

SPECIAL REPORT

The Behavioral Medicine Research Council: Its Origins, Mission, and Methods

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The Behavioral Medicine Research Council (BMRC) is a new, autonomous joint committee of 4 of the leading behavioral medicine research organizations, including the Academy of Behavioral Medicine Research, the American Psychosomatic Society, the Society for Health Psychology, and the Society of Behavioral Medicine. The BMRC's work has important implications for the science and practice of behavioral medicine. The distinguished senior scientists who comprise this new committee will identify a series of strategic research goals for behavioral medicine and promote systematic, interdisciplinary efforts to achieve them. This special report discusses the developments that led to the formation of the BMRC, describes the BMRC's mission, and explains the methods that its members will use.

Keywords: behavioral medicine, health behavior, multicenter studies, randomized controlled trials as topic, societies

The Behavioral Medicine Research Council (BMRC) is a new, autonomous joint committee of four of the leading behavioral medicine research organizations, including the Academy of Behavioral Medicine Research (ABMR), the American Psychosomatic Society (APS), the Society for Health Psychology (SfHP), and the Society of Behavioral Medicine (SBM). The BMRC's mission is to identify strategic research goals in behavioral medicine and to promote systematic efforts to achieve them. The creation of the BMRC is a significant development in the history of our field, and it has important implications for the science and practice of behavioral medicine. This article describes the origins, mission, and methods of the BMRC.

Origins

This journal played a key role in the birth of the BMRC. *Health Psychology's* recent editorial transition was guided by two related commitments. The first was to publish high-impact behavioral medicine research, and the second was to encourage more of it. The BMRC initiative was integral to both commitments. However, it also has deeper roots (Freedland, 2017).

Many experts in behavioral medicine have long been concerned that while behavioral and psychosocial factors play important roles in numerous medical conditions, evidence-based behavioral interventions play commensurate roles in very few of them. Among the reasons for this discrepancy, one of the most critical is that

stronger evidence is needed to convince the gatekeepers of health care services, including clinical guideline writers, policymakers, third party payers, health system administrators, and the clinical practice and prevention communities, to embrace evidence-based behavioral interventions. As behavioral scientists, we may have little control over some of the other barriers, but stronger evidence is unquestionably ours to produce.

Nothing else is as convincing for medical audiences as large, rigorous, multicenter trials that show clinically meaningful benefits, but there are few examples of such trials in behavioral medicine. The Diabetes Prevention Program (DPP) trial (Knowler et al., 2002) is one of the best. It is one of the crowning achievements in our field, and it has had a significant impact on diabetes prevention efforts. Unfortunately, DPP-like trials are rare in behavioral medicine. Evidence-based behavioral medicine could occupy a much larger niche in preventive services and clinical care than it does now, but this will happen only if we conduct large, rigorous, multicenter trials of well-developed behavioral interventions with clinically meaningful outcomes, and if effectiveness trials, dissemination and implementation studies, and other practice-based research efforts follow in the wake of impressive demonstrations of efficacy.

Major achievements like these do not happen overnight, despite the rapid pace of scientific and technological progress to which we have become accustomed. Large, definitive, multicenter trials such as the DPP build on years of preliminary research including epidemiologic, mechanistic, clinical, community, intervention development, and feasibility studies, as well as Phase II trials. After the empirical groundwork has finally been laid, it takes additional time and it may take multiple attempts to secure funding for a large, multicenter trial. It also takes years to conduct one. If its outcomes are favorable, it takes more time for clinical practice guidelines to incorporate the intervention, for policymakers and third-party payers to support it, for health care systems to adopt it,

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and for practitioners learn how to provide it. Thus, it will take well-organized, persistent efforts over many years to achieve long-term research goals and for evidence-based behavioral medicine to play larger roles in health care and prevention programs.

“Well-organized” and “persistent” are not the first words that come to mind when one surveys the field of behavioral medicine research. As individual scientists, we often seem to have more in common with frenetic day traders than with patient, long-term investors. We struggle to beat our competitors to the latest hot topic, publish our next article, and get our next grant. We are too busy trying to be nimble and innovative and to survive in our careers to dream about behavioral Apollo projects, much less to make them happen. The BMRC initiative encourages us to work together in a well-organized and persistent manner so that we *can* make them happen.

Several developments over the past decade helped to crystalize the need for the BMRC initiative. First, the National Institutes of Health (NIH) Obesity-Related Behavioral Intervention Trials (ORBIT) Consortium published—in this journal—the ORBIT Model for Behavioral Treatment Development (Czajkowski et al., 2015). ORBIT is one of several innovative approaches to translational research and to behavioral intervention development and testing that have recently emerged, such as the Multiphase Optimization Strategy (MOST; Collins, Murphy, Nair, & Strecher, 2005), the NIH Science of Behavior Change (SOBC) Common Fund Program (Nielsen et al., 2018), the Pragmatic Explanatory Continuum Indicator Summary (PRECIS-2) tool (Loudon et al., 2015), and the Translational Science Benefits Model (Luke et al., 2018). The ORBIT model differs from other approaches in its emphasis on the long-term goal of improving *significant health outcomes*. It frames the spectrum of translational research on health-related behavioral interventions as a means to the goal of improving health outcomes. It invites us to avoid lingering too long in whichever regions of the translational research spectrum happen to interest us the most, to work programmatically, and to remember the ultimate purpose of our collective scientific efforts, which is to improve human health.

The health outcome in question might be the onset or worsening of a chronic disease or functionally disabling condition, the need for expensive or invasive medical or surgical treatments, premature death, or some other major adverse medical event. The ORBIT model urges us to look beyond our theory-driven questions and our parochial interests in particular behavioral interventions, health behaviors, or psychosocial risk factors, and to keep our eyes on the prize of significant health outcomes. In the ORBIT model,

(t)he initial explicit identification of the clinical problem does several things. It encourages investigators to: (a) set sights on the Phase III efficacy trial which will test the benefit of the behavioral treatment on an outcome that is meaningful in clinical practice; (b) consider early on the primary behavioral, clinical, or biomedical endpoints in that efficacy trial; and (c) commit to achieving a sufficiently potent level of behavioral change to achieve meaningful change on the ultimate biomedical or clinical outcome. (Czajkowski et al., 2015, p. 5)

This is a radical departure from the less ambitious short-term goals that have traditionally motivated much of our research.

Second, the paucity of large, multicenter, Phase III efficacy trials in behavioral medicine has been a frequent topic of discussion over the past decade at the annual Summer Institute

on Randomized Behavioral Clinical Trials. The Summer Institute is supported by the NIH Office of Behavioral and Social Sciences Research and the National Heart, Lung, and Blood Institute. Its trainees represent many different disciplines and fields of research, and its faculty includes some of the leading experts in behavioral trial methodology. Numerous discussions of our field’s “Phase III famine” have led them to conclude that individual scientists and small collaborative groups cannot solve this problem entirely on their own, and that concerted efforts by the behavioral medicine research community are needed.

Third, a small but growing number of behavioral scientists have served as site principal investigators on multicenter projects or as members of grant review committees for multicenter trial proposals with multimillion-dollar budgets. For example, several behavioral scientists have served on the Clinical Trials Review Committee for the National Heart, Lung, and Blood Institute. Through these experiences, they have gained essential insights into the characteristics that distinguish between successful and unsuccessful multicenter trial proposals. They have seen that most successful multicenter trial applications address problems or outcomes that are widely recognized as having high clinical or public health significance, rather than ones that may be of considerable interest to researchers but of much less interest to patients, providers, or policymakers. They have also seen that successful applicants typically comprise a well-organized, well-led, multidisciplinary, multicenter collaborative network with a proven record of shared research productivity and credible ties to a well-established data coordinating center (DCC).

The scientific culture of the collaborative networks that conduct large, multicenter trials is quite unlike the more individualistic, *laissez-faire* research environments in which most of us have spent most of our careers. Consequently, too few of us are very well prepared to collaborate on multicenter trials, much less to organize and lead them. The behavioral medicine research community needs to find ways to encourage the development of collaborative research networks that exhibit the characteristics of successful applicants for multicenter trial funding.

Finally, the need for a pathfinding entity such as the BMRC has been discussed at several recent meetings of the ABMR. ABMR’s annual meetings convene leading scientists to discuss cutting-edge projects and new directions for behavioral medicine research. However, they are not designed to translate these new directions into communal research goals or action plans. Discussions of this gap suggested the need for an entity that could speak for a larger swath of the behavioral medicine research community and that could work in a more systematic and sustained manner to promote actionable research goals.

These developments led to a formal proposal to create the BMRC. The proposal was unanimously approved by the executive councils of all four of the founding organizations. This was followed by the selection of two distinguished senior scientists from each organization to serve on the BMRC,¹ and

¹ The founding members of the Behavioral Medicine Research Council are Drs. Karen Matthews and Greg Miller representing ABMR, Elissa Epel and Suzanne Segerstrom representing APS, Michael Diefenbach and Tracey Revenson representing SBM, and Karina Davidson and John Ruiz representing SfHP. Dr. Davidson is the BMRC’s first Chair.

the submission of an NIH conference grant application to convene the members of the BMRC, the leaders of the founding organizations, and a variety of stakeholders and advisors. The founding conference was held on December 10–11, 2018 in Washington, DC, and the terms of the first eight members of the BMRC officially began on January 1, 2019.

Mission

The BMRC's mission is to identify, prioritize, and promote strategic goals for behavioral medicine research. These are ambitious, long-term goals whose achievement depends on the concerted and persistent efforts of well-organized, well-led, multidisciplinary, multicenter research networks. Its mission encompasses two complementary types of goals: Significant Clinical Research Questions (SCRQs) and Significant Preclinical Research Questions (SPRQs).

Significant Clinical Research Questions

SCRQs concern behavioral or psychosocial risk factors for significant health outcomes. The question is whether modification of a behavioral or psychosocial risk factor or a combination of risk factors can prevent or delay the onset of a disease or improve a significant health outcome in a defined population. For example, the behavioral targets in the DPP trial were dietary behaviors and physical inactivity; the primary health outcome was the onset of Type 2 diabetes; and the target population consisted of middle-aged, overweight or obese adults who were at high risk for developing diabetes. The goals of the lifestyle intervention were to achieve and maintain weight loss of at least 7% of body weight by adhering to a healthy diet and engaging in at least 150 min per week of moderate physical activity. The 24-week, 16-session intensive phase of the lifestyle intervention was followed by additional individual and group sessions to promote maintenance of behavior change (Knowler et al., 2002).

Thus, the DPP did not simply test a particular diet or exercise regimen; it tested a multifaceted *behavioral intervention* that helped participants adopt and adhere to the recommended dietary and exercise patterns. This is a critical point because many trial reports focus on the effects of particular diets and/or exercise regimens while saying relatively little about the motivational, behavioral, or psychosocial strategies that were used to promote adoption of and adherence to these regimens (Ma et al., 2017). In addition, contemporary guidelines for preventing or managing chronic diseases tend to equate “lifestyle” with particular diets or exercise regimens while minimizing the role of the behavioral and psychosocial factors that determine whether patients will adopt and adhere to these regimens (e.g., P. A. James et al., 2014). Some of the newer guidelines, such as the latest guideline for the prevention and management of high blood pressure in adults (Whelton et al., 2018), do acknowledge the need for motivational or behavioral strategies to promote weight loss, exercise, and smoking cessation, but without recommending any specific, evidence-based behavioral interventions.

Thus, there are no guideline-recommended, widely available, evidence-based lifestyle intervention programs for the prevention or management of hypertension to which physicians can refer their patients. The status quo might be different if a large, multicenter,

DPP-like “Hypertension Prevention Program” trial had ever been conducted. In contrast, physicians can easily refer their prediabetic patients to the Centers for Disease Control and Prevention (CDC) National Diabetes Prevention Program (NDPP). This program is based on the DPP lifestyle intervention and on evidence from subsequent trials (Albright & Gregg, 2013). It is offered at numerous YMCAs, pharmacies, and other locations around the country (Jayapaul-Philip, Dai, Kirtland, Haslam, & Nhim, 2018). Initial evaluations have shown that the program is quite effective, although the outcomes are not as favorable as those of the DPP trial (DiBenedetto, Blum, O'Brian, Kolb, & Lipman, 2016; Ely et al., 2017; Ritchie, Carroll, Holtrop, & Havranek, 2018). This has stimulated research on strategies for increasing participation and improving NDPP outcomes (Nhim et al., 2018; Ritchie, Kaufmann, Gritz, Sauder, & Holtrop, 2018).

Besides lifestyle factors that contribute to the development of diabetes or hypertension, the BMRC will have to consider many other combinations of risk factors and disease outcomes to determine which ones to designate as SCRQs. Prevention of metastatic breast cancer is an example of one they might consider. Groundbreaking research by members of the National Cancer Institute (NCI) Network on Biobehavioral Pathways in Cancer has identified physiological mechanisms through which stress promotes metastasis (Cole, Nagaraja, Lutgendorf, Green, & Sood, 2015). Beta-blockers (Ganz, Habel, Weltzien, Caan, & Cole, 2011; Sørensen et al., 2013) and stress management interventions (Antoni et al., 2016) are promising methods for disrupting these mechanisms. Multicenter trials may be needed to determine whether stress management can prevent metastatic breast cancer and improve survival.

Numerous randomized controlled trials have tested interventions for behavioral or psychosocial problems that have been associated with adverse medical outcomes. Unlike the DPP, however, the primary outcomes in most of these trials have not been “hard” medical outcomes such as incident diabetes, major adverse cardiac events, rehospitalization, or all-cause mortality. The primary outcomes have been the behavioral or psychosocial problems that are targeted by the behavioral intervention. These outcomes can be studied with adequate statistical power in much smaller samples than are usually required for trials with hard medical outcomes. Consequently, most of these studies have been Phase II trials conducted at single sites.

Behavioral trials with modest sample sizes that have yielded robust differences between the intervention and comparison arms have shown that we can modify health-related behaviors such as physical inactivity and smoking and treat health-related psychosocial problems such as low perceived social support, depression, and posttraumatic stress. Some trials have also shown that we can improve “soft” medical outcomes such as chronic pain or health-related quality of life. However, few trials have convincingly shown that behavioral interventions can improve *hard* medical outcomes such as mortality. Much larger samples, and hence multicenter trials, are required to establish whether behavioral interventions can improve hard medical outcomes.

The BMRC initiative acknowledges that the gatekeepers of health care services are not easily impressed by evidence that our interventions can help people with health-related problems such as stress, physical inactivity, or anxiety. Trials that address SCRQs will generate the kind of evidence that *should* impress them, that

is, that behavioral interventions can help to prevent or delay the onset of chronic diseases or to improve the medical outcomes of preexisting conditions.

Just as there are gatekeepers of clinical care, there are also gatekeepers of community- and population-based prevention programs. For example, school system administrators and elected officials make decisions about whether to provide school-based programs to promote physical activity (Young et al., 2014). The BMRC initiative aims to influence both kinds of gatekeepers. Thus, SCRQs will not be limited to problems that are treated in clinical settings or to patients with established chronic diseases. The BMRC will consider SCRQs across the entire spectrum of primary, secondary, and tertiary prevention. Some of the trials that address these SCRQs may be conducted in community settings, while others may be conducted in clinical settings. The common denominator among them is that they will have primary outcomes that matter to people who are at high risk for developing chronic medical illnesses, patients with preexisting conditions, and the gatekeepers and providers of prevention programs and health care services.

Significant Preclinical Research Questions

The BMRC also evaluates strategic *preclinical* research questions that, if resolved, would facilitate research on important *clinical* research questions. Some examples of potential SPRQs include needs for refined phenotypes or endophenotypes in research on behavioral and psychosocial risk factors (e.g., Brody, Yu, Barton, Miller, & Chen, 2017; Cuthbert, 2014; Huppertz et al., 2016), questions about biobehavioral mechanisms linking risk factors to medical outcomes (e.g., Cole et al., 2015; Lutgendorf & Andersen, 2015; Miller, Chen, & Parker, 2011; Suls, Green, & Davidson, 2016; Wirtz & von Känel, 2017), and questions about behavior change processes as applied to behavioral or psychosocial risk factors for chronic medical illnesses (e.g., Brown, Smith, Epton, & Armitage, 2018; Epton, Currie, & Armitage, 2017; E. James et al., 2016; Larsen et al., 2017; Nielsen et al., 2018; Tate et al., 2016; Whelan, Morgan, Sherar, Orme, & Esliger, 2017; Winter, Sheats, & King, 2016).

Research on risk factors, biobehavioral mechanisms, and behavior change processes have been pillars of the science of behavioral medicine for the past several decades (Dekker, Stauder, & Penedo, 2017), so the BMRC would be preaching to the choir if it were simply advising us to do more of this kind of research. However, the purview of the BMRC is more specific than that. When the BMRC determines that an unanswered question in the basic science of behavioral medicine is a major impediment to the achievement of strategic clinical research goals, they will promote collaborative efforts to accelerate progress toward answering it as an SPRQ.

Method

Overview

The BMRC will commission expert writing groups to produce scientific statements on SCRQs and SPRQs. The committee must decide which statements to commission, out of the dozens of possibilities that they may consider. This is a challenging but

essential task. As Frank Wilczek, winner of the 2004 Nobel Prize in Physics recently said, “Part of the art of making progress in science is recognizing which problems are ready to be solved” (Wilczek, 2015). And as Sir Peter Medawar, winner of the 1960 Nobel Prize in Physiology or Medicine, once said,

Good scientists study the most important problems they think they can solve. It is, after all, their professional business to solve problems, not merely to grapple with them. The spectacle of a scientist locked in combat with the forces of ignorance is not an inspiring one, if, in the outcome, the scientist is routed. (Medawar, 1967, p. 7)

Once a decision has been made to commission a scientific statement, area experts will be recruited to scrutinize the question and write up their findings and recommendations. The BMRC will vet each statement and determine whether it is ready for submission. The editors of several leading behavioral medicine journals, including *Health Psychology*, *Annals of Behavioral Medicine*, and *Psychosomatic Medicine* have agreed to copublish the BMRC’s scientific statements. However, some BMRC statements may be suitable for submission to journals with considerably higher impact factors and larger circulations.

The BMRC will probably not commission an SCRQ statement unless the chances are reasonably good that it will turn out to be affirmative, that is, unless the expert writing group is (a) likely to conclude that the research question is indeed highly significant and (b) to call for a concerted effort to address it. The BMRC will gravitate toward areas of research in which substantial progress seems achievable. Most affirmative SCRQ statements will conclude that a definitive Phase III trial is a realistic objective in the foreseeable future, and that the potential impact of such a trial (e.g., on clinical practice guidelines) would make it worth the effort.

Negative SCRQ statements will probably not dismiss the research question as being unimportant, but they will conclude that the prospects are too remote for a definitive Phase III trial or for a meaningful impact on prevention services or clinical care. They may call for further basic research on the risk factor or for more early phase research on interventions that target it, but they will discourage any short- or intermediate-term plans for Phase III trials. In this circumstance, they might decide to issue an affirmative SPRQ statement rather than a negative SCRQ statement. They might also call for the question to be reconsidered (e.g., in 5 years) to determine whether there has been enough progress to issue an affirmative SCRQ statement.

Affirmative scientific statements will have little impact unless they are acted upon. Consequently, the area experts who write affirmative scientific statements for the BMRC will also be asked to take a leadership role in organizing a new, multidisciplinary, multicenter research network, or in engaging a suitable existing network, to pursue the strategic research goal in question. In some cases, two or more networks may pursue the same research goal, possibly focusing on different interventions, populations, and/or settings. The BMRC plans to develop an online registry of the networks that are pursuing SPRQs and SCRQs to facilitate communication and to highlight the progress that the networks are making. The achievement of the strategic goals that are articulated in the BMRC’s affirmative scientific statements will not be up to the BMRC itself; it will be up to the research networks that have committed to pursuing these goals.

Scoping Reviews

Many different behavioral and psychosocial factors have been linked to many different health outcomes. Consequently, the BMRC will have to sort through a wide range of possibilities to choose the topics of their scientific statements. They will do this by conducting scoping reviews. Most scientific scoping reviews are conducted to map the body of literature in an area of research (Pham et al., 2014). The BMRC's scoping reviews will extend beyond the research literature to other domains that will determine the relative priority of a potential SPRQ or SCRQ. They will cover a broad range of issues, but not in much depth. If the scoping review leads the BMRC to commission a scientific statement, the writing group will examine the topic in greater depth.

The basic unit of analysis for an SCRQ scoping review is a behavioral or psychosocial risk factor for a significant clinical outcome in a definable population. For example, posttraumatic stress disorder (PTSD) increases the risk of incident cardiovascular disease (CVD) in initially healthy civilians and in military veterans (Burg & Soufer, 2016). Consequently, the BMRC might decide to conduct a scoping review of PTSD as a risk factor for incident CVD in the general civilian population, in combat veterans, or in another severely affected subpopulation such as traumatized victims of natural disasters. Suppose that one of their reviews focuses on adult primary care patients. It would address a series of questions about PTSD as a risk factor for CVD in this population, including questions about (a) prevalence, (b) importance, (c) mechanisms, (d) efficacy, (e) opportunities for funding, and (f) opportunities for impact.

Prevalence. SCRQ statements will focus on problems that are common enough to justify investment in a multicenter trial and in the research that would precede and follow it. Thus, the scoping review would examine whatever might be known about the prevalence of PTSD, the incidence of CVD, and the coprevalence of PTSD and CVD in adult primary care patients.

Importance. All risk factors are not created equal; some are more strongly related than others to the incidence or outcomes of chronic diseases. For example, the health effects of PTSD may depend on whether it is because of a single traumatic event such as a natural disaster or to recurrent exposures such as in combat (McTeague et al., 2010). Furthermore, the relative importance of a risk factor depends on whether it is judged from the perspective of the individual or of the community to which the individual belongs. Whereas the importance of risk factors for individuals can be evaluated in terms of relative risks (RRs), their importance for the community can be evaluated in terms of population attributable risks (PARs). These two perspectives often lead to divergent rankings of the relative importance of risk factors. For example, over 12,000 men and women were followed up 21 years after their initial examination for the Copenhagen City Heart Study. By then, 5,599 of the men and 6,478 of the women had developed or died from coronary heart disease (CHD). Ten risk factors were studied, including diabetes mellitus, hypertension, smoking, physical inactivity, alcohol intake, hypercholesterolemia, obesity, low income, hypertriglyceridemia, and low education level. The risk factors were rank-ordered within sex, both by RR and by PAR. Among women, for instance, smoking ranked 2nd and obesity ranked 7th in terms of relative risk, but smoking ranked 1st and obesity ranked

4th in terms of population attributable risk (Schnohr, Jensen, Scharling, & Nordestgaard, 2002).

The BMRC will take both perspectives when deciding which risk factor(s) to prioritize for which medical outcomes, but they will have to be especially concerned about the relative risks of behavioral or psychosocial factors for individuals. The reason is that they will have to ponder a very difficult question: *How much of a difference will it take to make a difference?* In other words, how much of an improvement in the behavioral or psychosocial risk factor in question will it take to make a meaningful difference in the medical outcome?

Figure 1 displays a hypothetical relationship between a risk factor such as stress or physical inactivity and a disease outcome such as acute coronary syndrome. The risk factor is measured on a 0–100 scale, and the outcome is displayed as the percentage of individuals who experience the adverse clinical outcome within 5 years. The dashed line represents a weak relationship between the risk factor and the adverse event, that is, the relative risk is modest, such that an individual with a very high score on the risk factor is not at much greater risk than someone with a low score. The solid line represents a strong relationship; if the relationship is this strong, individuals who score high on the risk factor measure are at much higher risk than those who score low. The vertical line at 70 represents the estimated average baseline score on the risk factor among individuals who would qualify for enrollment in an anticipated clinical trial, and the vertical line at 60 represents the estimated average posttest score in the intervention arm. This suggests that the intervention is not very potent, that is, it does not produce dramatic improvement in the risk marker in most cases. To simplify the example, assume that the posttest score in the comparison arm is expected to be no better than it was at baseline.

The shaded areas project the between-groups risk factor differences onto expected differences in the risk of having an adverse event. (“Expected” refers to the best-case scenario, based on the best-available epidemiological evidence about the relative risk associated with high scores on the risk marker. The observed benefit of modifying the risk factor may not turn out to be that large.) The width of the shaded region represents the estimated between-groups difference in the clinical outcome. The projections show that this modestly efficacious intervention is likely to have a modest effect on the medical outcome if the relative risk is high; about 54% of the comparison group and about 48% of the intervention group would be expected to have adverse outcomes. In contrast, if the relative risk is fairly low, the same intervention will yield almost no improvement in the adverse event rate; about 20% of the comparison group and 19% of the intervention group would be expected to have an adverse outcome.

Figure 2 displays what to expect if a much more efficacious intervention can be brought to bear on the same risk factor. This intervention produces, on average, a 30-point posttreatment difference in average risk factor scores between the intervention and comparison arm. If the relative risk is low, we still would expect a fairly modest reduction in adverse events; about 20% of the comparison group and 15% of the intervention group would be expected to have adverse outcomes. If the relative risk is high, however, the same intervention would have a very large effect on the medical outcome; about 52% of the comparison group and about 35% of the intervention group would have adverse outcomes.

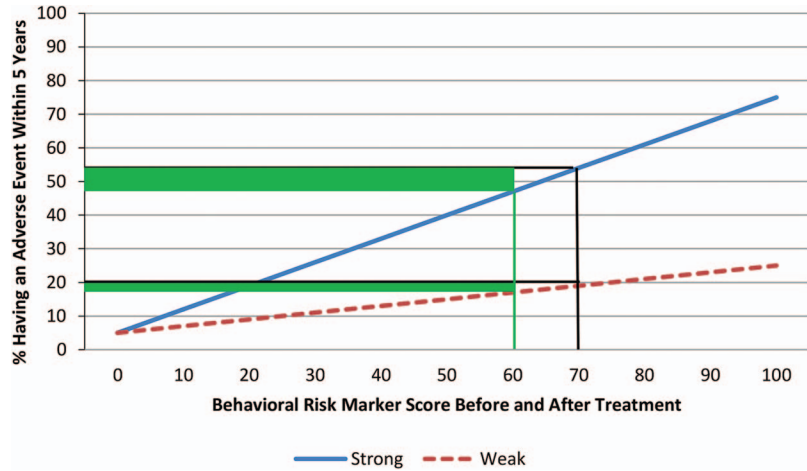


Figure 1. Treatment implications of strong versus weak linear relationships between a behavioral risk marker and an adverse medical event such as an acute myocardial infarction. In a hypothetical behavioral intervention trial, the average baseline score on the behavioral risk measure (black line) is 70. If the comparison group does not improve and the intervention group improves by 10 points on average (green line), the intervention would yield (at best) a 4–5% decrease in adverse events if the risk marker is strongly related to the clinical outcome, and a mere 1–2% decrease if the marker is weakly related to the outcome. The green shaded areas represent the decrements in adverse outcomes. See the online article for the color version of this figure.

These two figures are intended to illustrate the problem, not to present a realistic example. Taken together, however, they convey two important lessons. The first is that it is probably futile to try to improve medical outcomes by modifying a behavioral or psychosocial risk factor that is a weak predictor of adverse outcomes. Even if a highly efficacious intervention for the risk factor is available, it will not make much difference in terms of medical outcomes. The second lesson is that an intervention must have a moderate-to-large effect on a risk factor to have a clinically sig-

nificant effect on a medical outcome, even if the relative risk is high. In general, interventions have to make a moderate to large difference in a behavioral or psychosocial risk factor to make a meaningful difference in clinically important outcomes.

The scoping review will evaluate readiness to move from Phase II trials targeting a behavioral or psychosocial risk factor as the primary outcome to Phase III trials in which the same risk factor is targeted to determine whether doing so improves a medical outcome. The second lesson implies that it is not sufficient for a

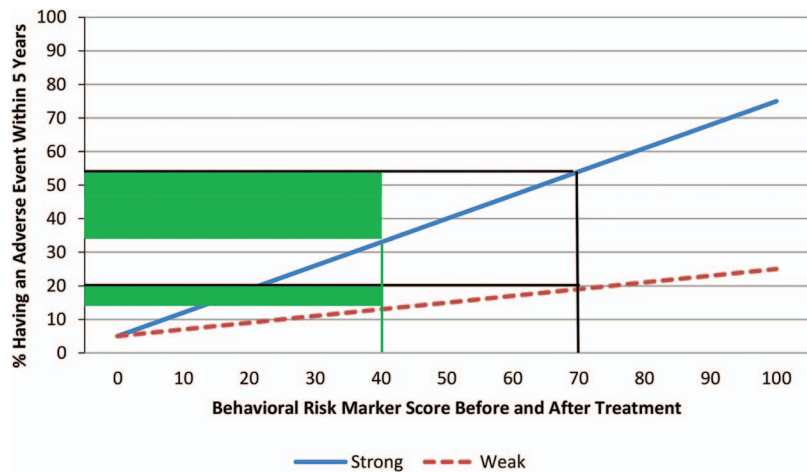


Figure 2. Treatment implications of strong versus weak linear relationships between a behavioral risk marker and an adverse medical event such as an acute myocardial infarction. In a hypothetical behavioral intervention trial, the average baseline score on the behavioral risk measure (black line) is 70. If the comparison group does not improve and the intervention group improves by 30 points on average (green line), the intervention would yield (at best) about a 17 or 18% decrease in adverse events if the risk marker is strongly related to the clinical outcome, and about a 3–5% decrease if the marker is weakly related to the outcome. The green shaded areas represent the decrements in adverse outcomes. See the online article for the color version of this figure.

Phase II trial to show a statistically significant difference in the risk factor between the intervention and comparison arm. It is not enough to replicate such findings, and it is not even enough to show *clinically significant* differences, if clinical significance is defined in terms of improvement in the risk factor itself. Instead, the efficacy effect sizes that emerge from Phase II trials must be judged in terms of whether they are large enough to make a difference in medical outcomes, given what is known about the strength of the relationship between the behavioral risk factor and the medical outcome. For example, a 30-min per week increase in physical activity might be regarded as clinically significant and beneficial for a particular population, and it would be great if Phase II trials were to show that a novel behavioral intervention is able to produce 30-min per week increases. However, if the epidemiologic literature suggests that it would probably take a 60-min per week increase to make a noticeable improvement in a medical outcome such as incident hypertension, a Phase III trial would be premature. Further intervention development research and Phase II trials would be needed to establish that 60-min increases are reliably achievable.

However, the second lesson assumes that there is a linear relationship between the risk factor and the medical outcome. Figure 3 illustrates a hypothetical risk factor that has a curvilinear relationship to the adverse medical outcome. In this case, an intervention that produces a mere 5-point improvement in the risk factor could yield a very large improvement in the medical outcome—but this would only hold for individuals who start out with severe risk factor scores. Even if we had an extremely efficacious intervention for individuals with moderately elevated risk scores, it would not improve their already-low risk of having an adverse medical event. Thus, it might be reasonable to aim for a small improvement in the risk factor score if the relationship between the risk factor and the outcome is curvilinear, but this would also mean that trial eligibility would have to be limited to individuals with very high risk factor scores.

When they ask how much of a difference it will take to make a difference, the BMRC will look for answers in the epidemiology literature. When too little is known about the relationship between a behavioral or psychosocial risk factor and a medical outcome to answer this question, they may conclude that further epidemiological research is needed to establish whether a large multicenter trial would be worth conducting. This might be the basis for an SPRQ statement.

Mechanisms. Many treatments have demonstrated efficacy in randomized trials long before the mechanisms underlying their effects were fully understood. In addition, many studies have successfully tested interventions for behavioral or psychosocial risk factors even though the biobehavioral mechanisms that link the risk factors to medical outcomes were poorly understood. Thus, it is not necessary to postpone clinical trials until the biobehavioral mechanisms are fully understood; a better strategy is to conduct clinical trials and basic research *concurrently*, so that they can inform each other (Kaufmann, 2003). Nevertheless, elucidation of mechanisms can facilitate the development of more effective interventions (Stanton, Luecken, MacKinnon, & Thompson, 2013) and increase confidence that modification of a risk factor could plausibly improve medical outcomes (Skala, Freedland, & Carney, 2006). Consequently, the BMRC will consider the state of mechanistic research when examining potential SCRQs.

Efficacy. The preceding discussion of the relative importance of risk factors suggested that it would be unwise to embark on a Phase III trial with clinical outcomes unless a moderately or highly efficacious intervention for the behavioral or psychosocial risk factor were available. There may be a variety of different ways to treat the problem, and some may have stronger empirical support or be more efficacious than others. The interventions that should advance from Phase II to Phase III trials are the ones that have convincingly demonstrated the largest efficacy effect sizes in Phase II trials. In its scoping reviews, the BMRC will be looking

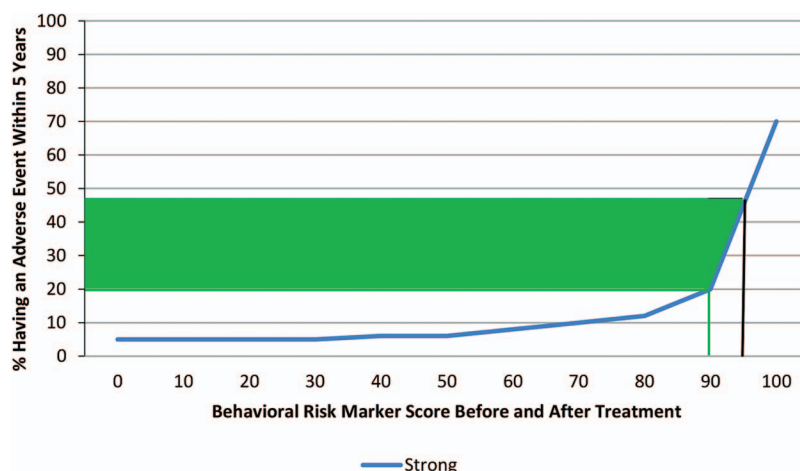


Figure 3. Treatment implications of a curvilinear relationship between a behavioral risk marker and an adverse medical event such as an acute myocardial infarction. In a hypothetical behavioral intervention trial, the average baseline score on the behavioral risk measure (black line) is 95. If the comparison group does not improve and the intervention group improves by 5 points on average (green line), the intervention would yield (at best) about a 36 or 37% decrease in adverse events. The green shaded areas represent this decrement. See the online article for the color version of this figure.

for evidence that at least one well-tested, highly efficacious intervention for the risk factor exists.

The most efficacious intervention may not be the simplest, least burdensome, least expensive, most cost-effective, or easiest one to implement. It is desirable to design interventions with these considerations in mind (Owen et al., 2017), but they should not outweigh the efficacy of the intervention if the goal is to conduct a Phase III trial to test whether modifying a risk factor improves medical outcomes. Maximal efficacy maximizes the chances that the intervention will improve medical outcomes. If the trial does not show that the intervention improves medical outcomes, there will probably be little interest in implementation.

Opportunities for research funding. The BMRC will espouse whichever goals it decides are high priorities for the behavioral medicine research community, regardless of whether they coincide with any active funding opportunities. However, their recommendations will take the availability or lack of funding opportunities into account. For example, if NIH funding is available for intervention development research directed toward a particular behavioral risk factor or chronic disease population, or if the Department of Veterans Affairs (VA) is funding trials in that area, the BMRC might place a higher priority on it than they otherwise would. However, funding opportunities might also have the opposite effect on the BMRC's decisions. For example, if a request for applications for proposals to conduct a major multicenter behavioral medicine trial were already active, the BMRC might decide that a scientific statement on this topic would not provide enough added value to justify the time and effort it would take. Whatever they decide, they will have to take the research funding landscape into account.

Opportunities for impact. The BMRC will search for signals that the gatekeepers of health care services would be likely to embrace a behavioral or psychosocial intervention if presented with compelling evidence about it from a definitive multicenter trial. If, for example, the BMRC were considering whether the time is right to plan a multicenter trial of a behavioral intervention for the prevention of high blood pressure, they would look to the latest American College of Cardiology/American Heart Association guideline (Whelton et al., 2018). They would see that it acknowledges the importance of lifestyle change with a Class I (Strong) recommendation that the benefits greatly outweigh the risks, and an "A" for the level (quality) of evidence, yet it does not recommend any specific, evidence-based behavioral interventions to promote the changes in diet and exercise patterns that would help to prevent high blood pressure. This raises the possibility that a definitive Phase III trial might convince the guideline writers to incorporate a specific behavioral intervention into the *next* revision of the blood pressure guideline.

The BMRC will also pay attention to United States Preventive Services Task Force (USPSTF) recommendations regarding behavioral interventions for primary care patients. For example, the USPSTF recently recommended that clinicians should refer adults with a body mass index (BMI) of 30 or higher to intensive, multicomponent behavioral interventions (Curry et al., 2018). This recommendation was given a "B" grade, meaning that they had a high level of certainty that the net benefit is moderate, or moderate certainty that the net benefit is moderate to substantial. Thus, there is room for the USPSTF to strengthen its recommendation if future trials demonstrate greater efficacy or better maintenance of weight

loss. This might lead the BMRC to judge further research on behavioral weight loss interventions for primary care patients as having considerable potential for clinical impact. However, they might focus instead on topics that have been given a lower grade, or even an "I" grade by the USPSTF, meaning that the current evidence is insufficient to judge the balance of benefits and harms of the intervention, because it is of poor quality, conflicting, or otherwise deficient (Kurth, Miller, Woo, & Davidson, 2015). If the existing evidence is insufficient for the USPSTF to recommend a particular behavioral intervention, a definitive Phase III trial might raise the grade to A or B. The potential impact of such a trial would be magnified by the Affordable Care Act, which mandates insurance coverage for preventive services that are graded A or B by the USPSTF (Siu, Bibbins-Domingo, & Grossman, 2015).

Opportunities for impact may reveal themselves in other ways as well. For example, a variety of patient-powered research networks (PPRNs) have been established by patients and caregivers with personal concerns about certain disorders or health disparities (PCORnet PPRN Consortium; Daugherty et al., 2014; Selby, Grossman, Zirkle, & Barbash, 2018; Warren et al., 2018). PPRNs can inform the BMRC about the concerns, interests, and priorities of individuals with chronic medical conditions and about the outcomes that matter to them.

Advisory input. The BMRC is a small committee with a limited budget and a challenging mission. Consequently, they need input from the behavioral medicine research community on the choice of topics for scientific statements and on related issues. The founding organizations host a variety of special interest groups, committees, and task forces that can provide the BMRC with information, advice, and recommendations on a range of topics. For example, when the BMRC is considering cancer-related topics, they might ask the Society of Behavioral Medicine's Cancer Special Interest Group to advise them about the quality of the evidence that a putative psychosocial risk factor such as hopelessness predicts morbidity or mortality in cancer patients, to identify the best available meta-analyses of psychosocial interventions for cancer survivors, or to inform them about relevant research funding opportunities. As another example, the Society for Health Psychology's Diversity Council might advise the BMRC on issues of minority health and health disparities. Leveraging the resources of the founding organizations and the expertise of their members helps the BMRC fulfill its mission and enables it to speak on behalf of the behavioral medicine research community at large.

Scientific Statements

The BRMC will conduct multiple scoping reviews to identify the topics that seem the most promising in terms of prevalence, importance, mechanisms, efficacy, opportunities for funding, and opportunities for impact. The ones that look the most favorable on these dimensions will be selected as topics for scientific statements. When a topic is selected, a member of the BMRC will invite leading experts on the topic to form a writing group and to write a scientific statement about it. The BMRC member will also chair the writing group. If possible, the chair will not be an expert on the topic. The chair's "outsider" perspective will help to counteract groupthink and the biases that the leading experts may harbor that favor of their own areas of research.

The writing group will use the BMRC's scoping review as its point of departure and then examine the topic in greater depth. If they are writing an SCRQ statement, they will evaluate the field's readiness for a definitive multicenter trial. Affirmative statements will designate the trial in question as a strategic research goal. They will not necessarily conclude that the time is right (i.e., right away) for such a trial. They are more likely to conclude that some additional preliminary work is needed, but that a definitive multicenter trial is a realistic goal for the foreseeable future. Negative SCRQ statements will conclude that the prospects for a successful multicenter trial are too remote to designate it as a strategic research goal. However, if the writing group determines that the prospects for a definitive multicenter trial would substantially improve if a major gap in preclinical research were filled, they might opt to write an affirmative SPRQ statement about this gap rather than a negative SCRQ statement.

The BMRC will vet each scientific statement before it is submitted for publication. When the statement is submitted for publication, it will be peer reviewed. Consequently, a writing group may be asked to revise some of its conclusions or recommendations. The BMRC will also vet any major revisions that may be made after the original version is submitted for publication. Thus, the BMRC's scientific statements will be authored by some of the leading experts on the topic, approved by a committee that is authorized to speak on behalf of the leading behavioral medicine research organizations, and independently peer reviewed by leading journals. This onerous process is designed to ensure that the behavioral medicine research community and funding agencies will regard these statements as credible and convincing.

Strategic Research Networks

Affirmative scientific statements will be for naught unless well-organized, well-led, multidisciplinary research networks respond to them and commit to the long-term pursuit of the BMRC's strategic goals. The authors of these statements will include some of the leading experts in their areas of research. If they produce an affirmative statement, they will be asked to form or engage a suitable existing research network to pursue the strategic research goal that they are advocating in their statement. This does not guarantee that the statement will have its intended effect, that is, that it will stimulate concerted and persistent efforts to achieve the strategic goal. However, it greatly increases the chances that this will occur. Who would be better equipped than the leading researchers in the area to get the ball rolling?

If the authors do form or engage a research network, they will not necessarily be the only ones who decide to pursue the statement's strategic goal. For example, there may be several different ways to intervene in a behavioral risk factor. The authors' research network may concentrate on one of the interventions, while an independent network might choose a different one. As another example, the authors' network may commit to conducting a definitive multicenter trial in the United States, while a different network commits to an international trial.

When an affirmative SCRQ statement is published, it may have to be followed by several years of Phase II (and possibly Phase I) studies before the investigators are ready to propose a Phase III multicenter trial. This will give them time and opportunities to develop a multicenter organizational structure and leadership plan,

to demonstrate shared research productivity across the network, and to produce essential preliminary data. This will put them in a much better position to propose a multicenter trial than they will be in at the inception of their network.

In addition, quite a few years may elapse between the publication of an affirmative SCRQ statement and the completion of the multicenter trial it promotes. The leading experts in most areas of behavioral medicine research are senior or midcareer scientists, so the initial leaders of the research networks will not necessarily be the ones who see the multicenter trials through to completion. This means that it will be essential for research network leaders to recruit early- and midcareer investigators and prepare them to assume leadership roles as the network matures.

Traditional criteria for academic advancement have incentivized early career behavioral scientists to concentrate on demonstrating independent productivity and creativity. Because of the ever-increasing scale and complexity of scientific research, however, a growing number of research mentors, academic administrators, and funding agencies are embracing multidisciplinary team science (e.g., Croyle, 2008). Thus, engagement in large-scale team efforts is becoming a viable career path for early career scientists (Committee on the Science of Team Science, Board on Behavioral Cognitive and Sensory Sciences, Division of Behavioral and Social Sciences and Education, & National Research Council, 2015; Libby, Cornfield, & Abman, 2016). Early career scientists may start out as "cogs in the wheel" of a strategic behavioral medicine research network but eventually wind up in prominent leadership roles.

One of the key challenges for the leaders of multidisciplinary behavioral medicine research networks is that they may have to establish collaborations with investigators they do not yet know across widely distributed centers with which they have had no prior involvement. The leaders will have to reach out to potential collaborators who have the kinds of expertise that the network needs as well as access to resources (e.g., patient populations, core laboratories, etc.) that will have to be in place before a multicenter trial can be proposed.

However, the networks should also be open to qualified researchers who may not be well connected with the leadership of the network or located at one of the network's major nodes, but who have something of value to offer and who want to get involved. For example, there are experts in behavioral measurement technologies such as ecological momentary assessment or actigraphy who hold positions in academic departments that have not been involved in many (or any) multicenter trials. If a network is going to need this kind of expertise, it could be advantageous for them to engage with experts who are not necessarily clinical trial "insiders." The research networks will need ways to make their needs, interests, and plans known to the behavioral medicine research community, and to put out virtual welcome mats to other researchers who would like to get involved. The BMRC plans to establish an online registry of the networks that are working toward the achievement of the strategic goals that are advocated in its scientific statements. One of the functions of the registry will be to facilitate communication with and outreach to researchers with relevant interests who would like to join a network.

What to Expect

The BMRC initiative will not produce many quick successes; it is not designed to do so. The BMRC's strategic goals will take years to achieve, and they will ask us to solve some of the most difficult problems that will ever be encountered in the field of behavioral medicine. They may extend to problems that we have failed to solve before or that we have not even tried to solve.

"Grit" is the tenacious, sustained, and passionate pursuit of long-term goals despite frustrations and setbacks (Duckworth & Gross, 2014; Duckworth, Peterson, Matthews, & Kelly, 2007). The members of BMRC will need plenty of grit to carry out their mission. The members of the research networks that pursue the BMRC's strategic goals will need even more of it to build and maintain durable and effective multidisciplinary collaborations and succeed in efforts that may take many years to complete. The rest of us will need patience and foresight to support the BMRC's efforts despite knowing how difficult they will be and how long they will take.

The BMRC's work officially began on January 1, 2019. Let's assume, optimistically, that it takes a year for the BMRC to commission its first scientific statement, 9 months for the writing group to complete its work, and 3 months for the statement to be accepted for publication. This would mean that the BMRC's first statement would be published in early 2021. Assume that a research network that is committed to pursuing the statement's strategic goal forms immediately and spends about 3 years working on intervention refinement and Phase II trials, and that it takes another year to secure funding for a Phase III trial and 5 years to conduct it. If the trial produces impressive results and they are published by 2029, the first effects of the BMRC initiative on clinical guidelines, prevention programs, reimbursement policies, and health care services might be discernible by 2030. Although 2030 may seem far away, all of these assumptions are optimistic; we may be well into the decade of the 2030s before the BMRC initiative starts to have a meaningful impact on health care services and outcomes. We have to be patient, but we cannot wait forever; there is no time to lose.

Some may wonder why we should expend so much time, talent, and money in pursuit of goals that are so difficult to achieve, but there are compelling reasons to do so. The BMRC's strategic goals represent a fundamental yet largely unfulfilled promise of our field. The reason that behavioral medicine exists as a field of research and practice in the first place is that during the last century, the United States and other wealthy industrialized nations underwent what are known as epidemiologic transitions. These are periods during which the traditional scourges of infectious diseases and high infant mortality rates are eclipsed by chronic and degenerative diseases (Omran, 1971). In the 1960s, epidemiologists and physicians started to realize that cigarette smoking and other health-related behaviors, as well as psychosocial factors such as stress, play key roles in the development and progression of many of the chronic conditions that dominated our epidemiologic transition (Wynder & Day, 1961). By the mid-1970s, behavioral medicine had emerged as the multidisciplinary field of research that would investigate the behavioral and psychosocial causes of chronic diseases and that would also develop prevention strategies and interventions to address them. The landmark Yale

Conference on Behavioral Medicine (Schwartz & Weiss, 1978) produced this definition: "Behavioral medicine is the field concerned with the development of behavioral science knowledge and techniques relevant to the understanding of physical health and illness and the application of this knowledge and these techniques to prevention, diagnosis, treatment and rehabilitation" (p. 7).

The pioneers of our field thought that we should and would play important roles in the prevention and treatment of chronic physical illnesses, and that physical disorders should be the end points of our efforts. In other words, it is not enough for us to content ourselves with modifying health behaviors, helping people cope with chronic illnesses, or discovering the mechanisms linking behavioral and psychosocial risk factors to adverse medical outcomes; it is also our job to prevent chronic diseases and improve the course and outcome of preexisting chronic conditions. Hopes and beliefs that we will fulfill this promise help to explain why there has been enduring interest in our field since the Yale Conference; disappointment that we have *not* fulfilled it could undermine support for behavioral medicine in the future. The BMRC initiative reaffirms our commitment to keep some of the bedrock promises of our field and it creates some of the critical infrastructure that we will need to fulfill them.

This is more than a matter of professional pride and identity; the BMRC initiative has the potential to improve the health and quality of life of millions of people in the decades ahead. This is what makes the difficulties, uncertainties, and expense of pursuing strategic research goals in behavioral medicine worth the effort. Whenever we find ourselves doubting their value or our ability to succeed, we should remember the immortal words of President Kennedy:

But why, some say, the moon? Why choose this as our goal? And they may well ask why climb the highest mountain? Why, 35 years ago, fly the Atlantic? Why does Rice play Texas? We choose to go to the moon. We choose to go to the moon in this decade and do the other things, not because they are easy, but because they are hard, because that goal will serve to organize and measure the best of our energies and skills, because that challenge is one that we are willing to accept, one we are unwilling to postpone, and one which we intend to win, and the others, too. (Rice Stadium "Moon" Speech, September 12, 1962)

President Kennedy did not live to see it, but we *did* make it to the moon by the end of the decade. It *was* hard, and the effort *did* organize and measure the best of our energies and skills. The BMRC initiative is behavioral medicine's Apollo Project. We choose to pursue strategic goals in behavioral medicine not because they are easy, but because they are hard. It will take the best of our energies and skills to achieve them. And in the long run, it will be well worth the effort.

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