CHAPTER 1

The Great Debate on the Contribution of Behavioral Interventions

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Although health psychology (or "behavioral medicine") has evolved as a legitimate area of medical intervention, there are still some skeptics. A major controversy was initiated by a 1985 editorial in the *New England Journal of Medicine* titled "Disease as a Reflection of the Psyche" (Angell, 1985). In the editorial, Angell argued that "the literature contains very few scientifically sound studies of the relation, if there is one, between mental state and disease" (cited in Relman & Angell, 2002, p. 1570). Angell made it clear that she excluded the effects of personal habits, such as tobacco use, alcohol consumption, and overeating. Instead, she focused on a poorly defined construct of "mental state."

Angell and colleague, *New England Journal of Medicine* editor Arnold Relman, were later invited to the meeting of the Psychosomatic Society to participate in a debate about the value of behavioral interventions. Relman and Angell (2002) debated with Drs. Neil Schneiderman and Redford Williams (Williams, Schneiderman, Relman, & Angell, 2002), and the contest came to be known as "The Great Debate." Both Schneiderman and Williams are major figures in the behavioral medicine field. Schneiderman developed the behavioral medicine program at the University of Miami and is a former president of the International Society of Behavioral Medicine and a former editor of *Health Psychology*. Williams is a psychiatrist and Head of the Division of Psychiatry and Behavioral Science at Duke University. He is a former president of the Society of Behavioral Medicine and the International Society of Behavioral Medicine.

Content of the Great Debate

Relman and Angell asked their opponents to provide the best examples of the benefits of psychosocial interventions. Willimans and Schneiderman offered 21 articles, and Relman and Angell contributed an additional two. The 23 articles were then systematically evaluated. After considering the 23 articles, Relman and Angell (2002) concluded that none offered evidence that psychosocial interventions had meaningful effects on health outcomes. The articles covered a wide variety

of diseases, including cancer, heart disease, infection, hypertension, psoriasis, and other conditions. The critiques were quite conventional and focused largely on methodology. For example, Relman and Angell argued that the studies did not apply traditional statistical techniques, such as the intention-to-treat principle. When patients are randomly assigned to treatment or to placebo groups, it is not uncommon for some patients to cross over and gain the treatment to which they were not assigned. Statisticians have concluded that the least bias occurs when patients are analyzed as though they got the treatment to which they were assigned, even though they crossed over. They use the expression "once randomized, always analyzed" (Hollis & Campbell, 1999).

It was argued that some of the better-known results, such as Spiegel, Bloom, Kraemer, and Gottheil's (1989) classic study on the effects of psychotherapy for breast cancer patients, could not be replicated by other investigators (Coyne, Hanisch, & Palmer, 2007). Similar criticisms were leveled at studies of interventions to reduce heart disease through modifications of Type A behavior (Friedman et al., 1986). We discuss the issue of Type A behavior later in the chapter. Relman and Angell (2002) also argued that the observational studies on psychosocial effects had serious methodological flaws, including confounding, weak effects, and overinterpretation of data because of multiple comparisons. Few of the studies were systematic clinical trials, and many of the inferences were based on correlational evidence. The critics argued that the psychosocial literature had failed to establish causal relationships and that investigators had often overinterpreted their results (Relman & Angell, 2002).

Williams and Schneiderman countered that virtually all studies have methodological problems (Williams et al., 2002). To dismiss an entire area because there are some methodological flaws in specific studies, according to their argument, was unreasonable. Furthermore, they presented persuasive arguments that most epidemiological studies have the same methodological problems identified in the psychosocial studies. Few evaluations of surgical techniques, for example, are based on randomized clinical trials. Furthermore, it was never clear what Angell meant by "mental state." Later, she attempted to exclude mood and sense of physical well-being from the definition. She claimed to be challenging "the view that mental state can *directly* cause or substantially modify organic disease independent of personal habits such as smoking, drinking alcohol, or overeating" (Relman & Angell, 2002, p. 560).

Differences in Interpretations

How could distinguished scientists, looking at the same evidence, come to such different conclusions? Some of the difference might just be disciplinary bias. Some might suggest that traditional medical scientists are inherently suspicious of or do not respect evidence from the behavioral sciences. However, many of the differences in interpretation reflect different methodological traditions, including the weight given to observational studies, differences in the sophistication of trial design, and attention and effort expended to obtain "gold-standard," clinical-to-outcome variables.

Causal Interpretation

Many of the studies supporting the importance of psychosocial variables are observational in nature. Although much of epidemiology is based on observational studies, traditional biomedical scientists place greatest credence on blinded randomized clinical trials. They regard observational studies as being weaker designs and are often concerned about "confounding variables," or factors that may have affected the outcome independently of the postulated causal factor (Greenland & Morgenstern, 1989, 1991, 2001). Statistical adjustment is often regarded as insufficient to correct for third-variable explanations (Greenland & Morgenstern, 2001). There are many good examples demonstrating that experimental studies and observational studies come to different conclusions (Barrett-Connor, 2004). For example, it was widely believed that hormone replacement therapy was associated with decreases in cardiovascular disease (Barrett-Connor & Bush, 1991; Barrett-Connor & Miller, 1993), osteoporosis (Barrett-Connor, Grady, & Stefanick, 2005), and some breast cancers (Grady et al., 2008). However, a randomized

clinical trial demonstrated that hormone replacement therapy actually increased the risk of breast cancer and may have slightly increased the risk of some cardiovascular outcomes, including stroke (Prentice, 2008; Prentice & Anderson, 2008). When there is a conflict between the results of randomized trials and observational studies, it is typically assumed that the randomized trial is correct and the observational study, incorrect. One concern is that few psychosocial studies are true randomized clinical trials that clearly demonstrate the causal benefit of treatment.

Trial Design

Over the course of the last 20 years, strict sets of rules have evolved for large-scale randomized clinical trials. Traditional biomedical researchers put the greatest weight on randomized trials that follow these very strict protocols. Furthermore, they like to see multiple identical or very similar trials in the same area of investigation, and they prefer large-scale trials with heterogeneous subject populations. Several rules for conducting and reporting clinical trials have evolved. These are best outlined in the Consolidated Standard of Reporting Trials (CONSORT) guidelines for reporting the results of randomized clinical trials (Moher, Schulz, & Altman, 2001). For example, there are specific protocols for participant randomization. Large trials often have rules for the specification of the primary specific outcome measures. This protects against investigators evaluating many different outcomes after the trial is complete and reporting only those outcomes that are statistically significant. There are also rules about how to handle participants who are randomly assigned to one treatment but ultimately decide to use an alternative treatment. Relman and Angell (2002) pointed out that many of the behavioral trials have not followed the execution and reporting rules required to ensure minimal bias.

Outcome Measures

Another component of the debate concerned choice of the primary definition of outcome variables. Many variables evaluated in behavioral studies might not be considered to be appropriate, clinically relevant outcome measures. The most persuasive evidence includes randomized studies in which the outcomes are disease events or death. Blood pressure, for example, is important because it is related to myocardial infarction (MI), stroke, and premature death. However, change in blood pressure, is not necessarily a clinically-relevant outcome. Instead, it is an intermediate outcome. In large epidemiological studies, investigators have been forced to demonstrate the meaning of these intermediate variables by showing that reductions in these variables ultimately result in changes in outcomes, such as significant disease events or death. For example, the Hypertension Detection and Follow-Up Program (HDFP) was a significant milestone because it showed that lowering blood pressure results in fewer deaths from heart attack and stroke (Hypertension Detection and Follow-Up Program Cooperative Group, 1979, 1982). There have been other examples in which changes in the intermediate factor did not result in the expected changes in outcome. Perhaps the best example is the Cardiac Arrhythmia Suppression Trial (CAST). Previous observational studies had documented an association between increased cardiac arrhythmias and death. Several drugs suppress arrhythmia, and it was assumed that these drugs would also lower the death rate from heart disease. Thus, clinical practice drifted to regularly using these drugs in people with cardiac arrhythmias. In CAST, despite usual clinical practice, patients were randomly assigned to take cardiac arrhythmia suppression drugs or a placebo. The study demonstrated that patients assigned to the drug actually had a higher death rate than those assigned to placebo, and the trial was stopped early because of clear harm to patients in the treatment arm (Cardiac Arrhythmia Suppression Trial [CAST] Investigators, 1989). A similar, unexpected finding emerged in a trial on the control of Type 2 diabetes. High blood glucose is related to diabetic complications and to early death from heart disease. Thus, it was assumed that aggressive management of blood glucose would reduce complications and cardiovascular events. The Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial randomly assigned 10,251 patients with Type 2 diabetes and other cardiovascular disease (CVD) risk factors to an

intensive regimen of blood sugar control or to usual care. Those in the aggressive therapy arm achieved significantly lower blood sugar levels. However, there were significantly more deaths in the intensive treatment group (Gerstein et al., 2008). Aggressive treatment of blood sugar achieves the goal of lowing blood sugar but does not achieve the goal of therapy—to extend life expectancy.

In the next section we review several major CVD trials that show the relationship between behavioral interventions and heart disease outcomes.

A Brief Review of the Psychosocial Evidence

Since "The Great Debate" considered only a limited number of articles, it may be worthwhile to provide a general overview. The argument that psychosocial factors affect health outcomes has been in the literature for at least 80 years. Canon (1936) in discussing homeostasis, argued that psychological stress provokes changes in the cardiovascular, respiratory, muscular, metabolic, immune, and central nervous systems. McEwen (2007, 2008a, 2008b) advanced the concept of allostasis and allostatic load. "Allostasis" literally means maintaining stability or homeostasis. Threats cause adjustments in the cardiovascular system to adapt to challenges. Continual exposure to these threats results in physiological changes, ultimately resulting in changes in immune function and health outcomes.

Although it is widely believed that stress can cause serious problems, such as coronary heart disease (CHD), the evidence has been mixed. The Institute of Medicine, as part of a systematic review, found results to be inconsistent across studies (Institute of Medicine (U.S.). Committee on Health and Behavior: Research Practice and Policy, 2001). The reason the literature appears to be so complicated is that stress clearly affects mediators of health outcome. For example, systematic research shows that stress can affect adrenal steroids and catecholamines, dehydroepiandrosterone, prolactin, growth hormones, and cytokines (McEwen, 2008a). There has been wide speculation that responses to stress in some personality types are associated with hypertension (Smith, 1992). There is little doubt that acute stressors cause blood pressure fluctuation (Smith, Ruiz, & Uchino, 2004). The critical issue is whether stress results in permanent changes and ultimately in increases in the chance of death or disability from heart attack or stroke (Smith et al., 2004). Large epidemiological studies tend not to support the belief that hypertension is related to personality. For example, the Coronary Artery Risk Development in Young Adults (CARDIA) study found that depression predicted the incidence of hypertension (Davidson, Jonas, Dixon, & Markovitz, 2000), although this finding was not replicated in a later reanalysis over a 10-year follow-up. However, in some subgroups, there were trends in this direction. In particular, there was a suggestive trend in white men (but not black men, black women, or white women) between depression and the development of hypertension. There was also a nonsignificant trend between anxiety and the development of hypertension in white men. The one variable in which there was better evidence for the 10-year follow-up was hostility, as measured by the Cook–Medley Hostility subscale of the Minnesota Multiphasic Personality Inventory (MMPI). However, the trend was only statistically significant for black women. There was a nonsignificant trend in the same direction for white men, white women, and black men (Yan et al., 2003).

The research on hostility grew out of a long-standing interest in Type A behavior. Over a half-century, more than a thousand scientific papers on Type A behavior were published. However, systematic reviews were not able to show that Type A behavior reliably predicted outcomes for CHD (Institute of Medicine [U.S.], Committee on Health and Behavior: Research Practice and Policy, 2001). Friedman and Adler (2007) noted that chronic anxiety, chronic anger, and depression may be better predictors. For many years, investigators were able to show systematic relationships between Type A behavior and mediator variables, including heart rate, blood pressure, lipids, and neuroendocrine functioning. Nevertheless, the real importance of mediating intermediate variables is the final expression through changes in disability or death. The Type A behavior studies were simply unable to document effects on important, clinically relevant health outcomes.

Clinical Trials

A variety of clinical trials have evaluated the effects of psychosocial interventions on health outcomes. The trials are summarized in Table 1.1. The Recurrent Coronary Prevention Project (RCPP), conducted between 1977 and 1985 (Friedman et al., 1986), was designed to determine whether Type A behavior can be altered, and if so, whether the altered Type A behavior results in a reduction of coronary disease. Eight hundred sixty-two white male patients were randomly assigned to a special behavioral treatment plus cardiac counseling or to a control group that got cardiac counseling without the special behavioral component. Over the course of 4.5 years, those in the behavioral plus cardiac counseling treatment group had significantly lower scores on Type A behavior questionnaires than those assigned to a cardiac counseling group. More importantly, there was a reduction in recurrence of MIs. After 4.5 years, 89% of those in the special behavioral cardiac counseling group had survived without recurrence of their heart attacks, in comparison to 80.2% in those who got counseling alone. After nearly 10 years, there was still a survival advantage for those in the special behavioral cardiac

TABLE 1.1. Summary of Major Behavioral Clinical Trials Relevant to Heart Disease

Trial	Reference	Subjects	Length of follow-up	Intermediate outcome	Outcome
Recurrent Coronary Prevention Project (RCPP)	Friedman et al. (1986)	592 special behavioral cardiac plus counseling (treatment); 270 counseling control; predominantly white male	4.5 years and 8.5 years	Reduction in Type A behavior in treatment group	Significant reduction in survival without cardiac recurrence in treatment group, maintained to 8.5 years
Ischemic Heart Disease Stress Monitoring Trial	Frasure-Smith et al. (1993)	397 psychosocial support; 372 control; all white and male; after dropout, 232 treatment, 229 control	7 years	Reduction in general distress in treatment	Mortality lower in treated group at 3 years, but not different by 6 years; reduction in recurrent myocardial infarction maintained
Montreal Heart Attack Readjustment Trial (M-HART)	Frasure-Smith et al. (1997)	692 treatment; 684 control; white males and females	1 year	Change in depression nonsignificant; change in anxiety nonsignificant	No effect on mortality, but borderline harm for women (p = .06)
Sertraline Antidepresant Heart Attack Trial (SADHART)	Glassman et al. (2002)	186 sertraline; 183 placebo; mixed ethnicity and gender	Varied—up to 3 years	Significant reduction in depression in sertraline group	No effect on left ventricular ejection fraction or mortality
Enhancing Recovery In Coronary Heart Disease (ENRICHD)	Berkman et al. (2003)	1,238 cognitive-behavioral; 1,243 control; good representation of black and white, male and female	3.5 years	Significant reduction in depression, increase in social support in cognitive-behavioral group	No effect on mortality or coronary heart disease events

group (77.2 vs. 71.0%). Analysis of intermediate variables showed that those in the special cardiac intervention group scored lower on Type A behavior, hostility, anger, impatience, life satisfaction, self-efficacy, social support, and depression. However, among these variables, only self-efficacy and depression changes predicted subsequent CHD events.

Perhaps the most influential study was the Ischemic Heart Disease Life Stress Monitoring Program was conducted between 1983 and 1986. The study led by Nancy Frasure-Smith was designed to determine whether emotional support during a time when people are highly vulnerable could reduce the rate of nonfatal MI or coronary death. The study involved random assignment of 769 white male subjects. The dropout rate in this study was relatively high. Among 397 men assigned to the treatment group, 58% completed the trial. In the control group, the dropout rate for 372 participants was equivalent (62%). The study authors were not allowed to use full randomization; instead the Institutional Review Board (IRB) instructed them to inform participants about the arm of the assignment, then see if they would consent. The study demonstrated that those exposed to the psychosocial treatment experienced a greater benefit in self-reported health. Furthermore, there was a reduction in cardiac mortality in the treatment group 3–4 years after the intervention. However, the treatment and control groups had comparable cumulative mortality rates about 6 years after the trial began. Considering cumulative MI occurrences, the results favored the intervention group (Frasure-Smith, Lespérance, & Talajic, 1993).

The Montreal Heart Attack Readjustment Trial (M-HEART) was designed to replicate the finding that emotional support at a time of high vulnerability can reduce the incidence of cardiac death and nonfatal MI. However, the study was designed to improve upon the earlier Frasure-Smith study by including both male and female participants, and usual randomization was employed. The study was conducted in Montreal between 1992 and 1997. White men and women (1,376 participants) were randomly assigned to emotional support treatment or to a control group, and follow-up to the primary outcome was almost 100% in both arms of the trial. The intervention did not have a significant effect on either depression or anxiety. Although there was no overall effect of treatment, one surprising result emerged from the study. There was a near significant ($p = .064$) higher mortality rate among women who had received the intervention. This effect was not apparent for men (Frasure-Smith et al., 1997).

Despite the inconsistent results from early trials, a variety of related results stimulated interest in treating depression among those with CHD. In the Sertraline Antidepressant Heart Attack Randomized Trial (SADHART; Glassman et al., 2002), patients who had experienced heart attacks and who met the criteria for a major depressive disorder were randomly assigned to take the antidepressant sertraline or placebo. Evidence from the study clearly demonstrated that sertraline was effective in lowering depression, particularly among those who experienced more than one major depressive episode. However, the intervention was not powered to examine major health outcomes, so it did not have significant effects for the major health outcomes, including death, MI, heart failure, stroke, angina, or a composite endpoint.

Perhaps the most important intervention trial conducted thus far is Enhancing Recovery in Coronary Heart Disease (ENRICHD) (Berkman et al., 2003). The goal of the study conducted between 1996 and 2004 was to determine whether 6-month treatment for depression and/or low social support shortly after an MI would result in a reduction in mortality or fatal heart disease. This carefully conducted study randomly assigned 2,481 subjects to either treatment or usual care. The treatment was cognitive-behavior modification, preferably in a group, and with antidepressant medication for those who were severely depressed. The intervention resulted in a statistically significant but clinically negligible reduction in depression, as assessed by the Beck Depression Inventory. Those in the intervention group, which included a social support component, also experienced significant improvements in a social support index. Figure 1.1 summarizes the cumulative proportion of deaths in the intervention and usual care groups for the 42 months following enrollment. As shown in Figure 1.1, there was no evidence that the

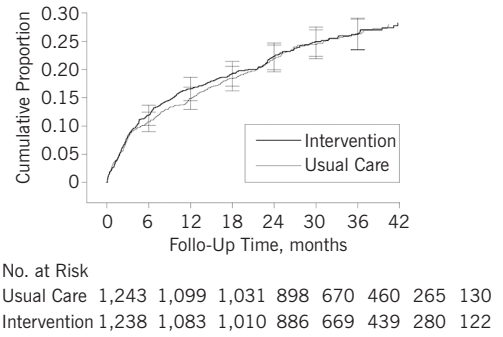

FIGURE 1.1. Cumulative mortality in intervention and control arms of ENRICHD. From Berkman et al. (2003, p. 3111).

intervention resulted in better health outcomes. Figure 1.2 summarizes hazard of death ratios for specific subgroups. Overall, none of the subgrouping factors resulted in changes in the hazard ratios. However, the near significant trend for women was in the unexpected direction; women in the usual care group had lower (although not statistically significant) chances of dying than did those in the intervention group. These results are similar to those reported in the Frasure-Smith M-HEART study (Frasure-Smith et al., 1997).

In summary, we remain uncertain about the potential benefits of psychosocial intervention for patients with heart disease. In 2005, the National Heart, Lung and Blood Institute convened a working group on the assessment and treatment of depression for patients with CVD. The group noted that a significant number of patients with heart disease meet the criteria for major depression (15–20%). Despite the inconsistent results from randomized clinical trials, the group recommended pharmacological or behavioral intervention immediately after MI for patients at risk. The group also concluded that the ENRICHD trial was too short to establish the benefit of treatment and argued that treatment should be extended for longer than 6 months. Finally, the group suggested that a new randomized controlled trial (RCT) involving patients with moderate depression be conducted (Davidson et al., 2006).

By way of summary, observational evidence consistently does show relationships between time urgency, anger, depression, and heart disease. However, RCTs evaluating the causal status of these psychosocial risk marker interventions have produced mixed results. The trials with the strongest experimental designs tend to challenge the benefits of psychological interventions for clinical health outcomes. Thus, we need significantly more investigation to determine the benefits of psychosocial intervention.

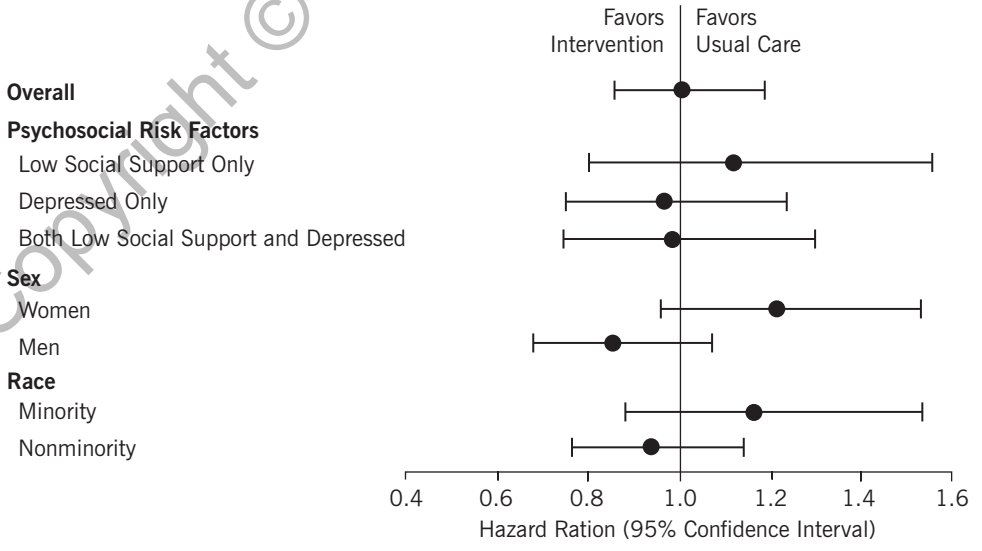

FIGURE 1.2. Effect of ENRICHD intervention on risk of death on nonfatal myocardial infarction. From Berkman et al. (2003, p. 3112).

Resolution of the Great Debate

"The Great Debate" lingered for years. However, by 2006, some of these issues had been resolved. One of the problems was that the entire debate focused on just 23 research studies. Many of these were nonexperimental, epidemiological investigations. The studies often included intermediate outcomes rather than real clinical outcomes, and they excluded from the debate studies on health behaviors, such as adherence, diet, and exercise.

Over time, it was acknowledged that some of the standards required by Relman and Angell (2002) were unrealistic. For example, they argued that many of the psychosocial effects were weak, and that stronger science would require odds ratios of more than 3 or 4 for psychological risk factors. This is an unusual standard that would require increases in risks of 300–400%. These odds ratios are larger than those for the effects of elevated low-density lipoprotein (LDL) cholesterol or blood pressure on heart disease outcomes, including those effects found in RCTs.

A related concern was the argument that good science requires an absolute understanding of the mechanisms of action. Although the mechanisms underlying effective psychosocial interventions have been difficult to elucidate, the same can be said about the mechanisms for many successful medical and pharmaceutical interventions.

Another issue was the relatively few large-scale RCTs on psychosocial interventions. One of the most important RCTs was the RCPP, mentioned earlier, in which 862 post-MI patients were randomly assigned to either regular counseling or specialized cardiac counseling. Those who received the specialized cardiac counseling had a 50% decrease in the recurrence of coronary events over an interval of 4.5 years. Although Relman and Angell (2002) acknowledged that this was an impressive effect, they dismissed some of the results, suggesting that the benefits of the cardiac counseling might be attributed to unmeasured indirect effects, such as changes in lifestyle or diet. This seemed like a weak argument because assignment to the treatment group, independent of what happened afterward, did result in better patient outcomes (Williams et al., 2002). More importantly, changes in lifestyle and diet are behavioral efforts. The positive outcomes should be regarded as a benefit of behavioral intervention, not as evidence against behavioral approaches.

Ultimately, both sides felt that they had prevailed in "The Great Debate." However, several years later, there is growing consensus that the debate stimulated better research and more critical thinking about the role of psychosocial interventions (Freedland, Miller, & Sheps, 2006).

What Was Left Out of the Debate?

Perhaps the most difficult problem in "The Great Debate" is what was left out. Relman and Angell (2002) systemically excluded the effects of health behavior on health outcome. Furthermore, they attempted to exclude everything other than what they referred to as "mental state." A careful look at the relationship between health behavior and health outcome reveals substantial evidence supporting the value of behavioral intervention. In this section we review a few examples. More detailed reviews may be found elsewhere (Fisher et al., 2010).

Tobacco

Cigarette smoking is the leading cause of premature death in the United States and soon will be the leading cause of death in the entire world (multiple references and datasets are available at *www.cdc.gov/tobacco*). Cigarette smoking is associated with most of the major causes of death, including cancer, cardiovascular disease, lung disease, and stroke (U.S. Public Health Service, Office of the Surgeon General, and National Center for Chronic Disease Prevention and Health Promotion, 2004). There is substantial evidence that behavioral programs can successfully reduce the rate of smoking in committed smokers, and that community interventions can prevent the use of tobacco in susceptible youths (Biglan, Ary, Smolkowski, Duncan, & Black, 2000). Furthermore, smoking interventions can reduce the burden of disease and death (Anthonisen et al., 2005). Health promotion strategies successfully reduce the use of tobacco in the United States and many other countries

(Hyland, Travers, Dresler, Higbee, & Cummings, 2008; Hyland, Wakefield, Higbee, Szczypka, & Cummings, 2006). These interventions were regarded as one of the most important public health accomplishments of the 21st century. In countries where tobacco use has declined, there have been significant reductions in CVD, lung cancer, and chronic obstructive pulmonary disease (Barzi et al., 2008).

Diet

The percentage of the U.S. population that is overweight or obese has systematically increased over the last 30 years (Wang & Beydoun, 2007; Wang, Beydoun, Liang, Caballero, & Kumanyika, 2008). Obesity is clearly related to diseases of the heart and gall bladder, to cancer, and to diabetes (Murphy et al., 2006).

The increase in obesity is related to the consumption of high-fat foods, sugar-sweetened beverages, and massive introduction of high-fructose corn syrup sweeteners (Bray, Nielsen, & Popkin, 2004). Many studies show that behavioral interventions can successfully control weight, although evidence for long-term control of weight outcomes has been inconsistent (Mann et al., 2007). Intervention studies using peer education techniques have been successful in a variety of communities (Perez-Escamilla, Hromi-Fiedler, Vega-Lopez, Bermudez-Millan, & Segura-Perez, 2008). Furthermore, RCTs have shown that cognitive-behavioral modification is associated with improvements in LDL cholesterol, blood glucose, and triglycerides (Epstein, Valoski, Wing, & McCurley, 1994; Kuller, Simkin-Silverman, Wing, Meilahn, & Ives, 2001). Dietary fat modification has been associated with better weight control in both adults and children. Ultimately, individual and community interventions have been successful. However, considerably more research and dissemination of information are necessary to conquer the American obesity epidemic.

Physical Inactivity

The obesity epidemic is also associated with physical inactivity. Evidence suggests that moderate activity is associated with decreases in all causes of mortality (Warburton, Nicol, & Bredin, 2006). Furthermore, physical activity lowers the risk of diabetes, heart disease, and other disabilities (Boule, Haddad, Kenny, Wells, & Sigal, 2001). Physical activity is also related to long-term weight control (Hawley & Dunstan, 2008). Physical activity may also be associated with lower levels of depression (Penedo & Dahn, 2005).

Systematic RCTs show that physical activity may reduce the chances of transition from prediabetes to diabetes (Knowler et al., 2002; Lindstrom et al., 2006), and may successfully moderate blood glucose levels in those with diabetes. A cost-effectiveness analysis of the trial showed that diet and physical activity were more effective and cost-effective in slowing the transition to diabetes than was metformin, the most commonly used medicine in this field (Herman et al., 2005).

Conclusions

"The Great Debate" achieved considerable attention. It considered whether psychosocial factors are important in biomedical and clinical science. That debate focused on 23 published articles, most of which dealt with psychological factors and personality.

Part of the difference of opinion highlighted in the debate is that biomedical scientists and behavioral researchers apply methodologies differently. Biomedical scientists are more focused on RCTs and outcomes, such as disease events or mortality. Greater concentration on these outcomes may help to advance behavioral science.

Perhaps the most important factor overlooked in "The Great Debate" is what was excluded. Systemically eliminated from the discussion were behaviors such as tobacco use, diet, and physical inactivity. When these factors are considered, it is clear that behavioral factors have a major impact on health outcomes.

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CHAPTER 2

The Biopsychosocial Model and the Use of Theory in Health Psychology

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> Data without a model is just noise.
> —CHRIS ANDERSON, Editor of *Wired*

> The biopsychosocial model is a scientific model constructed to take into account the missing dimensions of the biomedical model.
> —GEORGE ENGEL (1980, p. 525)

A few years ago, one of the authors (Suls) was having lunch with a new Health Psychology PhD who had arrived recently to take a postdoc at the university medical center. In response to "How are things going?" the postdoc reported that he was well but a bit frustrated about being unable to interest the physicians in one of his research ideas. He was especially disconcerted that they expressed no interest in a study's potential to test an important theory. Suls asked, "You didn't talk with them about *theory*?! Most physicians lose interest when they hear the 'T-word.' Why not discuss 'mechanisms of action' or the treatment implications the research might have?" While modern medicine has considerable respect for biological and biochemical theory, physicians tend to be quite skeptical about *behavioral* theories. Many are unaware of or have no ready access to efficacious, effective, and professionally relevant psychosocial interventions. Physicians are pragmatists who functionally practice within the biomedical model, even if they have awareness of psychosocial factors.

But was the young postdoc misguided in wearing his theoretical premises on his sleeve as he attempted to initiate a collaborative relationship with physicians? In the basic sciences, if a student is trying to pitch a new research study, then it is normative and rigorous to start with the theory and predictions before speculating about potential practical applications. But to gain access to medical collaborators, patient samples, and extramural funding from the National Institutes of Health (NIH), health psychology researchers must adopt a data-driven stance and move as quickly as possible to the implications for public health. In fact, when reviewers evaluate a grant application, they are instructed to give special weight to the project's impact, defined in terms of the potential benefits for public health. "Theory" is not completely missing from NIH grant

applications, but it tends to be presented in a low-key fashion—kept in the background and, arguably, serving as a kind of wallpaper. Articles published in medical journals have very brief introductions and discussion sections; theorizing is kept to a minimum. We think there is some evidence that health psychologists have followed the lead of medical researchers. This modus operandi has been successful. However, as we argue below, it may mean that health psychologists leave behind the behavioral theoretical frameworks that make them unique (see Epstein, 1992; Schneiderman, 1987). In fact, theory may represent one of the most distinctive contributions psychologists can bring to the health sciences and medical practice (methodological expertise is another).

The other characteristic that makes psychologists and other behavioral scientists unique is their reliance on and appreciation of the biopsychosocial model. As we argue below, behavioral theory development and the biopsychosocial model go together. Neither has received as gracious a reception from some parts of the medical establishment or from some health psychologists, as we think it should.

This chapter contrasts the traditional biomedical model with the biopsychosocial model and provides a survey of the reception and adoption of the latter perspective. Then we consider the role that both model and theory testing have played in contemporary health psychology and why theory has played a less than optimal role. Finally, we offer some suggestions about how this state of affairs might be improved.

A Brief Note about Scientific Medicine

"Medical science" is a common phrase, but it is often forgotten that a strong scientific research agenda in medicine is a relatively recent development. Lewis Thomas (1983), physician, experimental pathologist, policy advisory, and former administrator of the Memorial Sloan-Kettering Cancer Institute, described how medicine and medical education were principally about diagnosis and prognosis until the 1930s and 1940s, perhaps because that really was all it could accomplish. The introduction of effective medications for infectious diseases, medical technologies, and mechanism-based research changed that, but research still is not second nature to medical practice. Here is what Thomas said about medical education: "The M.D. program was not then, and still is not, very satisfactory training for research in biomedical science. Then, as now, the Ph.D. program provided a much more rigorous and profound experience in science, with a better grounding" (p. 154). He observed that the MD has the advantage in ensuring that physicians make connections between problems in biology and human disease. Thomas's focus on biology is appropriate because the dominant model of scientific medicine is molecular biology. However, Thomas did not acknowledge that this biological focus can cause physicians to give too little attention to the patient and the social context in which disease is manifested. Ironically, William Osler, one of pioneers of scientific medicine, is reported to have said, "It is sometimes more important to know what patient has a disease than what disease a patient has" (from Herman, 2005, p. 375).

Another contemporary feature of medicine and medical practice is its focus on specific diseases. This structure is most salient in the organization of the NIH into, for example, the National Heart, Lung and Blood Institute, the National Cancer Institute, and the National Institute of Diabetes and Digestive and Kidney Diseases. Writing about the modern scientific physician, Miettinen (2001) observed, "While countless ladies and gentlemen know the practices of their own specialties of medicine, they do not really know . . . the principles of medicine at all: the content is solely about particular illnesses" (p. 1327).

What is wrong about a focus on specific diseases? Kaplan (1990) has written about how the emphasis on a particular outcome can lead to spurious inferences. One of his examples is the Physicians' Health Study (Steering Committee of the Physician's Health Study Research Group, 1988), a large clinical trial, which demonstrated that taking an aspirin a day (vs. placebo) reduced the risk of heart attack. However, Kaplan pointed out that scrutiny of the results reported in the primary publication showed that the overall rate of mortality did not decrease; cardiac deaths were lower, but deaths from

strokes actually were higher. Thus, Kaplan asked whether aspirin actually conferred a benefit or only shifted cause of death from one category to another. A disease-specific approach risks inflating the importance of intervention effects and may fail to recognize the importance of quality of life as an outcome.

Epstein (1992) also observed the tendency for health psychologists to adapt a "reductionist approach within the field to reduce mechanisms responsible for behavioral effects and disease to biological influences" (p. 493). This leads to an exclusive focus on biological processes and reluctance to emphasize top-down and behavioral factors.

A limited role for behavioral theory, a narrow focus on specific diseases, and lack of attention to factors that are not strictly biological hamper our understanding of the complex causes of physical disease, health care, and health policy. As we describe below, many of these trends stem from the dominant, albeit often implicit, model in medicine.

The Biopsychosocial Model

PROFESSOR X (a psychologist): We must learn to speak the language of medicine.

PROFESSOR Y: We should understand the language of medicine, but making it our primary language is another story.

—Overheard at a Society of Behavioral Medicine meeting

The dominant model of disease among medical practitioners is biomedical, with molecular biology as its basic scientific discipline. The biomedical model holds that biological/physiological processes or mechanisms are sufficient to understand, prevent, and treat illness. The model is predicated on reductionism and mind–body dualism, and requires that explanations are reduced to physical–chemical terms before they have meaning (Engel, 1980).

The biomedical model also encourages so-called "magic bullet" solutions to health problems. These refer to prevention or treatment measures that "cure" a condition, usually with a surgical procedure, new medical technology, or medication. In the late 19th and 20th centuries, when infectious diseases were the predominant cause of death, the pursuit of magic bullets was very attractive, especially after the success of antibiotics (particularly, the sulfa drugs) and the polio vaccine. These successes and those of other medical technologies, such as insulin for treatment of Type 1 diabetes, created enormous support for the biomedical model. What is often forgotten is that the prevalence of infectious diseases actually dropped precipitously prior to the introduction of antibiotics, in large part as a consequence of public health measures, such as adequate sewage disposal, and improved nutrition and housing in the late 19th century (Friedman & Adler, 2007; McKeown, 1976). Even with these improvements, we currently live in an evolving public health environment, where infectious diseases are again major sources of mortality (e.g., AIDS, infant diarrhea, flu pandemics). Antibiotics and vaccines provided only a temporary and illusory magic bullet.

Public health measures had as much, if not more, to do with social and political reform as advances in biological science. As early as the 1840s, Rudolf Virchow, the father of cellular pathology who became a political and social reformer, declared medicine to be a social science after witnessing how the circumstances of Polish miners contributed to their health problems.

Nonetheless, proponents "of the biomedical model, claim that its achievements more than justify the expectation that in time all major problems will succumb to further refinements in biomedical research" (Engel, 1980, p. 536). The difficulty is that biomedicine's successes have been in areas for which the physical–chemical framework is appropriate, leaving other areas neglected (Engel, 1980). Susser and Susser (1996) provide an apt example:

> Peptic ulcer . . . illustrates the limitations of a narrow frame of reference for a chronic disease. The causal framework of the gastrophysiologist is likely to focus on the wall of the stomach and that of the neurophysiologist, on the autonomic nervous system. . . . The human geneticist considers familiality in blood groups and secretor status, and the microbiologist brings the recent discoveries about *Helicobacter pylori* to bear. The epidemiologist includes all the above and adds smoking as an individual risk factor. (p. 675)

However, even these factors are not sufficient explanations because ulcer prevalence rose mysteriously at the beginning of the 19th century and, no less mysteriously, began to decline in the 1950s. Susser and Susser observe that even if the explanation lies in the historical behavior of Helicobacter microorganisms, then the other levels of analysis are still important for diagnosis, explanation, and treatment.

The biopsychosocial model provides a framework to include physical–chemical factors *and* the areas neglected by biomedicine. George Engel (1977) was the first to articulate this approach to guide health researchers and practitioners in research, intervention, and practice (see also Matarazzo, 1980; Schwartz, 1982). The "biopsychosocial model" refers to the idea that biological, psychological, and social processes are integrally and interactively involved in physical illness and health, medical diagnosis, medical treatment, and recovery. The understanding of the full complement of influences at multiple levels of analysis was held as a goal by Engel. He observed that "while the bench scientist can with relative impunity single out and isolate for sequential study components of an organized whole, the physician does so at the risk of neglect of, if not injury to, the object of study" (1980, p. 536).

What does it mean to say that biological, psychological, and social factors are integrally involved in physical health? It means that single-factor, or even single-domain explanations are likely to be inadequate. Second, it argues that a change in one domain (e.g., the biological) necessarily results in changes in other domains (e.g., psychological and social). A third implication is medical diagnosis that considers the interaction of biological, psychological, and social factors should lead to improved diagnosis. Furthermore, interventions involving all of these elements should fare better than treatments grounded on any single class of variables (Schwartz, 1982; Suls & Rothman, 2004).

The biopsychosocial perspective advocates a multilevel approach to diagnose, explain, and treat any medical problem. Biological/physiological processes; cognition, emotion, and behavior; the immediate social context (family and friends); and macroprocesses (e.g., public health regulations) all play a role in the diagnosis, etiology, practice, and promotion of physical well-being. In short, the biomedical model directs the researcher and practitioner to look for a biological/physiological cause and curing agent, while the biopsychosocial model alerts the researcher, practitioner or policymaker to the need for multiple levels of analysis and appreciation of all potential domains that contribute to the problem and its "solution."

By insisting that a single level of analysis is probably insufficient, the biopsychosocial model can guide researchers and practitioners to the kinds of multiple variables that are potentially important. A more formal and systematic conceptual tool will be required, however, to direct the systematic search for relevant variables and possible relationships and/or mechanisms among them. That tool is "theory," by which we mean a consistent and well-defined framework to test a falsifiable hypothesis about the real world.

The Reception and Adoption of Health Psychology/Behavioral Medicine

The biopsychosocial model was formally introduced in the 1970s, but how has it fared since then (Schwartz & Weiss, 1978)? The field of health psychology certainly has made enormous progress in the last 40 years with the growth of new professional societies, such as Division 38 of American Psychological Association and the Society of Behavioral Medicine; the fuller integration of psychologists into older societies, such as the American Psychosomatic Society; and development of many special interest societies. A welcome by-product of the increasing number of societies hospitable to health psychologists is the increasing number of journals with which to disseminate research, such as the *Journal of Behavioral Medicine, Annals of Behavioral Medicine, Health Psychology, Psychology and Health*, and *Health Psychology Review.* Furthermore, already-existing journals, such as *Psychosomatic Medicine, Journal of Personality and Social Psychology*, and *Journal of Consulting and Clinical Psychology*, have also served as prestigious outlets. Similarly, graduate training programs have also multiplied, and the number of health psychologists serving on the faculties of universities or medical schools has increased markedly (Rodin & Stone, 1987).

The number of behavioral health-related grant proposals has also grown so large that at least four study sections are chartered at the NIH to evaluate health psychology/behavioral medicine research, and many more panels evaluate health psychological proposals. At one time physical health was a topic that received little attention from the American Psychological Association, but now mind–body interaction is a common topic, and the improvement of physical health has been included as one of the major missions of the organization (*www.apa.org/about*). The role of psychological and behavioral factors for physical health has been deemed so significant that in 1993 Congress established the Office of Behavioral and Social Sciences Research as a separate entity at the NIH to promote behavioral and social sciences, to integrate behavioral and biomedical knowledge, and to facilitate interdisciplinary research between social, behavioral, and biomedical scientists (Anderson, 1998). Finally, as the contents of this handbook attest, empirical advances by health psychologists have been made in disease etiology, health promotion, and treatment. But how significant have these changes been, and to what degree has the biopsychosocial model been received in other health-related fields?

The Biopsychosocial Model in Medical Education

Engel believed it was vital that an appreciation of patients and their social contexts be incorporated into the medical education of physicians. However, there are indications that not much has changed in medical education. A survey of medical school education indicated that about 50% of the schools queried offered less than 40 hours of instruction in psychosomatic medicine and health psychology (Waldstein, Neumann, Drossman, & Novack, 2001).

An Archival Inquiry

As a first approximation of the degree to which the medical establishment has adopted the biopsychosocial model, Suls and Rothman (2004) conducted MEDLINE searches of titles and abstracts from 1974 through 2001 for the terms "biomedical," "biopsychosocial," and "biobehavioral" (the latter is used almost synonymously with the second). The year 1974 was chosen as a starting point because Engel introduced the term "biopsychosocial" in 1977. Use of these terms does not mean that investigators or authors embraced this perspective, but at minimum, references to them indicate that the biopsychological model was recognized. An examination of Figure 2.1 shows an obvious increase in the use of the terms "biopsychosocial" and "biomedical" in the published literature, by a factor of five, but these terms were cited only once for every nine times that the term "biomedical" was mentioned.

Another index also was assessed in the archives: The number of times the word "behavior" appeared in the titles or abstracts of published articles was counted in four major medical journals—*New England Journal of Medicine, Lancet, Journal of the American Medical Association*, and *Annals of Internal Medicine*—from 1974 to 2001. *Behavior* was mentioned about 60 times from 1974 to 1977 but more than 100 times from 1998 to 2001. Although the count was doubled, the absolute number of appearances was small: The term "behavior" only appeared in 0.002% of articles in the early years and 0.004% in the years with its most frequent appearance (1990–1993). These indicators, however crude, suggest some acknowledg-

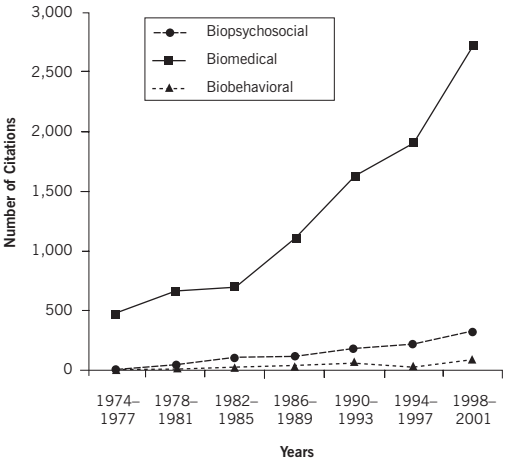

FIGURE 2.1. Frequency of citations of the terms "biopsychosocial," "biobehavioral," and "biomedical" in MEDLINE. From Suls and Rothman (2004). Copyright 2004 by the American Psychological Association. Adapted by permission.

ment of the biopsychosocial model by the medical establishment, but the perspective clearly has not been fully embraced.

The Biopsychosocial Model Instantiated in Research

Another, no less critical, index is whether health psychologists actually follow the biopsychosocial model. Suls and Rothman (2004) reasoned that one way to gauge research practices is to assess whether researchers actually measure the four kinds of variables (i.e., biological, psychological, social and macro [cultural, socioeconomic status, ethnicity]) in their studies. Accordingly, the authors read and coded the frequency with which each class of variables was measured and/or manipulated in all of the studies published in a year of the Division 38 journal, *Health Psychology*, between November 2001 and September 2002.

It comes as no surprise that psychological variables were represented in almost 95% of the papers. Social, biological/physiological, and macrovariables were each represented in about 50–55% of the papers. However, the macrovariables only referred to the sample, while the biological variables most often referred to a particular patient sample. Notably, only 26% of the studies included measures from all four domains. This means that most studies did not explore the interrelations and interactions across levels or classes of variables.

To summarize, while the biopsychosocial model has had an impact, it is modest with respect to impact on the medical establishment and has not yet been fully adopted even by health psychologists. Admittedly, Suls and Rothman (2004) only surveyed a single journal in a single year, so conclusions should be drawn cautiously. Also, in certain clinical literatures, such as family medicine or ambulatory pediatrics, behavior or behavioral issues are discussed more frequently, but the coverage in some areas of medicine is slight.

Theories in Health Psychology

In the preceding section, we presented archival data suggesting that only in a minority of instances do health psychologists measure variables that represent all of the levels of analysis assumed to be important in the biopsychosocial model. This has an implication for theory because the absence of one or more levels of analysis implies that missing levels are irrelevant, or it is acceptable to leave variables at the other levels free to vary.

Researchers often defend their decisions to narrow domains of inquiry by noting the conceptual, operational, and logistic difficulties associated with measuring variables at all levels. A similar difficulty is encountered in theory building and theory testing. The difficulty associated with conceptualizing how different levels interact discourages theorizing across levels and reinforces a narrow focus. However, lacking a theory, the investigator cannot identify those factors most plausibly related to the outcome of interest (Rothman, 2004).

Health Behavior as an Example

The area of health behavior is relevant because a number of scholars have examined the extent to which theory testing and development have been a concern there. An encouraging sign is Noar and Zimmerman's (2005) report that theoretically informed health behavior change programs tend to be more effective than those without a theoretical basis—supporting Lewin's (1943), "There is nothing so practical as a good theory" (p. 118). In another review of published studies on health behavior change, Painter, Borba, Hynes, Mays, and Glanz (2008) examined the proportion of published research that used no theory, was informed by theory, applied theory, tested theory, or built a new theory. "Theory" was only mentioned in 36% of the articles. The majority of those papers (68%) were informed by theory, that is, mentioned a theory or theoretical constructs, but none were actually measured. Eighteen percent of the sample applied the theory; that is, at least some of the constructs of the theory were operationalized in the study. Only about 4% of the research actually tested a theory or alternative theories, and only 9% involved the development of a new theory. Of the theories mentioned in this study sample, three dominated: transtheoretical model/stages of change (28%; Prochaska & Velicer, 1997), social cognitive theory (28%; Bandura, 1989), and the

health belief model (20%; Becker, 1974; Rosenstock, 1966).

Painter and colleagues (2008) concluded that use of theory was limited, that only a few theoretical approaches were represented, and that testing and advancement of theory were rare in the empirical health behavior change literature. They also noted that community-level theories were scarcely represented.

The Dangers of Imitating Epidemiology

An issue that we believe is closely related to the less than optimal utilization of theory in health psychology is the field's relationship and imitation of epidemiology. Several areas of health psychology depend heavily on epidemiological findings. Disease risk factors, especially of a behavioral nature, that have been identified in large sample population studies using epidemiological methods comprise a major category of factors studied by health psychologists in promotion, intervention, and understanding of etiology. Specific examples are socioeconomic status (Adler et al., 1994), hostility (Smith, 1992), and social support (Cohen & Syme, 1985; House, Landis, & Umberson, 1988).

Although health psychologists rely on epidemiological research findings, a narrow focus on risk factors without understanding the role they play with other factors is an atheoretical endeavor. Epidemiological methods are correlational and usually require very large samples and brief survey instruments. Adding measures to assess possible mediating factors is a luxury in large-scale population studies. Not surprisingly, epidemiology does not typically test theories. When health psychologists adopt such an approach there are dangers. One such example is represented by the two-decades-long effort to document the effects of the Type A behavior pattern (Rosenman et al., 1964), a construct that has now faded from the research agenda. One reason we think it failed is that Type A behavior was narrowly defined and studied apart from the broader literature on personality, individual differences, and person–situation interactions. It was treated as an epidemiological risk factor, simply entered with traditional cardiac risk factors in risk equations. As this area of study increasingly borrowed from psychological theory (Glass, 1977; Matthews, 1982), however, it became clear that Type A behavior did not comprise a single coherent construct, that only certain elements (i.e., hostility) were toxic, and that the latter conferred risk via plausible cognitive, social, and physiological mechanisms (Matthews, Gump, Harris, Haney, & Barefoot, 1994).

The reader might object that the steady decline in deaths from heart disease since the last 1970s results partly from a better understanding about the risk factors for cardiovascular disease and behavioral intervention (i.e., smoking cessation–prevention). These benefits partly occurred because of non-theory-driven identification of risk factors by epidemiologists. But we might ask whether the benefits would have been even greater if study of risk factors had been more theory driven.

Within the fields of epidemiology, there have been calls to incorporate theoretical frameworks. Krieger (2001) observed that epidemiologists tend to ignore the overarching question of what is the global factor or "spider" responsible for the particular pattern of factors. A lack of overarching theory in epidemiology or explanations of the current and changing health status of human societies results in a missed step in the research process because explanations of disease and etiology drive epidemiological hypotheses. In this light, imitating epidemiology in its traditional form seems like a poor strategy for health psychologists.

Translation

The NIH has placed great emphasis in the last decade on "translation." By this, policymakers mean the conversion of laboratory knowledge into new products, and the adoption of such products by providers into routine clinical practice (from bench to bedside). In this way, translational research can demonstrate a return on society's investment in basic science. In 2006, NIH initiated the Clinical and Translational Science Awards for support of centers to reduce the time it takes for laboratory discoveries to become treatments for patients, to engage communities in clinical research efforts, and to train clinical and translational researchers (see *www.ncrr.nih.gov/clinical_research_resources/clinical_and_translational_science_awards*).

Currently, 46 medical research institutions in 26 states have translation centers. One set of observers noted, however, that much of the work so far has been devoted to "finding surrogate biomarkers that can predict the outcome of new therapies" (Horig, Marincola, & Marincola, 2005, p. 706).

Translation can go in the opposite direction—using what is learned at the bedside to inform and to raise questions for bench science (see Lelford, 2008). However, Sonntag (2005) observed,

> So far, translational research/medicine has rather been a linear concept rooted in traditional (academic) approaches to provide therapies for diseases (from bench to bedside). . . . Little attention [has been paid] to patient-oriented research that involves understanding the underlying cause of disease and its treatments (from bedside to bench). (p. 1)

A promising exception is seen in implementation models, such as the RE-AIM (reach, efficacy, adoption, implementation, and maintenance) model and practical clinical trials (Glasgow, Davidson, Dobkin, Ockene, & Spring, 2006; Glasgow, Magid, Beck, Ritzwoller, & Estabrooks, 2005; Tunis, Stryer, & Clancy, 2003). Such models advocate attention to the implementation of interventions in real-world environments at the very earliest stages of research conceptualization and design. For example, an early consideration of the implementation environment influences the selection of dependent variables to make them maximally informative for practitioners and policymakers. The inclusion of such practical dependent variables has the potential to facilitate and improve the ultimate adoption of all sorts of health interventions.

A Clarification and Critique of Theory

Even when there is a commitment to behavioral theory (e.g., Painter et al., 2008; Suls & Rothman, 2004), some observe that "there is a growing concern that we are not tending to our theories as well as we ought" (Michie, Rothman, & Sheeran, 2007, p. 249; see also Brewer & Rimer, 2008). Some qualify as middle-range theories—the theory of reasoned action (Ajzen & Fishbein, 1980), self-regulation theory (Cameron & Leventhal, 2003; Carver & Scheier, 2001), or social cognitive theory (Bandura, 1989)—because their level of specificity derives propositions and predictions that permit empirical testing (in contrast to "grand theories" using large, abstract constructs that often cannot be readily operationalized in precise and concrete ways). However, even in the case of well-specified theories, there are barriers for development, such as reliance on correlational methods that prevents the researcher from being able to infer causation ($X \rightarrow Y$) and address the mediating variables in the causal path ($X \rightarrow M \rightarrow Y$) (Michie et al., 2007).

Another problem is connected with the multiple levels of analysis that the biopsychosocial model requires. How feasible is it to include all relevant constructs and processes in a single study to develop theory (Michie et al., 2007)? The answer, of course, is that one researcher cannot. Furthermore, insistence on taking the "kitchen sink" approach likely produces work that fails to identify the exact mechanism causing the effect. The need for small-scale experiments that provide a "causal chain analysis" seems like a more appropriate strategy, with a focus on understanding the mechanisms behind each individual link in the chain to understand fully the entire process in the future. Ultimately, this must be a collaborative effort; it is not enough for one investigator in isolation to plan a detailed research program to advance theory. As Weinstein and Rothman (2005) argue, "It takes a village to raise a theory" (p. 296). But how does one engage the scientific village? In the next section, we describe an approach that health psychology, the other behavioral sciences, and medical science may be able to adapt for their purposes.

The Full-Cycle Approach

> Health psychology has at least two masters; cognitive behavioral theory and clinical and public health practice. We are expected to contribute to theory by creating new models and adding to existent models of human behavior, and to contribute to improvements in health outcomes for the public.
>
> —LEVENTHAL, MUSUMECI, AND CONTRADA (2007, p. 381)

A new approach is needed to overcome the obstacles that face the full implementation

of the biopsychosocial model, and the development and testing of behavioral theory. In brief, the four major obstacles are (1) the dominant emphasis of practice-based solutions, which makes theory testing a subsidiary aim; (2) the conceptual and logistical difficulties for any single study to follow the biopsychosocial model's call to consider all relevant factors; (3) the contemporary political–economic climate which reinforces both biomedical "cures" and biomedical explanations; and (4) overemphasis on translation research that reinforces a one-way linear sequence, whereby better practice becomes the ultimate criterion of success and "curiosity-based" research is discouraged (see Weissmann, 2005).

We advocate the adaptation of the full-cycle approach developed by social psychologist Robert Cialdini and elaborated by sociologists Gary Alan Fine and Kimberly Elsbach, and organizational psychologists Jennifer Chatman and Francis Flynn. Because the full-cycle approach was developed exclusively for social behavioral topics, it is not a perfect match for the challenges in health psychology, but with some modifications (see below) it can be made appropriate.

Cialdini (1980) developed the full-cycle perspective in the context of experimental social psychological research. He was attracted to the virtues of laboratory experiments that can "(1) register even whisperlight effects and (2) allow no phenomenon but the one under direct study to produce the predicted data pattern" (p. 23). However, these appealing features have a downside because lab experiments "capture phenomena without regard for their importance in the course of naturally occurring human behavior" (p. 24). Stated differently, a theory speaks to the existence of effects it predicts, but "it does not speak to the ecological importance of those effects" (p. 24).

To compensate for these limitations, Cialdini argues that theory building should begin with hypothesis building through multiple real-world observations (i.e., induction). These observations, whether based on anecdotes, ethnography, surveys, archival sources, and so forth, provide hunches about both possible relationships between variables and indices of their ecological importance. These observations and hunches should then lead to specific laboratory tests (deduction) of the refined hypotheses under controlled conditions. But the process does not end there because the researcher should then cycle back to further real-world observations for refinement. "Naturally occurring instances should be employed not only to identify effects suitable for experimental study but also to check on the validity of the findings from that experimentation" (p. 43). The recursive design is a critical feature of the full-cycle approach and corrects for the tendency whereby researchers develop theory based on one methodological approach, then return to the same methodological approach to test their new ideas. As Chatman and Flynn (2005) note, "Full-cycle research travels back and forth between the naturally occurring phenomenon and controlled settings. This bidirectional flow enables researchers to draw theoretical insights from one setting and apply them to another" (p. 243).

The full-cycle approach also recognizes the importance of knowledge based on exploring, observing, and assessing a phenomenon as it exists naturally, and on manipulating or controlling the phenomenon. Linking the two different ways of knowing recursively has the virtue that both induction and deduction are critical and dependent on each other. In fact, cycling between induction and deduction is important because each provides feedback on the adequacy of the other approach. Furthermore, inductive–deductive cycles help to determine which peripheral ideas strengthen the core and which constitute new branches of inquiry.

The full-cycle approach also has another implication. Besides naturalistic observation that helps in discovery of new phenomena, "there are also cases where the impetus for an important line of research may come from observing a *lack* of an effect in the natural environment where there should be one" (Mortensen & Cialdini, 2009, p. 18). Theory and experimentation can then learn why expected effects are missing or how to create those effects.

Adapting the Full-Cycle Approach to Health Psychology

Modifying this approach for the biopsychosocial model makes "bench to bedside"

and "bedside to bench" part of the scientific cycle. It also reinforces the need for researchers and practitioners to be part of the same research team. Moreover, the vital roles that practice and medical outcomes play are clear as they serve as inputs and outputs in this dynamical approach.

Adapting this model to physical health requires an extra element. Cialdini thought only a single researcher would be sufficient to pursue the full cycle. In the field of social psychology, this may be feasible, but the biopsychosocial model embraces more levels of analysis, each with its own body of knowledge, measurement, and technology. Advancing the understanding of physical well-being demands not just interdisciplinary teams but scientist-practitioner teams whose members play various roles depending on the phase of the cycle.

With respect to theory development and testing, it is important to appreciate that it is probably impossible for a theory to be simultaneously general, accurate, and simple (Fine & Elsbach, 2000; see Thorngate, 1976). The more simple *and* accurate a theory is, for example, the less generalizable it is likely to be in a variety of contexts. The more generalizable *and* simple the theory, the less likely it is to be accurate. As Weick (1979) notes, the dilemma is that to maximize any two of the virtues of generality, accuracy, and simplicity, the researcher automatically has to sacrifice the third one. So bench research might be simple and accurate but questionable in its generalizability. Large-scale surveys may be simple and generalizable but accuracy may be quite limited. In summary, *any single method* of data collection results in trade-offs in the resulting theory's simplicity, generalizability, and accuracy.

A search for a method that combines all three elements—accuracy, simplicity, and generalizability—might be futile, but theory may be built by alternating among sets of data that provide one or more of these elements, or by incorporating the research of others with data that complement one's own (Weick, 1979). Nothing speaks better for the need for interdisciplinary teams. As noted earlier, in the case of behavioral medicine, those teams require scientists and practitioners engaged in the full cycle together. By adopting this approach, NIH-supported Clinical Translational Research Centers could be a real boon for behavioral health, but the mode of operation will have to take a full-cycle *and* recursive form to be maximally effective.

Obstacles

The essential components of a full-cycle approach are available. The biopsychosocial model also provides a viable guide to suggest the kinds of factors that should be explored; however, there are barriers to adoption of such an approach.

Chatman and Flynn (2005) acknowledge that academic journals tend to specialize in a limited set of methodologies. Editorial reviewers may be selected more on the basis of their expertise in a particular methodology but be less familiar with different methods (see Suls & Martin, 2009). Reviewers expect new results to be grounded in existing research findings, which usually means collecting data with the same conventional methodology. These are not intractable problems, but they can slow down the progress to a truly translational full-cycle approach.

Where Do We Go from Here?

> It seems a universal characteristic of the scientific enterprise that the mining of any vein of research and theory, however enthusiastically initiated and however diligently prosecuted, tends to go deeper rather than broader and ultimately to become isolated unless diverted into new directions by outside influences.
>
> —ESTES (1975, p. 15)

To avoid this predicament, we propose that collaboration between basic scientists and clinical practitioners be seen as not just a bonus but as a necessity, and we recommend the creation of a special NIH funding mechanism (e.g., a special kind of R01) to facilitate such collaborations. In action, persons desiring to be funded would be required to consult with researchers of different backgrounds than their own. For example, an applied application for funding would need to outline a budget to retain a basic researcher on salary, as well as the regular team of health psychologists, physicians, or public health researchers. This would aid the infusion of theory into the applied work. Similarly, an application addressing a basic research question would need to recruit a clinician or educator for consultation. As a

result, the basic researcher would be advised of the practical reality of the health system. This should serve to produce work that is more feasible and more easily translated.

Another proposal is that clinical translational science centers encourage (if not require) scientists in the basic biological and behavioral sciences to spend structured time on medical wards or in the community and with practitioners and patients to learn about the real world of medical care. (This is being done at some clinical translational centers already.) Comparable experiences in the basic research setting should also be created for medical practitioners. This would encourage the kind of back-and-forth, recursive, and cyclical experiences that provide fuel for basic theory, research, and implementation.

Conclusions

The previous section offers some top-down, hierarchical strategies to encourage the adoption and dissemination of the full-cycle approach for health psychology and medical science/practice. But we are not so foolish as to think that great science, practice, or intervention requires a "road map." Great scientists and practitioners rarely follow road maps or bureaucratic rules (Weissmann, 2005). Curiosity, anecdote, careful observation, sustained thinking, hard work, serendipity, and a community of (heterogeneous) scholars (the "village" referred to earlier) are required. We would add that both the biopsychosocial model and the full-cycle perspective also need to be in the air. We end with another quotation from Lewis Thomas (1974, quoted in Weissman, 2005). What research and practice "need is for the air to be made right. If you want a bee to make honey, you do not issue protocols on solar navigation or carbohydrate chemistry, you put him together with other bees . . . and you do what you can to arrange the general environment around the hive. If the air is right, the science will come in its own season, like pure honey" (p. 1762)

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