CALIFORNIA TECHNOLOGY ASSESSMENT FORUM℠

Comparative Effectiveness CEPAC Public Advisory Council

Integrating Behavioral Health into Primary Care

Summary of Public Comments And Response on Draft Report

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ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

Response to Public Comments

The Institute for Clinical and Economic Review (ICER) produces publicly-available evidence reviews for consideration by the California Technology Assessment Forum (CTAF) and the New England Comparative Effectiveness Public Advisory Council (CEPAC). As part of this process, ICER welcomes public comment from individuals and organizations on its proposed project scope, voting questions, and evidence assessment. For transparency, all those submitting comments during the public comment period are acknowledged in this response document. However, detailed responses are focused on those comments pertaining to the project scope, evidence assessment, and major assessment findings.

This document responds to comments from the following parties:

Comments on CTAF Draft Report

- Macaran A. Baird, MD, MS, Professor and Head, UMN Department of Family Medicine and Community Health, Minneapolis, MN
- Roger Kathol, MD, CPE, President, Cartesian Solutions, Inc., Burnsville, MN
- Jürgen Unützer, MD, MPH, MA, Professor and Chair, Psychiatry and Behavioral Sciences, University of Washington; Director, AIMS Center, Seattle, WA
- Saul Levin, MD, MPA, CEO and Medical Director, American Psychiatric Association, Arlington, VA
- Rachel Wick, Program Officer – Health Care and Coverage, Blue Shield of CA Foundation, San Francisco, CA
- Florence C. Fee, JD, MA, Executive Director, No Health without Mental Health (NHMH), San Francisco, CA – Arlington, VA

Comments on CEPAC Draft Report

- Gregory K. Fritz, MD, Professor and Director, Division of Child and Adolescent Psychiatry, Vice Chair, Dept. of Psychiatry and Human Behavior, Warren Alpert Medical School of Brown University, Providence, RI
- Neil Korsen, MD, MS, Medical Director, Behavioral Health Integration, MaineHealth, Portland, ME
- Alexander Blount, EdD, Professor of Clinical Family Medicine, Director of Behavioral Science, Department of Family Medicine and Community Health, University of Massachusetts Medical School, Worcester, MA
- Jürgen Unützer, MD, MPH, MA, Professor and Chair, Psychiatry and Behavioral Sciences, University of Washington; Director, AIMS Center, Seattle, WA
- Saul Levin, MD, MPA, CEO and Medical Director, American Psychiatric Association, Arlington, VA

Comments on CTAF Draft Report		
	Comment	**Response**
Macaran A. Baird, MD, MS, Professor and Head, UMN Department of Family Medicine and Community Health, Minneapolis, MN		
1	My caution about your current draft is that much other work has been done by others to distinguish specific types of integration that adds value to primary care and does generate significant benefits in cost and quality especially when one considers the cost and quality impact of non-integrated and fragmented care. One recent source of relevant information has been assembled by the Patient-Centered Primary Care Collaborative (PCPCC) in their 2015 report "The Patient-Centered Medical Home's Impact on Cost and Quality". That report points to the need to integrate behavioral health into primary care effectively to show the benefits. It is somewhat more optimistic than your report as currently stated but is consistent with many your overall findings and recommendations including the need for changes in the reimbursement model away from fee-for-service. Showing the cost benefit has much to do with viewing the larger picture of health care costs that accelerate when care is fragmented vs integrated.	Thank you for your comments and the PCPCC report reference. We agree about the need to integrate behavioral health into primary care effectively to realize the benefits, and our policy recommendations based on the policy expert interviews and policy roundtable discussions at the CTAF and CEPAC meetings include moving away from FFS. We agree that the economic impact of behavioral health integration must consider its effects on total health care costs, and we used this perspective in seeking such evidence from available economic evaluations.
Roger Kathol, MD, CPE, President, Cartesian Solutions, Inc., Burnsville, MN		
1	While the literature review was extensive, there was no attention given to the bigger picture in the report, i.e., 1) that the majority of medical patients with BH comorbidity have no access to BH services and refuse to access standalone BH services; 2) that untreated BH comorbidity in the medical setting is associated with annual doubling of total health costs, 80% of which are for medical services; and 3) that there are now models of BH intervention that demonstrate both clinical and economic value in primary care settings, particularly collaborative care.	Thank you for your comments. We acknowledge that many patients with behavioral health comorbidities have limited or insufficient access to behavioral health services or avoid seeking behavioral health services in specialty settings, and that behavioral health comorbidities are a significant contributor to total health spending. These points are emphasized in the background (Section 1) of the final report, as well as the policy discussion (Section 10). We agree that the vast majority of the literature on the efficacy of BHI is based on the collaborative care model (CCM), and we have reframed the evidence review to the highlight the evidence for the CCM. We agree that there is substantial evidence on the economic value of collaborative care, and this is reviewed extensively in our report. Importantly, as noted in our report, the evidence on cost-effectiveness is more robust than the data on cost savings.

		The final report also makes clear which economic studies focused on collaborative care vs. other models of behavioral health integration.
2	It is apparent that the authors of this report lumped all BHI rather than differentiating value-added BHI for separate consideration. Whether this was because the authors, none of whom come from BH backgrounds, do not understand nor differentiate value-added from non-value-added BHI or just chose to ignore what to informed practitioners at the interface is obvious is uncertain. What is certain is that this report will set back access for medical patients with comorbid BH issues by decades in California and have a negative impact nationally on what many consider a major opportunity to contribute to the Triple Aim as "reformed" health care matures.	We disagree – both the evidence review and comparative value sections make specific mention of targeted uses of BHI (e.g., depression and diabetes). As mentioned above, we now make clear which evidence does and does not pertain to BHI, and the concept of "valued-added" BHI is now mentioned in the summary of the comparative value section.
3	You may wish to read a slightly different take on the ability of BH to contribute to future health in primary care and other medical setting by reading a Chapter from a recently published book on ACOs by several national health care leaders, including a CEO of a major ACO (FP), a Brookings Institute policy physician (internist), a Milliman actuary, an MBA, and myself. It comes to a diametrically opposed conclusion but does not focus on "any BHI." Rather, it looks at those that demonstrate evidence of value for the system. Without moving in the direction of value-added BHI, the system will continue to hemorrhage health care resources, mainly through excess medical spend, since medical patients with ineffectively treated BH (40% of medical patients) demonstrate medical treatment resistance and increased medical complications.	Thank you for the reference. As mentioned above, it is now cited in the comparative value section of the final report.
Jürgen Unützer, MD, MPH, MA, Professor and Chair, Psychiatry and Behavioral Sciences, University of Washington; Director, AIMS Center, Seattle, WA		
1	We strongly suggest revising *Integrating Behavioral Health in Primary Care: A Technological Assessment* to accurately reflect the robust empirical evidence for Collaborative Care and to minimize the chance that a misinterpretation of research findings will undermine support for policies that promote the adoption of Collaborative Care that has been shown to be effective and cost-effective. A common misuse of the rigorous and robust scientific literature for Collaborative Care is to generalize it to other integrated care models that have not been proven to be effective. The implication of this misinterpretation has been the widespread proliferation of non-evidence based integrated care models. *Integrating Behavioral Health in Primary Care: A Technology Assessment* appears to have made the reverse misinterpretation: taking insufficient empirical evidence for other integrated care models and applying it to the effectiveness of the Collaborative Care model. This is a potentially much more harmful misinterpretation because it has the potential to impede policy development that promotes the adoption of the evidence-based Collaborative Care model.	Thank you for your comments. As noted above, in the final report, we distinguish the evidence on collaborative care from other models of BHI in both the evidence review and comparative value sections.
2	Integration and collaboration are NOT the same thing. Collaboration is necessary to improve outcomes, but effective	While terminology in the field is used inconsistently, we agree and conclude in

	collaboration can be achieved with varying levels of 'integration' or colocation. Integration and co-location are not necessary for effective collaboration.	the evidence review that effective collaboration can be achieved with or without co-location.
3	There is little scientific evidence that integrating care in and of itself improves patient outcomes. Thus, it cannot be concluded with confidence that integration alone is sufficient to improve outcomes.	For purposes of our review, we consider the CCM to be an approach to behavioral health integration. As noted above, in the final report, we distinguish the evidence on collaborative care from other models of BHI in both the evidence review and comparative value sections.
4	It is invalid to conclude that Collaborative Care is ineffective because of the lack of scientific evidence for integration generally.	We did not intend to imply that the CCM is ineffective; we hope to have clarified any misunderstandings in the final report.
5	To fully comprehend the nuances of the scientific evidence, it is critical to understand the terminology. Developed by expert consensus, AHRQ defines Collaborative Care as "Multiple providers, with their patients, combine perspectives to understand and identify the problems, opportunities, and treatments…to continually revise the treatment as needed to hit treatment goals". In contrast, it defines integrated care as "Tightly integrated, on-site teamwork with unified care plan as a standard approach to care for designated populations." AHRQ concludes that in the Collaborative Care model, "Significant improvements in symptom severity, treatment response, and remission were consistent across the integration levels." In other words, the Collaborative Care model works, regardless of whether the collaborating providers are co-located and integrated. Your report misinterprets this finding and instead reports a "lack of correlation between level of integration and treatment response." The AHRQ finding that co-location and integration are not correlated with outcomes must not be mistakenly interpreted to mean that the Collaborative Care model is not effective.	As noted above, we did not intend with the draft report to imply that the CCM is ineffective; that should be clear in the final report.
6	A further misinterpretation of the evidence stems from the report's use of the integrated care framework developed by SAMHSA/HRSA. This framework, which remains unpublished in the peer-reviewed scientific literature and has little empirical support, assumes that both collaboration and integration are necessary to improve outcomes. Combining collaboration and integration into a single integration index is contrary to the available evidence and thus, the conclusion that collaboration is not correlated with outcomes is unsubstantiated.	We present the SAMHSA-HRSA CIHS levels as one approach to a conceptual framework in the final report. Because it is the current framework produced and disseminated by the federal agency focused on substance abuse and mental health services, commonly used by practitioners, and has been used to assess clinical evidence such as that summarized in this report, we adopted this framework (described briefly below) as an organizing tool in the evidence review (section 7).
7	Collaborative Care has been proven to more effective than care as usual and to be clinically worth doing at a population level. Integrating behavioral health care into primary health care works	As noted above, we have highlighted the efficacy of the CCM in the final report. In addition, we have a section

	well IF it's done right, and we should focus our collective efforts on putting the right pieces in place to facilitate implementation of evidence based integrated care programs such as Collaborative Care.	specifically focused on components associated with success.
Saul Levin, MD, MPA, CEO and Medical Director, American Psychiatric Association, Arlington, VA		
1	Frequently lexicon issues can stand in the way of progress, creating a lack of clarity in what is being discussed. As the literature suggests, there are four key approaches to integrated care: medical or health homes, accountable care organizations, collaborative care models, and the location of medical services in specialty behavioral health facilities. Our preferred way to discuss the integration of behavioral health in primary care and decrease confusion is to rank or categorize research and evidence for each of the four models. Where there is solid or emerging evidence on a model studied, the elements for the success of this model should be identified and defined. For example, the elements of the collaborative care model (CCM) include: (1) care coordination and care management; (2) regular/proactive caseload monitoring and treatment to target using validated clinical rating scales; and (3) regular consultation for patients who do not show clinical improvement. There is an extraordinary amount of evidence substantiating this very specific model. No other model of integration, or model mislabeled as collaborative care, has this level of evidence. Other models that may have some good evidence of success may or may not have some of the three elements that define CCM. These other models need scientific study and defining. There are over eighty randomly controlled trails substantiating the evidence for the above defined collaborative care model. These studies demonstrate significant improvement across populations, settings, and outcome domains. The CCM evidence also indicates improvement for a variety of mental health disorders (beyond depression and anxiety) as well as for medical comorbidities. There have been numerous cost-effectiveness studies demonstrating that CCM provides good economic value. Unützer found for every dollar spent on the CCM there was a return on investment of $6.50.	Thank you for your comments. As noted above, we agree that BHI can be more effective than usual care and that the evidence is strong for the clinical effectiveness of CCM, and the final report reflects this. We urge researchers and practitioners to work together to develop the evidence base for other integrated care models. As noted previously, the literature on the cost-effectiveness and other economic impacts of CCM is comprehensively reviewed in this report, and the final report better distinguishes CCM from non-CCM approaches.
2	The APA asks that CTAF base its decisions on the available science and not use an unsubstantiated framework. It is the APA's view that it is essential that the CTAF make bright-line distinctions where the evidence supports specific models such as CCM. CCM is population based care, measurement-based care with caseload based review, and integration of psychiatry expertise into primary care. It clearly represents significant improvement and value over usual care.	As noted above, in the final report, we distinguish the evidence on collaborative care from other models of BHI in both the evidence review and comparative value sections.
Rachel Wick, Program Officer – Health Care and Coverage, Blue Shield of CA Foundation, San Francisco, CA		
1	There are a number of issues raised in CTAF/ICER's research that are reflective of what the Foundation has observed among its 10 grantee partners seeking to advance behavioral health integration in local communities across California:	Thank you for your comments.

	There is a strong belief, coupled with emerging practice-based evidence, that behavioral health integration is a critical and effective strategy for improving health outcomes among low-income Californians. The emergence of team-based care models that include a behavioral health professional who can conduct screening, brief intervention, counseling, care coordination and case management is a preferred approach in safety net settings. However, there is concern that the staffing ratios for behavioral health professionals in primary care settings is not yet commensurate with the level of need among the population, due to policy and financing barriers as well as workforce shortages.	
2	The financing of primary care, mental health and substance use services remains silo-ed and separate in California, creating barriers to the growth and expansion of integrated care. Medi-Cal managed care plans have responsibility for the mild to moderate mental health benefit, while counties retain responsibility for the seriously mentally ill. Counties may soon assume responsibility for developing a continuum of substance use treatment services under a pending Substance Use Disorders Services (SUDS) waiver. These financing silos pose challenges to providers at the local or county level who seek to integrate primary care and behavioral health, provide "whole-person care" and manage population health. An August 2014 report, "*State Strategies for Integrating Physical and Behavioral Health Services in a Changing Medicaid Environment*," further elucidates the challenges and potential solutions for states like California that have carved out behavioral health services.	We appreciate the reference to the 2014 report.
3	Improved care coordination is seen as an effective tool for managing across silo-ed financing and delivery systems. However, reimbursement for care coordination and real and perceived barriers related to confidentiality in information sharing across the three disciplines are barriers to more widespread use of care coordination in California. Both legal guidance and provider education are needed to overcome these barriers. A recent Foundation-funded report, "*Opportunities for Whole Person Care in California*," outlines some of these challenges.	We agree and appreciate the reference to the report.
4	Federally Qualified Health Centers, a critical access point for a number of low-income and uninsured Californians, face additional challenges to financing integrated care, including the inability to bill for two visits on the same day and to seek reimbursement for behavioral health services provided by marriage and family therapists. A prospective payment system pilot project is being developed to test an alternative payment methodology for Federally Qualified Health Centers in California, but interim solutions are needed to more broadly address financing and workforce shortages that prevent further integration.	The proposed FQHC pilot project (SB 147, Hernandez) is described briefly in the final report, as is AB 690 to address the MFT billing issue.
5	The racial and ethnic diversity of California's population will require culturally responsive approaches to behavioral health integration that span clinical and community settings. The *Statewide Strategic Plan to Address Mental Health Disparities*, and Community Partners in Care's community-based participatory research on depression care in South Los Angeles and Hollywood-Metro LA offer insights	Thank you for your comments and these references.

	into culturally responsive care and new approaches to integration that should be further explored. In addition to its grantmaking, the Foundation has recently released a report, "*Exploring Low Income Californians and Preferences of Low Income Californians for Behavioral Health Care*," that highlights results from a recent survey by Gary Langer Research and Associates. Its findings are reflective of the evidence on the impact of integration on patient satisfaction, and also demonstrate patients' preference for behavioral health integration.	
Florence C. Fee, JD, MA, Executive Director, No Health without Mental Health (NHMH), San Francisco, CA – Arlington, VA		
1	We urge ICER to consider the rigorous, robust scientific data that demonstrates the distinction between proven, evidence-based models of integrated medical/behavioral care, such as the collaborative care model, and other models of integrated care. The CC model has the most robust data to support its efficacy in improving health outcomes for patients. That essential point did not come across in the draft report. CC substantially improves patient outcomes for depression and anxiety in primary care. And as a nonprofit patient advocacy organization we know how important it is to keep a disciplined focus on outcomes, what is shown to work.	Thank you for your comments. As noted above, in the final report, we distinguish the evidence on collaborative care from other models of BHI in both the evidence review and comparative value sections.
2	Considerable confusion and over-simplification currently exists around the entire topic of behavioral integration in primary care. NHMH has a concern your report may inadvertently add to it, as presently written. However, this report could, on the other hand, go a long way to set an example in the health policy/scientific discussion arena by establishing a framework for discussion where there is strict adherence to rigorous scientific knowledge, precise definitions, and abundant supportive material reference (the latter you already seem to have done). ICER could contribute considerably to debate and discussion by making clear exactly what the term "integrated care" refers to, that is, its accepted consensus in the medical-scientific community, and make clear the distinction between models of integrated care proven effective favorably impacting patient outcomes, and those that do not. In that respect, the collaborative care model is presently in a class by itself showing substantial clinical improvement in outcomes. Your report needs to reflect that reality, and focus on how barriers to its wider scaling can be achieved.	We agree that terminology in the field is not clear, and we have added explanations of what the report means by the terms "behavioral health" and "behavioral health integration". We focused on a subset of the AHRQ definition of behavioral health for our report given time and resource constraints, as well as the large number of individuals affected by depression and anxiety who are treated in primary care. As noted above, the final report reflects the evidence on the clinical effectiveness of CCM.
3	NHMH hopes that in future your Institute may focus on the need for adequate evidence-based collaborative care in the specialty mental health setting. While the seriously mentally ill in this setting are a small population, compared to patients with mild mental disorders, overwhelming data shows significant early mortality rates and long lapses between first symptoms and access to any treatment let alone diagnosis for the SMI. Yet, many of the principles found to be effective in behavioral health integration in primary care may also be applicable in integrating adequate, quality	While the integration of primary care into specialty mental health settings was outside the scope of our initial report, we would consider this topic for future assessments.

	medical care for this patient population in specialty mental health care.	
4	We urge ICER to consider that evidence-based integrated care models such as collaborative care not only have the potential to improve access to evidence-based mental treatment for millions in the U.S., it also importantly has the potential, we believe, to gradually over time eliminate the pernicious social stigma that surrounds mental disorders in our culture today keeping many patients from even seeking treatment. That is why our independent nonprofit is so supportive of the collaborative care model: in simple terms, it gets what works to the patients… who desperately need it.	As noted above, in the final report, we distinguish the evidence on collaborative care from other models of BHI in both the evidence review and comparative value sections.
Comments on CEPAC Draft Report		
Gregory K. Fritz, MD, Professor and Director, Division of Child and Adolescent Psychiatry, Vice Chair, Dept. of Psychiatry and Human Behavior, Warren Alpert Medical School of Brown University, Providence, RI		
1	My only criticism is that I couldn't find a description anywhere making it clear that these data are only dealing with adults in the adult health care arena. It appears that this was taken for granted, as a given. Two concerning assumptions follow: 1) that children's integrated pediatric and mental health needs and consequences are so similar to adults' that adult findings are readily applied to children, or 2) that because the costs of children's health care are small in comparison to adults', it's appropriate to ignore the former for now. In either case, it's problematic in my view—but I think this report should be clear up front as to which rationale is behind ignoring the unique aspects of integrated care as they apply to the pediatric population.	Thank you for your comments. We did not exclude studies in the pediatric population from the review, and several were included. To make this more explicit in the final report, three studies focused on the pediatric population are now specifically highlighted in the evidence review section.
Neil Korsen, MD, MS, Medical Director, Behavioral Health Integration, MaineHealth, Portland, ME		
1	My first comment relates to the choice of the SAMHSA Levels of Integration framework. This is a descriptive but not operational framework that does not capture the details of which components of integrated care are being used. One example of the shortcomings of this framework is that the Collaborative Care model, the most commonly tested model in the studies included in the evidence review, is assigned to multiple different levels in spite of the fact that the underlying model (that includes elements of primary care practice redesign, use of care managers to communicate with patients between visits to monitor treatment and barriers to adherence , and population review by consulting psychiatrists) is much more similar than different. A more functional, operational framework such as the AHRQ Lexicon, might be more useful to identify which elements of integration are included in a given implementation (and to study which elements are predictive of improved outcomes).	Thank you for your comments. We present the SAMHSA-HRSA CIHS levels as one approach to a conceptual framework in the final report. Because it is the current framework produced and disseminated by the federal agency focused on substance abuse and mental health services, commonly used by practitioners, and has been used to assess clinical evidence such as that summarized in this report, we adopted this framework (described briefly below) as an organizing tool in the evidence review (section 7). The AHRQ Lexicon was presented as another approach in the draft report; it is also included in the final report.
2	Another comment related to 'models' is that the various models described in the evidence review are really a variety of local adoptions and adaptations of a few basic approaches to integration:	As noted above, in the final report, we separated out the analysis of the CCM from other models. This should help elucidate where the evidence is

	• Collaborative care model, previously described • Child psychiatry access model, which may include a triage function, a phone consult by child psychiatry, availability of formal psychiatry consultation, and a PCP educational component. • Behavioral health consultant model – an onsite behavioral health clinician who helps manage the practice panel and can be accessed through a 'warm handoff'. Confusion about models and levels would certainly contribute to lack of certainty about effectiveness of BHI in a real life setting.	adequate for BHI vs. where additional evidence is needed. We urge researchers and practitioners to work together to develop the evidence base for other integrated care models.
3	Another concern that I have about the review is the relatively narrow perspective on which outcome measures should be included in looking for evidence of potential benefit of BHI vs. usual care. When we at MaineHealth made the decision to expand our focus from depression in primary care (after more than 5 years of grant funded work using the Collaborative Care model) to behavioral health integration, our goals related to issues broader than clinical outcomes. We knew the literature from Kessler and others about the small percentage of people who are referred to specialty behavioral health settings who even have one visit, so we wanted to improve access to this care by bringing the entry point to behavioral healthcare into a comfortable, familiar place – the primary care office. We also knew from our work with primary care practices on depression that the challenges of access and communication related to behavioral health care were a significant source of frustration in practice. We measure primary care provider satisfaction periodically as part of our program evaluation, and it is very clear that most primary care clinicians are very pleased to have integrated services available. We believe there may be an increase in provider productivity by adding this new member to the team, but have not yet had the access to data or resources to measure that. We intend to do so in the future.	Thank you for raising this important issue. Improving the satisfaction of each member of the care team is integral to improving care for patients and has been reported in uncontrolled observational studies. It has rarely been reported in the randomized trials. The IMPACT trial reported improved provider satisfaction with the intervention using a pre- post-design. It would be helpful to see measures of provider satisfaction and burn out compared in the cluster randomized trials to better gauge the impact of the CCM on provider satisfaction.
4	The issue of cost impact of integration is challenging on a number of levels. You make the very important point on page 72 of the report that a modest increase in cost of care when adding integration may be acceptable (and even desirable) due to the chronic underfunding of both primary care and behavioral healthcare. Even so, as I do the math on the estimated PMPY costs for adding integration to primary care of $33 are very modest. Further, as I read the recent report by Milliman for the American Psychiatric Association, even modest success in the implementation of integration for people with chronic medical illnesses and co-morbid behavioral health conditions would more than offset that small increase. Knowing the lead author of that report and knowing actuaries in general, I suspect that is a conservative estimate of potential savings.	As noted in the comparative value section, there is substantial evidence on the *cost-effectiveness* of BHI, most prominently for collaborative care approaches, but only very limited evidence on *overall cost neutrality or cost savings*. While it may be a common opinion that BHI has the potential to substantially reduce overall costs, this has not yet been demonstrated consistently in published studies.
5	One other point regarding cost effectiveness or cost savings relates to what I think is the potential for integration as it matures. There are populations that have substantial psychosocial components to their health conditions who currently receive low value care. Those	As noted previously, we have revised the final report to suggest that future studies focusing on BHI for targeted or "value-added" populations such as

	groups include people with complex sets of chronic illnesses and socioeconomic challenges, those with common somatic symptoms, and those dealing with common life transitions such as new parents and those at the end of their lives. There will need to be evidence to help us understand how best to target and deliver services, but there is great opportunity to improve health, care and cost effectiveness for these populations. We are not doing very well in their care or outcomes now!	those described here may demonstrate cost savings.
6	One other point relates to limiting the evidence review to randomized controlled trials. I understand that the RCT is considered the gold standard in terms of evidence for testing of the efficacy of a new treatment. My concern about its limitations in looking at impact of integration is that integration is a complex intervention that is substantially impacted by the context into which it is introduced, the degree of success of implementation, and the successful targeting of populations for which it is likely to be helpful. An example is the DIAMOND project in Minnesota. Collaborative care, the most evidence based model of integration, was introduced to a large number of practices. It is my understanding that there is substantial variation in the uptake of the model and in the outcomes achieved from one practice and organization to another. Since the model is the same, that argues that the relevant question is not 'does collaborative care work?' but rather 'in what circumstances and for which patients does collaborative care work?' That question may best be answered by well-designed observational studies and qualitative methods.	We agree that high quality observational data would be a welcome complement to the RCT evidence, and some sections of the report, such as the "Summary of Select Models for BHI", attempt to do so. In the evidence review, we looked for comparative observational data but did not identify any high-quality studies. In order to add to the literature based on more than 90 randomized trials, the observational studies would need to be large, methodologically rigorous comparative studies. For example, we reviewed four publications on the DIAMOND project: 1. Beck A, Crain LA, Solberg LI, et al. The effect of depression treatment on work productivity. *The American Journal of Managed Care.* 2014; 20(8):e294-301. 2. Crain AL, Solberg LI, Unutzer J, et al. Designing and implementing research on a statewide quality improvement initiative: the DIAMOND study and initiative. *Medical Care.* 2013; 51(9):e58-66. 3. Rubenstein LV, Danz MS, Crain AL, Glasgow RE, Whitebird RR, Solberg LI. Assessing organizational readiness for depression care quality improvement: relative commitment and implementation capability. *Implementation Science: IS.* 2014; 9:173. 4. Solberg LI, Crain AL, Jaeckels N, et al. The DIAMOND initiative: implementing collaborative care for depression in 75 primary care clinics. *Implementation Science: IS.* 2013; 8:135. None compared outcomes with CCM to those without CCM although additional results are likely to be published.

Alexander Blount, EdD, Professor of Clinical Family Medicine, Director of Behavioral Science, Department of Family Medicine and Community Health, University of Massachusetts Medical School, Worcester, MA		
1	This study represents an impressive amount of work and analysis. It was carried out with care to represent the field fairly. I was one of the "experts" interviewed for the barriers chapter and found the people I spoke to knowledgeable and very open to whatever I offered. I think they did a nice job of summarizing the information they heard without letting any particular person's unique experience carry too much weight. They offer a balanced qualitative approach to understanding the barriers.	Thank you for your comments.
2	I think in the evidence section, their focus narrowed inappropriately and that their write up, while accurate in what it reports, fails to represent the field fairly. Their focus on disease based RCTs, I believe, needs to be balanced by the same sort of qualitative setting of the context that is used in the barriers chapter.	We have clarified in the evidence review section that we focused on randomized trials and high-quality observational data. Other sections of the final report provide context in terms of background needs and descriptions of high-quality projects. Recommendations 2 in the final report addresses this issue, and the rationale for the recommendation states: While RCTs are an extremely important tool to assessing the comparative effectiveness of different interventions, they may not be possible for most organizations that cannot randomize patients or clinics. RCTs may not adequately capture factors crucial to the successful implementation of integrated programs. Other evaluation approaches, such as high-quality, well-controlled pragmatic trials; approaches using aggregated quality improvement information; or observational studies using both quantitative and qualitative data, can generate compelling clinical and economic evidence and should be pursued by the research and practice communities.
3	It is important to be able to explain one crucial contextual factor in the development of integrated behavioral health, why it is developing so broadly using models for which there is less clinical outcome evidence than there is for other models. In 2003, I published a paper that addressed this question, and the discussion in that paper is apt today, though the data has long since gone out of date. The paper makes the point that there are multiple types of outcomes that are valued in the clinical community (increased access, provider satisfaction, patient satisfaction, improved adherence, cost effectiveness, and cost reduction) to name a few. The stakeholders in the integration of behavioral health integration might be:	Thank you for the reference. Our report includes several of the broader outcomes of interest identified, including patient satisfaction, cost effectiveness, and budget impact. We also recognize and appreciate the various stakeholders mentioned in your comment, and we interviewed individuals with many of these perspectives to formulate the final set of recommendations included in the report.

	• The payers for healthcare, the employers, government health plans and private health plans who believe, with good reason, that targeted behavioral health integration will save on the cost of care. • The advocates of whole person care, those who are committed to the Patient Centered Medical Home as a model for the future of healthcare who have now made the integration of behavioral health a recommendation (PCPCC) or a requirement (NCQA) of PCMH designation. • People committed to access to care for mental health disorders (NAMI, SAMHSA) or substance abuse disorders (SAMHSA for SBIRT). All of these have endorsed the view that the vast majority of people with MH and SA needs will not go to mental health or substance abuse agencies, but will accept care for these in primary care. • Advocates for social justice in access to services. Since Surgeon General Satcher's report on race and culture in MH, the observation that ethnic and racial minorities are less likely to seek or accept services in specialty MH and SA settings, the issue of access and the role of BHI in access for minorities has been highlighted. Minorities prefer to get these services in primary care. • Medical administrators, both physicians and non-physicians, who have to maintain a stable physician/PCP workforce in primary care. The clear advantage in terms of physician satisfaction with their work that BHI confers has been demonstrated making the anecdotal accounts of improved physician retention following BHI quite believable.	
4	Many of these outcomes are easier to achieve than the remission from depression, but they are worth working toward for many practices, health plans, and state agencies, as long as better outcomes for depression also may be possible down the road. More physicians and administrators are finding that primary care without any way to support PCPs as they attempt to address mental health, substance abuse and the myriad health behavior needs they encounter is unacceptable on its face, once another approach is possible. A broader list of valued outcomes and therefore a much broader list of models that are achieving those outcomes would make the field more understandable to those who don't know it.	We look forward to additional high quality observational and randomized studies reporting on these outcomes. The PCMH holds great promise, but little data have been reported specifically on the impact of the BHI component of PCMH models of care. We did explicitly address the issue of minority outcomes in the updated evidence review section. We found little data on provider satisfaction (see response to comment #3 of Dr. Neil Korsen above).
5	Finally, I want to ask that you re-think the use of the SAMHSA-HRSA standard levels. The basic distinctions of the system, coordinated care, co-located care and integrated care, were first used in the paper I mentioned earlier (Blount, 2003). By the time the levels system was put together, they had become a common set of distinctions in the field. What the authors of the levels did not see is that they were explicitly put forward as not being mutually exclusive and therefore not hierarchical. It is not uncommon to find practices in which some aspects are integrated, some are co-located and some are coordinated. These categories are meant to	We present the SAMHSA-HRSA CIHS levels as one approach to a conceptual framework in the final report. Because it is the current framework produced and disseminated by the federal agency focused on substance abuse and mental health services, commonly used by practitioners, and has been used to assess clinical evidence such as that summarized in this report, we adopted

	allow an observer to describe the relationship of medical and behavioral services in a particular service. They do not form a hierarchy of integration for a whole practice.	this framework (described briefly below) as an organizing tool in the evidence review (section 7).
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