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## Developing an Evidence Base in Clinical Psychology



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We suggest a process for clinical psychologists to collect an evidence base and join the evidence-based movement already underway in many areas of medicine. To illustrate this process, we review the history of cholesterol discovery, evaluation, and management as an evidence-based process, extracting lessons applicable to the field of psychology. By examining these lessons and building consensus, clinical psychologists can advance the movement along an evidence-based practice continuum, improve client care, build a more informative evidence base, and promote equitable reimbursement for psychological practice. © 2005 Wiley Periodicals, Inc. *J Clin Psychol* 62: 259–271, 2006.

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Psychologists have greatly increased the professional scope of their field by declaring themselves health care professionals. No longer restricted to addressing mental health alone, psychologists now aim to promote both mental and physical health, address behavioral pathogens that are risk factors for major chronic diseases, and improve the public's quality of life. The good news is that this new field is vast and full of opportunities for professional growth. The neutral news is that this field has long been populated by other groups of health care providers (such as physicians, nurses, physical therapists, and rehabilitation counselors) who have established certain standards of engagement. The bad

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news is that, in the current health care climate, insurers have become sophisticated in demanding evidence that reimbursement is warranted. Lacking compelling evidence that traditional psychotherapies improve outcomes and are cost effective, insurers and other agencies often use cost containment as the deciding principle for reimbursement of psychological services.

Psychology practitioners can improve client outcomes, make complex treatment decisions, and propel the field of psychology into evidence-based medicine if they choose to understand the evidence-based rules and perhaps improve them. Paired with a strong evidence base for psychological practices, this evidence-based process may lead to more equitable reimbursement.

#### Where Could an Evidence Base and an Evidence-Based Movement Take Psychology?

Imagine a health care system in which clients and patients are routinely screened for major psychological problems that cause suffering and compromise healthy functioning. There would no longer be controversy about how this screening should be conducted, who is qualified to do this screening, and what psychological problems constitute disorders. Screening would identify appropriate persons for education or self-help techniques with monitored supervision, as well as those persons who require interventions by psychologists. Evidence would be available to help practitioners determine who will benefit and which educational materials are effective. For those patients who require interventions offered directly by psychologists, a system would be in place to refer, treat, and reimburse these professional services. A practicing psychologist's typical day might be spent treating patients with relatively complex presenting problems; advising paraprofessionals about appropriate services for patients with more easily resolved mental health issues; and reviewing the progress of patients using self-education; with reimbursement for all these services. The delivery of these professional services will require clinical judgment and skill at judging the appropriateness of each intervention for each patient; data will have definitively demonstrated that these clinical skills are critical for successful patient outcomes. These professional services will be reimbursed because insurers, health care policy makers, and politicians will have been shown programmatic data supporting the benefits of these services.

The rate of mental illness in the United States will be low, and projections will be trending downwards. Conversely, material assessments of the World Health Organization's definition of health (World Health Organization, 2000) will be trending upwards. These assessments include not only the absence of major mental disorders, but also the presence of well-being, productivity, and high quality of life. Practicing psychologists will identify problems or rare combinations of issues for which treatments with clear benefit are not yet known or tested. Researchers would then focus on these issues, conducting research with real-world clients and typical therapists and collecting data persuasive and relevant to clients, psychologists, and insurers. This scenario can be the outcome of participating in the evidence-based movement. Can this scenario become reality?

#### What Is an Evidence Base and an Evidence-Based Movement?

The described scenario is a reality in many areas of medicine because a body of scientific evidence supports the assertion that screening, intervening in specific ways, referring complex clients to specialist care, and evaluating progress have led to improved public health. Standardization and consensus in assessment and practice have not led to

compromises in tailoring treatment to patients or professional judgment. This type of evidence-based movement or process is:

. . . the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice. Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients' predicaments, rights, and preferences in making clinical decisions about their care. By best available external clinical evidence we mean clinically relevant research, often from the basic sciences of medicine, but especially from patient centered clinical research . . .

(Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996)

The first requirement of evidence-based practice is the systematic accumulation of evidence on many aspects of a public health problem from different perspectives. This accumulated information is commonly known as the evidence base. This evidence base is then paired with a process—an evidence-based movement—that usually involves input from practitioners and evaluation by regulatory bureaus, policy makers, and reimbursement agencies. This process leads to the creation of clinical standards of care, reimbursement for certain practices, and improved outcomes for clients. The evidence-based movement is mindful and respectful of the professional acuity of practitioners since they evaluate the relevance of the evidence to the individual client who requires care.

#### *Why Should Psychology Join the Evidence-Based Movement?*

In its most simplistic form, the argument for creating an evidence base in psychology and pursuing this vision of health care is irrefutable. Who would disagree with the principles of doing no harm, benefiting clients, using data to guide practice, requiring good clinical judgment, and considering client values, characteristics, and preferences in implementing these ideals? To disagree with these principles would be heretical, yet the history of the evidence-based movement, within medicine and more recently within psychology, has been full of conflict and setbacks.

Practitioners are required to make difficult decisions about treatment types, duration, and intensity, often without any practical research guidance or information about what helps or what harms. The evidence-based movement offers practitioners systematic tools to draw inferences from data relevant to individual practice in ways that were not possible before such an approach existed. However, if practitioners are concerned about and suspicious of this movement or view it as irrelevant to the practice of their profession, the evidence available will be scant, ill informed, and underutilized. The evidence base will also be vestigial and irrelevant to clinical practice if scientists pursue the rewards of rapid promotion in academia by conducting quick analogue studies using student therapists, undergraduate clients, and proxy outcomes. Evidence that is based on surrogate outcomes may aid the scientist's tenure and promotion goals, but this evidence is often incompatible with the creation of an evidence base in psychology. We call on practitioners and career researchers to unite and influence the nascent evidence-based movement in psychology because it has much to offer the profession of psychology. Fortunately, the American Psychological Association has begun this process with the publication of the Policy Statement on Evidence-based Psychology Practice (see [www.apa.org/practice/ebpreport.pdf](http://www.apa.org/practice/ebpreport.pdf)). What can we learn from the evidence-based medicine movement to inform our own progress of creating true evidence-based psychology practice?

*Example of an Evidence-Based Movement*

We review an example of progress (and setbacks) from medicine to elucidate the process likely to be encountered in psychology. Specifically, we review the history of cholesterol or lipid discovery, evaluation, and management and illustrate an evidence-informed practice that has irrefutably benefited patients. The current standard of medical care is to screen all adults for hyperlipidemia (i.e., high cholesterol) and to offer treatment to those with elevated levels (National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2002). The majority of American adults with health insurance are screened for hyperlipidemia, and behavioral interventions to alter diet and reduce weight are initiated in patients with moderate hyperlipidemia (National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2002). Reimbursement for this preventive service is unquestioned since both the screening and the behavioral interventions are recommended by practice guidelines. The incidence rates of coronary heart and artery disease—the consequence of untreated hyperlipidemia—have decreased substantially (2004). In addition, ongoing research has focused on patient subgroups who have not benefited as expected (e.g., women), with the goal of improving their health outcomes (Mosca et al., 2004).

It might be presumed that the standard of care for hyperlipidemia was established via a quick and linear course, something that is unattainable in psychology. But the course was neither quick, nor linear. At first, basic scientists studied the cholesterol phenomenon in isolation. Then practitioners and researchers argued about the nature, relevance, and modifiability of cholesterol. The initial interventions failed. Practitioners in typical practice could not feasibly measure cholesterol for a long time, so cholesterol assessment remained irrelevant to the practice of preventive cardiology. However, as evidence mounted about the risks associated with hyperlipidemia and the efficacy of interventions to reduce cholesterol, a sophisticated evidence-based practice gradually emerged.

Studying such a story may enable psychologists to recognize the necessity of recent struggles in the field of psychology related to joining the evidence-based movement. These struggles may well be a transitional phase out of which good outcomes can emerge.

*Cholesterol Story: Defining the Area*

Assessing the components of patients' cholesterol or lipid levels is important for determining cardiovascular health risk because high-density lipoprotein (HDL) and low-density lipoprotein (LDL) have different risk profiles. As long ago as 1949, HDL and LDL were identifiable. However, the arguments about which one constituted the critical risk factor, how to measure and label the elements, how much coronary disease risk each one conferred, and how to modify this risk, kept scientists and practitioners antagonistic toward each other for another 25 years (Fredrickson, 1993). During this contentious time, basic laboratories around the United States and the world proposed different assay methods to determine the various lipid components that were being discovered and argued about which ones were critical to patients' health.

*Lesson: Defining an Area Is Controversial.* The extended debate over defining terms was analogous to the debate in psychology about stress conceptualization and measurement (Coyne & Whiffen, 1995; Spaccarelli, 1994), which has also endured for some time (Spring, 1981). Should stress be construed as a stimulus, a biological response, or a cognitive appraisal in which demands outstrip resources? How should it be assessed? By

quantifying stress, are we “carving nature at its joints” (Gangestad & Snyder, 1985), that is, positing a theoretically meaningful construct and an assessment process that capture key mechanisms that influence important patient outcomes? Active controversy about the stress construct continues at this basic level, as it once did about the cholesterol concept. Struggles about definitions will continue as the evidence base of psychology for this area grows (Andreasen, 2004; Brummett et al., 2004; Gearon, Bellack, & Tenhula, 2004; Grey, 2004; Newport, Heim, Bonsall, Miller, & Nemeroff, 2004; Seedat et al., 2004; Weber & Reynolds, 2004; Yehuda, Halligan, Golier, Grossman, & Bierer, 2004).

### *Cholesterol Story: Standardizing the Area*

In the 1940s and 1950s, conventional wisdom held that total lipid levels themselves and not specific components (such as LDL) predicted premature coronary disease. However, whether this was merely a correlational or a causal association was unknown. After Gofman heretically proposed that only some lipid components (such as LDL) were predictive of premature coronary disease, the then National Advisory Heart Council (now the National Heart, Lung, and Blood Institute of the National Institutes of Health) set up a collaborative observational study to test this controversial hypothesis. Throughout the study, colloquially known as the uncooperative-cooperative study, investigators continued to change the exact lipid component proposed to be predictive of premature coronary disease. They not only changed the component they were proposing as health damaging, but also changed the method for assessing lipid components. These changes would be analogous to conducting a study of stress in which the measurement of stress and the hypothesized destructive component of stress were changed multiple times throughout the course of the study.

In the late 1960s, competing nomenclature for lipid components remained (Fredrickson, 1993). Each naming convention had embedded scientific theories or implications, so the different sides refused to yield. As a result, similar findings on similar phenomena were being published using different names and different keywords. Common sense finally prevailed, and journal editors insisted that one naming system be adopted.

Despite the difficulties and scientific controversy during the 1960s, the American Heart Association, the National Heart Institute (now the National Heart, Lung, and Blood Institute), and other groups enlisted practitioners in organized campaigns to reduce the risk of premature coronary disease. This began the process of uniting practitioners to advocate about the importance of lipids in the development and recurrence of coronary disease. At this time, most practitioners were unable to assess lipid components in their patients using the gold standard assessment tool (a preparative ultracentrifuge) because it was not affordable for the typical practitioner. Patients had to be referred to one of a few research laboratories to benefit from some of the controversial advances in the understanding of lipid components.

The assessment standardization process was helped immeasurably by a consensus conference convened by the National Heart and Lung Institute in 1970. The conclusions, which were fiercely debated before consensus was reached, had far-reaching consequences: (1) it was possible to agree upon a standard classification of lipid components for diagnosis and management of hyperlipidemia (n.b. no classification was offered at this time; only an agreement that a standard classification should be proposed); (2) it would be beneficial to establish a national network of lipid research clinics to develop population standards and final assessment methods over the next five years; and (3) it would be wise to conduct a large randomized prospective trial to determine the effect of treatment of hyperlipidemia on the incidence of coronary disease (Fredrickson et al., 1970).

*Lesson: Everyone Needs To Be Involved in Standardizing an Area.* Professional organizations, regulatory bureaus, funding agencies, and practitioners must play a large role from the start in standardizing an area. Someone influential needs to call for standardization of naming and assessment methods. The area then needs to regulate itself to follow these conventions once established. Conversations about the feasibility of the proposed assessment must ensure that the proposed standard will work in the real world. Are the assessment tools cost-effective? Can the assessment be conducted by practitioners in the field? For example, it would be unreasonable to expect psychologists to routinely implement a 10-hour assessment battery or to expect clerical staff to perform interventions requiring highly specialized training. Such considerations and decisions allow the evidence in one area to accumulate programmatically.

### *Cholesterol Story: Proposing Mechanisms of Change*

Agreeing to test whether the construct of interest is modifiable and whether the intervention results in meaningful improvements in patient outcomes are a few crucial steps in establishing an evidence-based movement. Determining the most efficient mechanisms of change is key in the evidence-based world.

By the 1960s, there was extensive epidemiological evidence linking total lipids to coronary disease recurrence (Steinberg & Gotto, 1999), although it remained unclear whether the relationship existed for all components or for only some. Also, primary prevention trials were far more costly than secondary prevention trials. Therefore, the first clinical trials were designed to test whether modifying total lipid levels through diet or other means affected coronary disease recurrence. However, all three randomized controlled trials published between 1961 and 1965 showed that intervention attempts failed to prevent coronary disease recurrence (Ball et al., 1965; Oliver & Boyd, 1961; Rose, Thomson, & Williams, 1965). Editorials concluded that once coronary disease was established, secondary prevention by lowering lipid levels was doomed to failure (Ball et al., 1965). These first-generation tests of lipid modification theories were inadequately powered, had simplistic models of how diet and lipid levels were associated, and did not necessarily select patients appropriate for intervention. These were just a few of the painful lessons learned from conducting first-generation trials in a new area (Califf & DeMets, 2002).

*Lesson: Tests of Mechanisms of Change Require Persistence and Patience.* Before an evidence base that informs clinical practice can be built, there must be reasonable evidence that the construct of interest is modifiable and that some of the mechanisms of change are discernable. Negative results can sometimes be as informative as positive results in building an evidence base. Without such differential information—what works and what does not work—we cannot know what type of interventions, what type of providers, and what change processes should be used to benefit patients.

### *Cholesterol Story: Testing Possible Interventions*

In 1972, a statistician provided an algebraic estimation of LDL to clinicians to obviate the need for an ultracentrifuge in every office (Friedewald, Levy, & Fredrickson, 1972). This algebraic estimation not only enabled clinicians to determine the coronary disease risk for their patients, but also paved the way for large trials to be conducted within representative sites and employing typical clinicians from around the United States. Animal,



genetic, and biochemical studies then accrued, supporting the plausibility of LDL as a causal factor in the development and worsening of coronary artery disease (Cleeman & Lenfant, 1998). In addition, the Framingham epidemiological study supported the assertion that higher lipid levels were associated with a greater risk of coronary artery disease incidence (Kannel, Castelli, & Gordon, 1979). The results of the large multi-site medication trial planned by the first consensus panel were then reported. This trial provided evidence that lowering high lipid levels in human participants reduced risk for coronary disease (Anonymous, 1984). In 1984, another consensus panel was formed and that group concluded that high lipid levels are a cause of coronary disease and that lowering lipid levels reduces the risk of coronary disease (Anonymous, 1985). After consensus was established across various constituencies interested in lipids, momentum was unstoppable (Cleeman & Lenfant, 1987). The earlier dietary trials for example led to a randomized controlled trial that compared the Mediterranean diet to the American Heart Association diet in patients with heart disease. Results indicated that patients who consumed the Mediterranean diet survived more frequently (de Lorgeril et al., 1994), and modified diet recommendations were promoted as practice recommendations (Kris-Etherton et al., 2001). Multiple medication and lifestyle clinical trials were initiated. Although some of these studies had negative results, the results in other studies led to large Phase III trials whose results now influence practice, and professional reimbursement for those who conduct these interventions (Grundy et al., 2004).

*Lesson: Test Many Interventions Early and Often.* Perseverance is one of the difficult lessons for all involved in creating evidence bases. Practitioners need to be politically active to increase awareness about pressing public health issues for which care should be provided. Basic scientists need to refine or isolate the culprit risk marker. Interventionalists need to first test theories about the modifiability of the risk marker and then make the interventions feasible and generalizable. All this requires consensus on the direction that is being taken.

### *Cholesterol Story: Translation*

Because trials that were large enough to answer the clinical question of outcome benefit had been designed, funded, and conducted, answers of clear relevance to practice were obtained. Hence, leaders in the field were ready to educate the public, patients, practitioners, and policy makers about the risk of hyperlipidemia and how this risk should be assessed and managed. The National Cholesterol Education Program was then launched with this educational objective, as well as the mandate to rapidly translate new evidence into meaningful improvements in clinical practice and public health. The education programs and evidence-based guidelines of the National Cholesterol Education Program were built on firm science and were constructed with all the partnering organizations and agencies (now over 40) concerned with the care of patients at risk for or with coronary disease. A quick review of the evidence-based practice guidelines on cholesterol (Anonymous, 1988; Anonymous, 2001; Grundy et al., 2004) shows an evolving consensus on practice patterns and improvement in services provided to patients. Nevertheless, the latest guideline is careful to begin with the premise that

This evidence-based report should not be viewed as a standard of practice. Evidence derived from empirical data can lead to generalities for guiding practice, but such guidance need not hold for individual patients. Clinical judgment applied to individuals can always take precedence over general management principles. Recommendations of ATP [Adult Treatment Panel]

III thus represent general guidance that can assist in shaping clinical decisions, but they should not override a clinician's considered judgment in the management of individuals . . . (Anonymous, 2001, p. 3158).

*Lesson: There Are Rewards!* The benefits of building the evidence base for cholesterol are numerous: patient outcomes have improved throughout the development of the evidence base; patients are more satisfied with the choices available to lower their LDL levels; practitioners have both data and reasonable options for treating hyperlipidemia; and practitioners are reimbursed for their professional services. Treatment algorithm suggestions for complex cases (patients with comorbid diseases, dietary restrictions, or drug allergies) are being actively pursued. The increased sophistication of the practice recommendations, the consideration of interventions within special populations (e.g., for those with special dietary needs or preferences or for those with type 1 diabetes mellitus), and the ability to present data understandable and easily accessible to practitioners are laudable achievements. But these improvements in content, presentation form, and evidence for almost every conceivable clinical need did not occur in a vacuum; rather they occurred because researchers working side by side with practitioners through hard-fought and sometimes bitter controversies constructed the evidence base.

#### *What Can Psychologists Learn From This Evidence-Based Example?*

In summary, a process can be followed to build an evidence base in clinical psychology and then join the evidence-based movement (see Figure 1). In stage 1, the definitional stage, disagreements about basic concepts in research, such as how to assess and what to name the underlying construct, are the foremost issues. Arguments and controversies emerge during the definitional stage, and not until someone demands standardization in terms and concepts can the creation of an evidence base truly start. Next, the underlying theories of change and the interventions that derive from these theories are debated, and compromise and negotiation are unacceptable for many at this stage. Examples in psychology exist in areas as divergent as categorization versus dimensional understanding of mental disorders (Beach & Amir, 2003; First, Pincus, & Frances, 1999; Goldman, 1991; Pincus, Zarin, & First, 1998; Schmidt, Wagner, & Kiesler, 1993; Spitzer, Williams, & Rieder, 1999), etiology of multiple personality disorder (and agreement as to its existence) (Barton, 1994; Merskey, 1994), and the usefulness of eye movement desensitization and reprocessing therapy (Greenwald, 1996). In all of these examples, the underlying tenets required to build an evidence base—that everyone agrees on the construct—are not yet in place.

In stage 2, standardization begins and uniform nomenclature is proposed, and reasonable assessment techniques and the need for risk categorization and prevalence estimates for real-world patients emerge as resolvable issues (see Figure 1).

Phase I trials start and are completed, but these trials have flaws: the researchers ask unrealistic questions, the study is inadequately powered, the study tests unhelpful interventions, the intervention is based on an unhelpful or rigid manual, or the study includes unrepresentative clients. However, further data collection can overcome some of these obstacles as a field moves into stage 3, the change mechanism stage.

Both formal and informal consensus about what is known and what is not known builds first among the researchers and then between researchers and practitioners. Agreement emerges on the principles of the evidence-based movement, at least as applied to one practice area. Practitioners participate more fully both in the generation of evidence



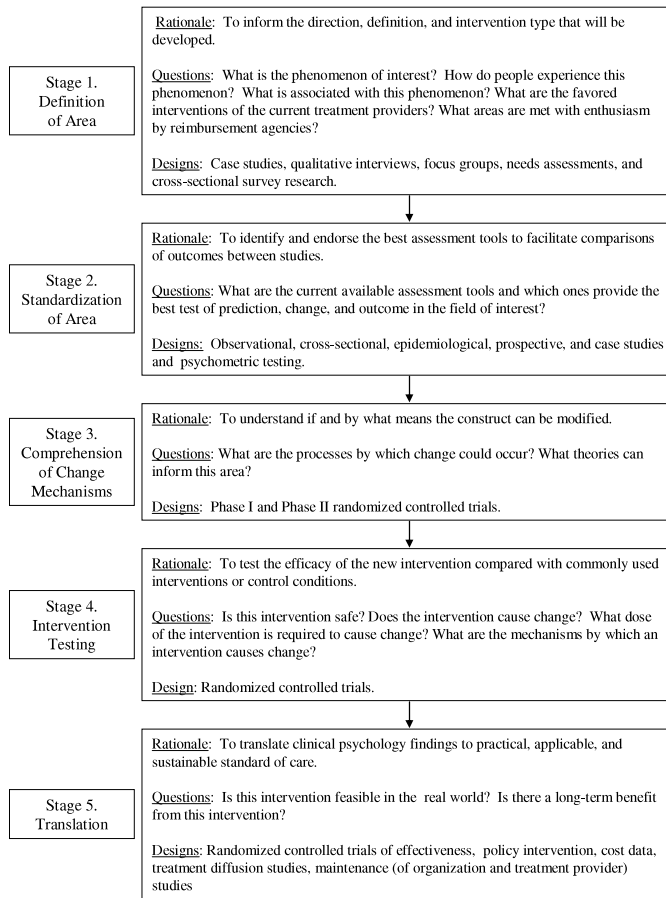


Figure 1. The stages of evidence-based psychological health care.

and in the process of determining what information is needed. In stage 4, larger, more practical trials are required to answer questions about the policy of implementing, and then reimbursing the treatments that are seen as the most promising.

With time, the evidence is accepted and insurers reimburse assessment and practice. Clinical exceptions, empirical reasons for variations in clinical practice, and further explanations of the mechanisms by which risk is conferred are codified. The hallmark of stage 5 is that guidelines are updated in much less contentious ways. Once stage 5 is under way, the search begins for the next area of evidence-based practice.

### Where Does Psychology Go From Here?

The profession of psychology is on a promising path. Although the path is not easy we are actively beginning an evidence-based movement. Although in some domains we are in the definitional stage because we are arguing over basic constructs, in other areas we have agreed upon nomenclature (standardization stage) and interventions (intervention testing stage). The stage of the evidence-based movement involving reimbursement is just starting, and examples include the health and behavior codes that psychologists may use for reimbursement from Medicare/Medicaid (Pedulla, 2003).

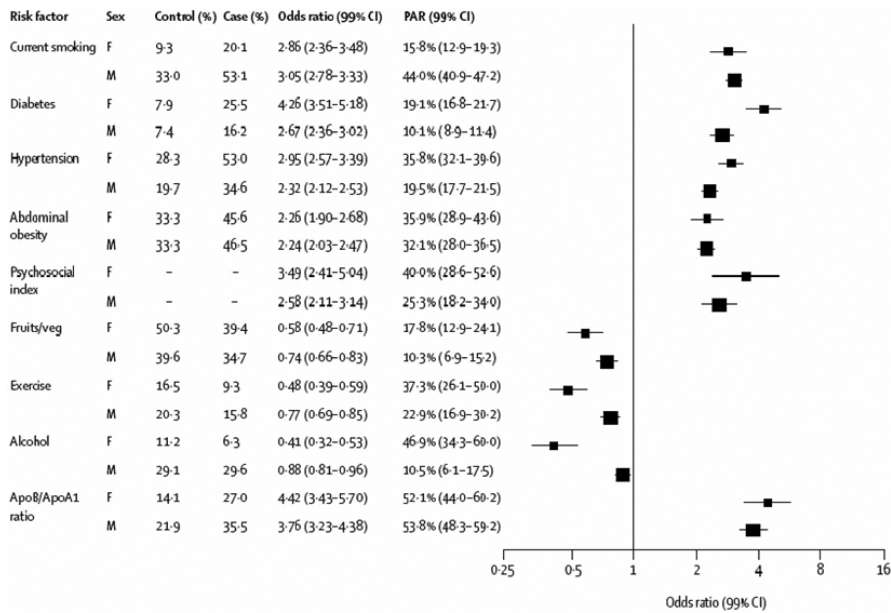


Figure 2. Risk factors for acute myocardial infarction in men and women after adjustment for age, sex, and geographic region. NB Odds ratios (a relative measure of risk, estimating how much more likely it is that someone with the risk will develop the outcome as compared to someone without the risk) are presented on a doubling scale (the X-axis show values that increase by a factor of two, indicating increments of 2, 4, 8, and 16). From “Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART study): Case-control study,” by S. Yusuf, S. Hawken, S. Ounpuu, T. Dans, A. Avezum, F. Lanas, et al., 2004, *The Lancet*, 364(9438), p. 944. Copyright 2004. Reprinted with permission from Elsevier.

Although psychologists struggle with ways to join the evidence-based movement, this struggle is necessary. Psychologists notice the flaws of the evidence-based processes used in other areas, but they have the resources and the knowledge to fix these flaws. Psychologists can influence the evidence-based movement by contributing to the evidence available and the consideration of the role of clinical judgment, and patient values, preferences and other relevant characteristics that have been poorly attended to within medicine. Thus, psychology can aid decision makers in the process of incorporating practitioners’ judgment into evidence-based practice recommendations. The involvement of both practitioners and clinical researchers is crucial to improving the evidence-based process. Finally, involving regulatory bureaus and reimbursement agencies is key to making the evidence-based movement productive and beneficial to all parties: psychology researchers, practitioners, and most importantly, our clients.

The rates and risks of depression and other psychological and behavioral disorders are increasing worldwide (Murray & Lopez, 1997). According to recent international data on the risk factors for coronary heart disease, psychosocial factors constitute one of the greatest risk factors for myocardial infarction, and the other major risk factors are almost exclusively behavioral (see Figure 2; Yusuf et al., 2004). Herein, we have outlined the benefits of creating an evidence-based movement for psychology and we have suggested how psychologists can learn from and influence the overall movement. Will clinical psychologists play a role in defining the shape and direction of the psychology evidence-based movement, or will psychologists sit this one out?

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