contrast to no data at all, is much more likely to result in the development of programs that do indeed improve health behavior and ultimately the human condition.

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Donaldson does a fine job outlining the importance of mediator and moderator analysis and its uses in program development. He provides an important practical and theoretical perspective by including discussion of these issues from a variety of disciplines, including psychology, program evaluation, and sociology. There are many of us who agree with Donaldson. Mediation and moderator analysis has the potential to increase scientific understanding of behavior as well as to improve the effectiveness of programs. Also, program development is a critical phase for the application of moderator and mediator methodology. Given the many reasons for use of these approaches to program development, it is surprising that they are not used more often. At least part of the reason for this failure is a lack of understanding of the usefulness of these approaches. Donaldson’s chapter should help remedy this situation.

The purpose of this commentary is to expand on several points in the chapter and raise a few new ones. I start with several comments on the variables suitable for moderator and mediation analysis, and then I discuss some topics specific to mediation analysis. As mentioned in the chapter, it is not yet clear whether programs have differential effects across subgroups of subjects. Because most programs are delivered to persons who differ in gender, age, and ethnicity, these are likely candidates for moderator effects in most studies. The socialization and cultural effects of ethnicity and gender are important to consider in program development (Pinderhughes, 1989). Age is another critically important moderator variable because of the different maturational processes involved at different ages, particularly among children. Programs designed for elementary schoolchildren, for example, are obviously different from programs for high school students. The mediators targeted also may have different meaning across levels of the moderator variable (e.g., age).

Often, however, it is difficult to determine whether a variable is a moderator or a mediator. For example, gender, age, and ethnicity are clearly potential moderator variables because they are immutable, at least for most reasonable programs. Other variables, especially personality variables, could potentially be changed by a health behavior program and, as a result, may be thought of as mediator variables. However, for most health behavior programs, the program intensity required to change these variables is often unrealistic. In this quandary, variables such as risk-taking tendency and antisocial personality, for example, may be best thought of as moderator variables. That is, the determination of whether a variable is a mediator or moderator depends, in part, on the mutability of the variable.

One important moderator of program effects is the level of the outcome variable before the program is delivered. Probably the best example is the moderator variable of drug use with subgroups such as never users, experimenters, and regular drug users. Prochaska, DiClemente, and Norcross (1992) suggest that there are different stages of drug addiction, and programs that target each stage must focus on different mediating variables to be effective. A program designed to prevent the onset of drug abuse may affect only the subgroup of never users and may not affect experimental or regular users. Any major outcome of a study can be
conceptualized in this manner (e.g., educational achievement, fitness, and body image). In prevention research, these different levels of the outcome variable have been called primary, secondary, and tertiary prevention (or, similarly, universal, selective, and indicated prevention), corresponding to preventing a behavior that has not yet occurred, prevention of a behavior before it becomes more serious, and prevention of further symptoms among persons who are at the riskiest level on the outcome, respectively (Last & Wallace, 1992). Effective programs are presumably those that address the specific mechanisms of these three different types of prevention.

However, to make matters more confusing, it is possible that a variable could serve as both a moderator and a mediator. A program may change a mediating variable, which then changes the outcome variable. At the same time, the effect of the program may depend on the level of the mediator. Statistical methods to examine these types of variables are only now beginning to appear (Merrill, 1996). The relevance for program development is that some individual differences variables are most reasonably conceptualized as moderator variables but also may act as mediators.

A critical decision in the consideration of moderators in program development is how to incorporate significant moderator effects into a new prevention program. For the case of gender, ethnicity, and age, it is often not difficult. At least for gender and age, it is reasonable to separate the subgroups prior to the delivery of special programs. Most prevention programs are appropriately delivered to different age groups, and there are situations when programs are delivered to one gender (e.g., high school football players) (Goldberg et al., 1996). Separation of persons by ethnic groups seems a bit more problematic but may be reasonable in some situations.

Tailoring a program to most other moderator variables, however, is very difficult. For example, it may be impractical for a prevention study to separate persons merely depending on their level of drug use. This strategy actually may be counterproductive if the subgroup of regular users, for example, reactively develops its own even more extreme prodrug use norms. Labeling of students by other students in the school also would be counterproductive. Separation of persons, depending on their risk taking or other personality characteristics, has a similar risk of negative labeling and may not be practical for ethical and other reasons. Larger unit-level measures of these variables (e.g., school, clinic, hospital) may be more useful in the delivery of specialized prevention programs to high-risk youth, for example, as the labeling of these youth has occurred naturally.

There is a lack of receptivity to the moderator approach to program development, perhaps due in part to the above-stated ethical issues. Typically, the criterion for a successful theory is that it applies across many settings and across subgroups, including subgroups defined by moderators. Theories that are inaccurate when applied to subgroups usually are discarded. Very few studies have included a theoretical analysis of subgroup characteristics that is detailed enough to predict different program effects across subgroups. Such an analysis might lead to more effective programming, however. Program development is the ideal stage to develop these types of hypotheses based on theory.

In my opinion, mediation analysis is a more fruitful area for program development than moderator analysis primarily because of the difficulty of including moderators in program development and the limitations just discussed. From the mediation perspective, program design is based on the commonsense notion that a program that changes a variable causally related to the outcome variable will lead to a change in the outcome variable.

There are two important steps in program development based on the mediation hypothesis. First, the theoretical and empirical evidence for how the proposed mediators are related to the outcome must be described. Theoretical and empirical research should be used to identify mediators. It is useful to create a conceptual theory table consisting of the mediators across the top of a table and the outcome variables listed along the side of the table. The entries in this table correspond to the mediator and its relationship to the outcome variable. Ideally, some measure of effect size, such as the partial correlation squared (Cohen, 1988, pp. 412-421), for the mediator-outcome relationship is included in the table. It is important to list all mediating
variables, including ones that are unreasonable to change in a short program, such as personality or risk-taking behavior. The purpose of this conceptual theory table is to clearly list the theory and other backgrounds from which the mediators were selected, thereby providing a perspective on the program.

A second important task of program development is to create an action theory table consisting of the mediators targeted by the program and the program components designed to change the mediators. Here, the mediators are listed across the top of the table, and the program components or sessions are listed on the side of the table. The entries in the table are the indicators of which components target which mediator. Often, the table demonstrates that a program actually targets only one mediator, and the program can be improved by targeting additional mediators. Another important addition to this table is to provide some estimate of the amount of change in a mediator (e.g., the partial correlation squared effect size) that can be expected from a particular program component. Reliable measures of this type of information are likely to be achieved far in the future, but attempts to identify these values serve a useful purpose of gauging approximately just how much of an effect can be expected from the program. It is critical to consider whether the program can reasonably change the mediator using the planned program components.

Both the conceptual theory and action theory tables provide critical insight into the extent to which a program component can change a mediator and the extent to which the mediator is related to the outcome variable. By carefully completing these tables, the theoretical and empirical rationale of the program is clearly laid out. Besides clarifying the program mechanisms for the program developers, the basis of the program is clarified for others; furthermore, the mediating processes identified in these tables can help guide the data analysis plan.

As described in the chapter, use of mediator and moderator analysis is important whether or not a significant overall program effect is obtained (Chen, 1990). Mediation analysis can provide insight as to why the program did not work. If there are no program effects on the mediators targeted by the prevention program, then it is not surprising that program effects were not observed on the dependent variable. This is an action theory failure described by Chen, corresponding to the action theory table described earlier. If there are significant program effects on the mediator but not on the dependent variable, then there is evidence that the theoretical and empirical basis for the prevention program is faulty because the mediators targeted by the program were changed, yet the dependent variable was not changed. This is a conceptual theory failure described by Chen, corresponding to the conceptual theory table described earlier. In the case of no overall program effects, moderator analysis can help identify subgroups in which the program had differential effects.

There are at least three limitations to the mediation approach to program development aside from the focus on variable versus person-oriented models mentioned in the chapter. First, if the delivery of the intervention is randomized, then the relationship between exposure to the randomized manipulation and the mediator is a reasonable estimate of the causal effect of the program on the mediator. This is not the relationship between the mediator and the dependent variable, which is based on a correlational relationship. It is possible that the dependent variable causes the mediator, rather than the mediator causing the dependent variable, the latter relation being hypothesized in the mediation model. Careful consideration of these issues is important for accurate interpretation of results.

Another problem is that the relationship between the mediator and the outcome may be changed by the intervention. In this case, methods to examine this differential correlation across groups are necessary. Finally, several researchers have conducted a detailed causal analysis of the mediation model (Holland, 1988), showing that it is often difficult to demonstrate causal relations among the independent variable, the mediator, and the outcome variable. The action theory and conceptual theory tables described earlier and replication studies can further clarify the roles of these variables and address these limitations.

The statistical methods to estimate mediation effects and their standard errors are widely available in major computer software packages such as EQS (Bentler, 1997) and LISREL (Jöreskog & Sörbom, 1993).
Calculation of the mediated effect and its standard error is relatively easy to compute by hand from ordinary regression analysis (MacKinnon, 1994), and these models are easily extended to multiple-mediator models and longitudinal models. As described in the article, the number of studies applying these analyses has increased. Future studies should greatly increase our understanding of program mechanisms that will further inform program development.

In summary, mediation and moderator analysis holds great promise for the development of program evaluation as a science. Explicit detail regarding the mediators targeted and how the program will change the mediators improves theory and enhances the practical effects of programs. It is hoped that mediators and moderators found in one study will apply across studies and that theory used to explain program effects for one outcome variable also will explain program effects for other variables. Although it is too early to tell, mediation and moderator analysis has the potential to significantly increase our understanding of health behavior, as well as improve health behavior programs. The success of these methods depends on continued theoretical work in program development.

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