

# Effective Health Care Program

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Future Research Needs Paper  
Number 3

## **Future Research Needs for the Integration of Mental Health/Substance Abuse and Primary Care**



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# *Future Research Needs Paper*

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Number 3

## **Future Research Needs for the Integration of Mental Health/Substance Abuse and Primary Care**

**Identification of Future Research Needs  
from Evidence Report/Technology Assessment No. 173**

**Prepared for:**

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## Preface

The Agency for Healthcare Research and Quality (AHRQ) conducts the Effective Health Care Program as part of its mission to organize knowledge and make it available to inform decisions about health care. As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress directed AHRQ to conduct and support research on the comparative outcomes, clinical effectiveness, and appropriateness of pharmaceuticals, devices, and health care services to meet the needs of Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).

AHRQ has an established network of Evidence-based Practice Centers (EPCs) that produce Evidence Reports/Technology Assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care. The EPCs now lend their expertise to the Effective Health Care Program by conducting comparative effectiveness reviews (CERs) of medications, devices, and other relevant interventions, including strategies for how these items and services can best be organized, managed, and delivered.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews are useful because they define the strengths and limits of the evidence, clarifying whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about systematic reviews, see <http://effectivehealthcare.ahrq.gov/reference/purpose.cfm>.

AHRQ expects that CERs will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. In addition, AHRQ is committed to presenting information in different formats so that consumers who make decisions about their own and their family's health can benefit from the evidence.

As part of a new effort in 2010, AHRQ has supported EPCs to work with various stakeholders, including patients, to further develop and prioritize the future research needed by decisionmakers. The Future Research Needs products are intended to inform and support researchers and those who fund research to ultimately enhance the body of comparative effectiveness evidence so that it is useful for decisionmakers.

Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site ([www.effectivehealthcare.ahrq.gov](http://www.effectivehealthcare.ahrq.gov)) to see draft research questions and reports or to join an email list to learn about new program products and opportunities for input. Comparative effectiveness reviews will be updated regularly.

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# Executive Summary

The Effective Health Care Program was initiated in 2005 to provide valid evidence about the comparative effectiveness of different medical interventions. The object is to help consumers, health care providers, and others in making informed choices among treatment alternatives. Through its comparative effectiveness reviews, the program supports systematic appraisals of existing scientific evidence regarding treatments for high-priority health conditions. It also promotes and generates new scientific evidence by identifying gaps in existing scientific evidence and supporting new research. The program puts special emphasis on translating findings into a variety of useful formats for different stakeholders, including consumers.

The full report and this summary are available at [www.effectivehealthcare.ahrq.gov/reports/final.cfm](http://www.effectivehealthcare.ahrq.gov/reports/final.cfm).

## Background

Half of the care for common mental disorders in the United States is delivered in general medical settings.<sup>1</sup> Integrated mental health and general medical care models involve the systematic linkage of mental health and primary care providers and require communication or coordination between providers to meet both the mental and general health needs of the patient.

In 2008, the Agency for Healthcare Research and Quality (AHRQ), commissioned the University of Minnesota Evidence-based Practice Center (EPC) to conduct a systematic review of the literature evaluating the integration of mental health and substance abuse treatment with primary care. The review addressed six key questions (KQ); Table A lists a summary of findings, limitations, and future recommendations.

The report found substantial evidence for improved outcomes through integrated care, although most of the evidence was for treatment of depression in primary care settings. Studies reported positive results for symptom severity, treatment response, and achievement of remission when compared with usual care. The level of integration did not seem to be related to treatment outcomes. Most of the studies addressed the integration of mental health professionals into primary care; few examined the integration of primary care into mental health. The majority of the studies involved older patients. Some studies that found improved outcomes with integrated care have been largely composed of minority populations. The main barriers to a broader use of integrated care include programmatic costs, insurance coverage, and relationships with multiple payers. The U.S. Department of Veterans Affairs (VA) was shown to offer a good model of a sustained program. Key elements of successful models included active support at all levels of the organization and through specific funding.

**Table A. Summary of findings, limitations, and recommendations from the 2008 AHRQ review (modified using table 19 of the original report<sup>2</sup>)**

<b>Key Question</b>	<b>Results of Literature Review</b>	<b>Limitations</b>	<b>Future Research Recommendation</b>
1. What models of integration have been used? What is the evidence that integrated care leads to better outcomes?	<ul style="list-style-type: none"> <li>• Multiple models have been used and most show positive results</li> <li>• Level of integration is not related to outcomes</li> <li>• Most models integrate mental health into primary care; fewer do the opposite</li> </ul>	<ul style="list-style-type: none"> <li>• Most of the evidence is for treatment of depression in primary care settings</li> </ul>	<ul style="list-style-type: none"> <li>• Test explicit variations</li> <li>• Compare integrated care to systematic practice</li> <li>• Expand coverage of mental health problems beyond depression (substance abuse, anxiety, multiple mental illnesses)</li> <li>• Test for fidelity of integration principles, evidence-based intervention, communication among clinicians, followup to what is delivered</li> </ul>
2. To what extent does the impact of integrated care programs on outcomes vary for different populations?	<ul style="list-style-type: none"> <li>• Most of the work has been done with older patients</li> <li>• Some positive results with minority populations</li> </ul>	<ul style="list-style-type: none"> <li>• Little available research on the impact of integrated care on younger populations, rural populations, or for those with serious and persistent mental health conditions</li> </ul>	<ul style="list-style-type: none"> <li>• Who is most likely to benefit from this type of care?</li> <li>• Will this approach work with children and adolescents?</li> <li>• Will this model work in rural settings?</li> <li>• Can such practices afford a health manager?</li> <li>• Is this approach consistent with cultural values of various minority groups?</li> </ul>
3. What are the identified barriers to successful integration and sustainability?	<ul style="list-style-type: none"> <li>• Costs and coverage; multiple payers, each with their own rules</li> <li>• Most practices involved were volunteers; may not be typical of practices in general</li> <li>• Poor payment for care coordinators</li> </ul>	<ul style="list-style-type: none"> <li>• The findings failed to show evidence of the sustainability or generalizability of various integrated models</li> </ul>	<ul style="list-style-type: none"> <li>• More models of integrated payment needed</li> <li>• How generalizable is this practice?</li> <li>• Can consistent patterns of care be sustained?</li> </ul>
4. To what extent did successful integration programs make use of health information technology (IT)?	<ul style="list-style-type: none"> <li>• Minimum use of IT</li> </ul>	<ul style="list-style-type: none"> <li>• Little is known about the use of IT in integrated models of care</li> </ul>	<ul style="list-style-type: none"> <li>• How can IT be better used to support integrated care?</li> <li>• Does the use of IT improve outcomes in integrated care?</li> <li>• Could telephonic mental health consultations be enhanced with integrated IT systems?</li> </ul>
5. What financial and/or reimbursement structure was employed in successful integration programs? Is any specific financial/reimbursement strategy superior to another?	<ul style="list-style-type: none"> <li>• See KQ3</li> </ul>	<ul style="list-style-type: none"> <li>• Little was found on financial models for integrated care</li> </ul>	<ul style="list-style-type: none"> <li>• What is the business case for integration?</li> </ul>

**Table A. Summary of findings, limitations, and recommendations from the 2008 AHRQ review (modified using table 19 of the original report<sup>2</sup>) (continued)**

Key Question	Results of Literature Review	Limitations	Future Research Recommendation
6. What are the key elements of programs that have been successfully implemented and sustained in large health systems?	<ul style="list-style-type: none"> <li>• VA offers a good model of sustained program</li> <li>• Active support at all levels</li> <li>• Special funding</li> </ul>	<ul style="list-style-type: none"> <li>• While the research found overall improvement in health outcomes with integrated care, few studies examined key elements for success</li> </ul>	<ul style="list-style-type: none"> <li>• What elements of integration are vital?</li> <li>• Do the standard elements of successful continuous quality improvement (CQI) implementation pertain here?</li> </ul>

The authors of the 2008 AHRQ review (Evidence Report/Technology Assessment No. 173) identified multiple research gaps and limitations (summarized in Table ES-1), including conditions other than depression or care integration in younger populations. Other gaps included research in rural areas, examination of the use of information technology (IT), and development of financial models. One of the largest gaps was on integrating medical care into mental health care for patients with serious and persistent mental illness.

In February 2010, AHRQ commissioned the RTI International–University of North Carolina at Chapel Hill Evidence-based Practice Center (RTI-UNC EPC) to work with stakeholders to develop a prioritized list of future research needs in this area that would inform researchers, funders, practitioners, advocacy groups, patients, and family members. A structured approach, including the AHRQ population, intervention, comparator, outcome, timeframe, setting (PICOTS) framework, to future research needs prioritization is new: this project, therefore, also served as a pilot for development and testing of methods to conduct such an evaluation. In the future, it is anticipated that all AHRQ-sponsored comparative effectiveness research systematic reviews will contain a documentation of future research needs.

## Methods

We developed a comprehensive list of research gaps from the 2008 report and identified ongoing research projects through searches of relevant databases. We mapped each research project to its corresponding research gap. We conducted a scan of the peer-reviewed literature on integrated care published since 2008 and found that this continues to be a very active research area. We did not update the systematic review but used the literature scan to demonstrate the volume of research activity.

The 10-member stakeholder panel included representatives of advocacy groups, researchers, providers of care, federal government funders of research, and professional organizations. A variety of methods were employed to screen and select stakeholders. When screening stakeholders for participation, we evaluated a broad spectrum of organizations and interest groups, including federal agencies. We used moderated group discussion, email, and online prioritization to solicit input on multiple occasions. We reviewed conflict-of-interest forms. Had a substantial conflict of interest been discovered, the stakeholder would have been considered ineligible for participation on the panel and another stakeholder would have been approached in his or her place. To avoid any unfair advantage resulting from future requests for applications (RFAs) arising from this report, the stakeholders prioritized the final list of gaps individually and were not privy to the final rank order prior to publication of the report for public comment.

We used several methods to prioritize research gaps: a combination of teleconference, online Web meetings, and email. During an initial conference call, the stakeholder group recommended adding several gaps to the initial gaps list. We used an online priority-setting exercise for the initial prioritization. We presented the 10 stakeholder panelists with 40 non-rank-ordered research gaps and asked them to rate the gaps twice, using different methods. First, stakeholders were asked to use a 1-5 Likert scale of “importance” to indicate whether each gap was of low or high priority for future research, and second, we provided an online forced prioritization exercise in which each stakeholder was given a total of 20 “chits” of which a maximum of 5 could be assigned to any one gap. We held a second online meeting to review the initial findings and refine the list. The second round of prioritization also utilized an online exercise. Stakeholders were presented with a nonranked list of 20 gaps and provided a total of 12 chits to assign to gaps, 4 of which could be used for any one gap. The results from the second prioritization exercise formed the basis of the final prioritized list of further research needs. The final list of 13 research needs incorporated all gaps receiving two or more chits from stakeholders. We developed each future research need into a potential future study by specifying potential PICOTS, study design considerations, and, where relevant, power calculations.

We evaluated potential study design considerations for each of the prioritized future research needs against specific criteria such as stage of research, generalizability, feasibility, cost-effectiveness, and ethics. For instance, we suggested demonstration pilots for studies that require preliminary data on acceptability and feasibility before considering large studies or trials. We considered case studies where testing is necessary across multiple settings. When outcomes are available from claims data, we suggested secondary data analysis as a cost-effective method of using existing data to study identified outcomes. When controlled trials may be infeasible due to high costs and administrative difficulty, we suggested observational studies. We suggested randomized trials when practical and feasible for studies examining the efficacy of one treatment or system compared with another. We determined trial feasibility by conducting power analysis and examining the practicalities of clustered randomization, contamination, setting, and timeframe. A general discussion of sample size considerations in these practice-based studies was developed. Meta-analysis was considered when existing trials could be combined.

## Results

The following is the final prioritized list of future research needs, derived from an initial list of 40. Research priorities are listed from 1 to 13. The first three topics had the same amount of enthusiasm by the stakeholders and share the position of top future research need. The research gap, as defined by the authors of the 2008 AHRQ report and modified and prioritized by the stakeholders, is presented initially, followed by a restatement as a research need incorporating the population and comparator, when appropriate. Key study design considerations are briefly described. The full report includes full descriptions of the PICOTS and additional study design considerations, which include advantages and disadvantages of approaches to addressing the research need. A rationale for each future research need is included in Appendix A.

**Research Need #1.** What are effective methods of integrating primary care into specialty mental health practice settings? Studies would include both mental and general health outcome(s) (e.g., obesity and depression).

**Among adults with serious mental illness seen in specialty mental health settings, what are effective methods of integrating primary care components such as preventive interventions and chronic disease management, into their mental health care, compared with referral to primary care?**

**Study Design Considerations.** We could envision several study designs to enhance understanding of integration of primary care into mental health.

- Demonstration pilots to determine the acceptability and feasibility of this type of integrated care.
- Use of claims data with propensity matched controls and difference-in-difference models as a low-cost approach to assessing patient-level outcomes.
- Prospective observational studies with control for clinic and patient characteristics, although with the expected challenges of the need to control for case mix and practice environmental differences between settings.
- Randomized trials of integration of primary care into specialty mental health practice will require randomization at the level of the practice, with analysis using clustered methods. Randomization at the level of the individual would likely be administratively infeasible. The primary unit of analysis in such studies would be at the patient level.

**Research Need #2. Effectiveness of cross-cutting models/strategies for integration of mental health into primary care.**

**Can the same personnel successfully provide integrated mental health services to primary care patients who may have any one of several mental health diagnoses, such as depression, anxiety disorder, or problem drinking, and will this lead to different outcomes when compared with separate programmatic initiatives?**

**Study Design Considerations.**

- Studies of the feasibility and fidelity of cross-cutting integrated care will be case studies. Are integrated care principles in a cross-cutting framework acceptable and feasible for practices, providers, and patients in several primary care settings?
- Once feasibility is established, studies of the efficacy of the cross-cutting approach can employ randomized trials, with the practice site as the unit of randomization. Depending on the comparator used (usual care vs. diagnosis-specific care), the required sample size would be either moderate or very large (see power analysis, pp. ES-11, 21).

**Research Need #3. Studies examining the use of information technology (IT) including text messaging, use of the Internet, and effective use of electronic health records for integrated mental health care and general medical health care.**

**Among adults or children with mental health diagnoses seen in primary care, what is the effect of using IT to provide integrated mental health care, compared to integrated care without the use of health care IT, on clinical outcomes, costs, and patient and provider satisfaction?**

**Study Design Considerations.** We could envision several study designs to enhance understanding of the use of information technology in the integration of mental health care into primary care.

- Demonstration projects at a limited number of sites could be used to assess the feasibility of such interventions.
- Randomized trials or observational studies with a contemporaneous control group. The practice would need to be the unit of randomization. Randomizing patients within a practice would likely not be possible due to administrative complexity and possible contamination of the control patients.
- If the comparison arm is integrated care without health IT components, the effect on outcomes would likely be modest. This would necessitate a very large sample size, on the order of 12,000 patients.

**Research Need #4.** Studies examining sustainability of integrated care without external support, such as grant funding. Integrated care can be delivered with special grant funding but are there ways of supporting it following or in lieu of grant funding?

**In primary care practices that successfully integrate mental health care, what practice and program characteristics are associated with program sustainability in the absence of grant funding?**

**Study Design Considerations.** Case studies of both successes and failures to sustain integrated care.

- Both qualitative and quantitative information could be used. Qualitative information might include interviews with practitioners, administrators, and payers. What led them to continue with the program after the end of the initial grant or contract? Which components were sustained and why? Quantitative information needed includes the financial aspects of the grant that the integrated care system started with, as well as documentation of any internal transfers that are occurring after the end of the grant.
- If data were available, larger secondary analyses could be conducted of integrated care systems. An example might be examination of VA systems or state mental health systems if they had sufficient variability across practices.

**Research Need #5.** Studies examining the dissemination of successful models/strategies into community settings. How can efficacious interventions be incorporated into everyday practice in the face of weak incentives and competing medical priorities?

**What factors facilitate the adoption of integrated mental health care models into community-based primary care practices serving adults or children with mental health diagnoses?**

**Study Design Considerations.**

- One approach would be to re-conduct randomized trials of integrated care in community settings including smaller practices, private practices, and rural practices. Such study replication would be expensive, and integrated care has already been demonstrated to be effective in multiple trials.

- Studies examining the fidelity of the integrated care intervention would be qualitative and organizational.
- Given that relatively little research has been conducted to date on integration of primary care into specialty mental health practice, studies examining the generalizability of those models may be premature pending additional efficacy studies.
- Since the studies are largely qualitative and organizational, the main focus will be on lessons learned from implementation in community settings. What are the common adaptations necessary for successfully implementing integration practices in the community setting? Several case studies will be needed for each type of practice. Given the variety of settings and populations, at least 8-12 practices will need to be examined. Small or rural practices may need to adapt integrated care interventions to their circumstances, and documentation regarding how interventions change will be useful to the practitioner community.

**Research Need #6. Studies examining effective models/strategies of integrated or “bundled” payment for integrated care. Are there effective ways of combining primary care reimbursement mechanisms with reimbursements for mental health care services?**

**Among primary care or specialty mental health practices employing integrated care services, what is the effect of bundled payment systems on the costs of services compared with nonbundled fee-for-service payment?**

**Study Design Considerations.**

- Randomization at the level of the practice would be ideal but may be organizationally difficult.
- The most feasible study design will be an observational study comparing organizations that are using bundled payment with those that are not. Organizations that are early adopters of bundled payment may be systematically different from later adopters.
- Description of types of payment could be based on figure 13 from the 2008 AHRQ review<sup>2</sup> (Appendix B), although this framework may need to be modified as new payment systems are developed.

**Research Need #7. Studies identifying the effectiveness of various components of integrated care, and determining the value added by each component individually and synergistically. What are the efficacious elements of integrated care?**

**Among patients with mental health diagnoses seen in primary care practices, what is the effectiveness of components of integrated care services when compared with each other or with programs incorporating multiple components of integrated care, in leading to improved mental health outcomes?**

**Study Design Considerations.** A number of study designs could be considered to answer this question.

- Randomized trials could be designed to test various components in a 4-cell matrix of integrated care but this would be expensive given the variety of approaches and individual components in question. The differences between the intervention and

comparison groups are likely to be modest, necessitating large sample size, up to 80 practices and 12,000 patients (see power analysis). Descriptive case studies may be a more feasible option to identify successful and unsuccessful integration components. Both qualitative and quantitative information could be used. Qualitative information would include interviews with practitioners, patients, and administrative staff to discern which program elements were vital to success, considering cost and administrative complexity.

- As with research need #5, the main focus will be on lessons learned from successful implementation. Sample sizes will not need to be large but different types of interventions will need to be examined.

### **Research Need #8. Cost-effectiveness of integrated models from the societal perspective.**

**Among adults or children with mental health diagnoses who receive integrated care in either primary care or specialty mental health practices, how does the cost-effectiveness of care compare with that of nonintegrated care?**

#### **Study Design Considerations.**

- A cost-effectiveness analysis conducted from the societal perspective using the cost per quality-adjusted life year (QALY) as the outcome measure. Depression-free days (or its counterpart for other conditions) can be cross-walked to QALYs. Cost per QALY could be assessed using incremental cost-effectiveness ratios, the net benefits framework, cost-effectiveness planes, and acceptability curves. Clinical characteristics of the patients should extend beyond depression. Cost-effectiveness of the integrated care intervention may vary depending on the case mix and severity of the mental health problems addressed.
- The “societal perspective” in this case may be close to the perspective of the insurer, but a true societal perspective will also include assessments of indirect costs, such as cost of time off work and disability payments.

### **Research Need #9. Studies examining the business case for integration.**

**When a practice or system invests in integrated care staffing and services, what are the revenues generated, and what are the effects on downstream costs, such as hospitalization?**

**Among primary care or mental health specialty practices that implement integrated care programs for adults or children, what revenues are generated, and what costs are borne by the practice, including costs and revenues related to hospitalizations?**

#### **Study Design Considerations.**

- This research need requires observational studies. Given the variability in integrated care and the patient populations treated, adequate description of the intervention and patient case mix will be critical. The business case may be more readily achieved among patient populations who are more severely mentally ill, because they are the highest-cost patients.

- The number of cases for study will likely need to be at least 8, in order to assess variability across practice size, patient case mix, and type of organization. If great variation in business case results is found, more case studies may be needed.

**Research Need #10. Effectiveness of measurement-based integrated care for case identification, treatment, and monitoring, focusing on mental health conditions other than depression.**

**Among adults with common mental health diagnoses other than depression seen in primary care practices using integrated mental health care, what is the additional benefit, if any, of measurement-based care (use of valid short instruments) with regard to the identification of mental health problems and mental health clinical outcomes?**

**Study Design Considerations.**

- These studies presuppose that short screening and measurement tools exist for diagnoses such as anxiety disorders, posttraumatic stress, and others.
- Clinical outcomes for the patients would need to be assessed using valid instruments, but the treating clinician would need to remain masked to the study instrument outcomes in order to prevent contamination of the comparator group. Ethical and practical issues of such masking will be significant design issues.
- Intervention would need to be at the level of the practice, not the provider, in order to avoid contamination of the comparator group.
- Randomized trial design, with the randomization occurring by practice, would be optimal.

**Research Need #11. Effectiveness of integrated care for patients with dual Medicaid and Medicare.**

**Among adults with mental health diagnoses who are dually insured by Medicare and Medicaid and seen in primary care or mental health practices, what is the effectiveness of integrated care on clinical outcomes when compared with usual care (i.e., referral), and how does this relative effectiveness of integrated care compare to the relative effectiveness of integrated care for adults with mental health diagnoses who are not dually insured by Medicare and Medicaid?**

**Study Design Considerations.**

- Subgroup analysis of dual eligibles could be conducted within a larger trial or observational study. Ideally the population of dual eligibles would be defined in advance and intended as a subgroup question. The difficulty with such studies is having enough power to answer a secondary question.
- A meta-analysis of subgroup data across existing trials has the advantage of providing adequate power by pooling data from different sources including small inadequately powered studies.
- Secondary analysis of large datasets offers a potentially efficient and cost-effective method of studying integrated care for patients with dual Medicaid and Medicare eligibility. Datasets might include national comorbidity data, Substance Abuse and Mental Health Data Archive (SAMHDA), and linked Medicare and state Medicaid data sets.

Research Need #12. Effectiveness of integrated care in the presence of both general medical comorbidities such as diabetes or chronic pain, as well as mental health comorbidities, such as depression and anxiety.

**Among patients with serious mental health conditions and general medical and/or mental health comorbidities, what is the effectiveness of integrated care compared with usual practice on receipt of guideline-concordant care and on mental health and general medical patient outcomes?**

#### **Study Design Considerations.**

- One of several potential designs would be subgroup analysis within a larger trial or observational study, ideally powered to answer the secondary question.
- A meta-analysis of subgroup data across several trials could answer this question and has the advantage of providing adequate power by pooling data from different sources including small studies. Whether the component studies could support such a meta-analysis would need to be assessed.
- Secondary analysis of large datasets offers a potentially efficient and relatively low-cost method of studying integrated care for patients with dual comorbid mental and general medical conditions. Drawing information on medical conditions from an electronic medical record would also have efficiency advantages.
- Randomized trials would require randomization at the level of the practice, with analysis using clustered methods. The primary unit of analysis in such studies would be at the level of the patient. Sample size would depend on the size of any practice effects and on the outcome measure used. Observational studies with control for clinic and patient characteristics are another option, but with the challenge of case mix adjustment.

Research Need #13. Effectiveness of the medical home as a model/strategy for integrated care.

**How does the effectiveness of the primary care medical home model compare with that of integrated care models for patients with mental health conditions in primary care and specialty mental health practices?**

#### **Study Design Considerations.**

- A scan of gray literature on the topic might be helpful because the concept of medical home is relatively new as a model for integrated care.
- Surveys of current PCMH accredited practices could be conducted, comparing their activities with those of primary care practices using integrated mental health care principles. If the PCMH practices are not addressing mental health issues, then conducting a study comparing the outcomes would not be very productive. Cross-walking the principles of care management will be very useful, because similar practices may use different terminology.
- Only after the first several steps are taken will it be wise to conduct cohort studies comparing the outcomes of patients with depression or other mental health diagnoses seen in PCMH with those of patients seen in integrated care practices that do not consider themselves PCMH. Randomization would very difficult given the complexity of PCMH accreditation.

Power analyses were conducted based on several hypothetical designs for cluster randomized trials that would fit one or more of the research needs outlined in this report. The objective was to determine the approximate numbers of practices and patients needed in order to have power of 0.80 to detect a clinically meaningful difference in outcomes with a two-tailed test at a significance level of 0.05. Various assumptions were used for the treatment effect size and the amount of variation between sites in the treatment effect. For a comparison of mental health outcomes in primary care practices, assuming an effect size of 0.3 and an intraclass correlation of 0.05, the required sample size would be about 500-700 patients and 40-80 practices, with at least 6-17 patients per practice (depending on the number of practices). For trials designed to test the effects of interactions between person-level characteristics and the treatment effect (as in research need #11 on dual eligibles), the required sample sizes may be larger than those reported above. The study team recommends that for any new trial being contemplated, the investigators conduct a separate, detailed power analysis specific to the proposed study.

## Conclusions

This pilot engaged stakeholders, developed a process for prioritizing future research, and developed a framework for considering the most feasible study designs to employ for each identified research need. We identified 13 potential future research projects in the area of integrated care and developed study design options within the PICOTS framework. Because many of the future research need topics can be addressed through use of more than one study design, many more than 13 studies could be derived from this priority list. We have illustrated the advantages and disadvantages of approaches in the sections on study design considerations.

Our findings suggest that future research in the area of integrating mental health and primary care should first focus on (a) identifying methods of integrating primary care into specialty mental health settings; (b) identifying cross-cutting strategies for integration across multiple mental health diagnostic categories as opposed to a separate strategy for each diagnostic category; and (c) examining the use of information technology for integrating mental and general medical health care. Other important priorities for future consideration include examining the sustainability of successful integration models, identifying methods of disseminating integration programs into various settings, examining the business case for integration as well as methods of payment, assessing the cost-effectiveness of integration, and identifying key components of successful strategies. The importance of sustainability and economic justification for integrated care strategies was a theme throughout the prioritization process and in conference calls with the stakeholders. The literature and the stakeholders indicated that the efficacy of integrated care has been established; however, its ability to be sustained in everyday practice remains to be proved, and will in part depend on the level of incentives and support provided through payment system reform, as well as the ability of the practices to provide the care efficiently.

Although our final list of 13 research need statements was substantially reduced from the original list, when we mapped the research needs back to the 2008 analytic framework, the needs posed related to a range of elements of integrated care in mental health as described in the 2008 AHRQ report including screening, integration of providers, formation of teams, followup, and patient issues.

Our examination of sample size as one of the key study design considerations was useful. Some of the research gaps could be addressed relatively inexpensively through secondary data analysis or through case studies of 8-16 practices. Other questions, however, will require prospective data collection and large sample sizes. The need for very large sample sizes

necessitates consideration as to whether the importance of the question is worth the large investment in research funding and effort.

Challenges included focusing stakeholders on the specific gaps and coming to agreement on an initial list of gaps. Stakeholders tended to redefine the questions asked in the report or sometimes posed questions that were outside the scope of the original systematic review. Stakeholders tended to define some gaps very broadly and others narrowly. This led to variability in the scope of the initial drafts of the future research needs. The decision to split or group research needs required much discussion. We felt that a relatively specific description of research needs was best; broad research aims or goals may be difficult to operationalize in the PICOTS framework. Nesting specific needs under broad headings may be an alternative approach but this presents technical challenges for online prioritization, since stakeholders may interpret such nested lists differently. At the end of the process, we still had a large number of identified priorities. Given this large number of potential projects, we did not develop any “value of information” analyses; this would have substantially lengthened the project and probably not have provided substantial new information.

The level of public and policy interest in this area will necessitate continued relatively rapid translation of these research gaps into studies and then to policy implementation.

## Background

Mental health problems are among the most common problems encountered by primary care providers.<sup>3</sup> Half of the care for common mental disorders in the United States is delivered in general medical settings.<sup>1</sup> Primary care providers commonly diagnose and manage conditions such as dysthymia, major depressive disorder, problem drinking, and anxiety disorders. Multiple challenges exist in delivering high-quality mental health care in primary care settings.<sup>4</sup> The quality of the care delivered in the primary care setting may vary: providers may have difficulty making referrals when needed to mental health professionals; the supply of mental health professionals may be inadequate in some areas; and patients may be reluctant to see a second provider. Patients with serious and persistent mental illness such as schizophrenia are often seen predominantly in specialty mental health settings yet often have substantial unmet general health needs including obesity, diabetes, and cardiac risk factors, sometimes exacerbated by medication treatment of their mental illness.<sup>5</sup>

“Integrated care” is one approach to addressing these currently unmet needs. In integrated care models, there is systematic linkage of mental health and primary care providers requiring communication or coordination between providers to meet both the mental and general health needs of the patients.<sup>2</sup> The exact nature of the consultation and collaboration varies greatly across models, and may include telephonic or information technology. Often, a mental health professional is placed, permanently or intermittently, in the primary care practice. A key difference is that the integration implies a much closer and more coordinated system of care than prior consultation or referral models. Also key is the involvement of a second health care professional, which distinguishes integrated care from interventions that train primary care providers to treat patients with mental health conditions without the involvement of a mental health professional.

In 2008, the Agency for Healthcare Research and Quality (AHRQ), working with the University of Minnesota Evidence-based Practice Center (EPC), conducted a systematic review of the literature evaluating the integration of mental health and substance abuse treatment with primary care. The review addressed six key questions. A summary of the 2008 report’s conclusions, findings, limitations, and future recommendations is listed in Table 1.

The Minnesota EPC authors found 33 trials examining the impact of integrating mental health specialists into primary care; 26 trials addressed depression. The studies reported positive results for symptom severity, treatment response, and achievement of remission when compared with usual care. The level of care integration did not seem to be related to treatment outcomes. The EPC authors also reported that the level of integration did not appear to be related to outcomes. Most of the studies addressed the integration of mental health professionals into primary care; few examined the integration of primary care into mental health. A majority of the studies have involved older patients, and some positive studies, having found improved outcomes with integrated care, have been largely composed of minority populations. The main barriers identified to a broader use of integrated care include programmatic costs, insurance coverage, and relationships with multiple payers. The VA was felt to offer a good model of a sustained program. Key elements of successful models included active support at all levels of the organization and specific funding.

**Table 1. Summary of findings, limitations, and recommendations from the 2008 AHRQ review (modified using table 19 of the original report<sup>2</sup>)**

<b>Key Question</b>	<b>Results of Literature Review</b>	<b>Limitations</b>	<b>Future Research Recommendation</b>
1. What models of integration have been used? What is the evidence that integrated care leads to better outcomes?	<ul style="list-style-type: none"> <li>Multiple models have been used and most show positive results</li> <li>Level of integration is not related to outcomes</li> <li>Most models integrate mental health into primary care; fewer do the opposite</li> </ul>	<ul style="list-style-type: none"> <li>Most of the evidence is for treatment of depression in primary care settings</li> </ul>	<ul style="list-style-type: none"> <li>Test explicit variations</li> <li>Compare integrated care to systematic practice</li> <li>Expand coverage of mental health problems beyond depression (substance abuse, anxiety, multiple mental illnesses)</li> <li>Test for fidelity of integration principles, evidence-based intervention, communication among clinicians, followup to what is delivered</li> </ul>
2. To what extent does the impact of integrated care programs on outcomes vary for different populations?	<ul style="list-style-type: none"> <li>Most of the work has been done with older patients</li> <li>Some positive results with minority populations</li> </ul>	<ul style="list-style-type: none"> <li>Little available research on the impact of integrated care on younger populations, rural populations, or for those with serious and persistent mental health conditions</li> </ul>	<ul style="list-style-type: none"> <li>Who is most likely to benefit from this type of care?</li> <li>Will this approach work with children and adolescents?</li> <li>Will this model work in rural settings?</li> <li>Can such practices afford a health manager?</li> <li>Is this approach consistent with cultural values of various minority groups?</li> </ul>
3. What are the identified barriers to successful integration and sustainability?	<ul style="list-style-type: none"> <li>Costs and coverage; multiple payers, each with their own rules</li> <li>Most practices involved were volunteers; may not be typical of practices in general</li> <li>Poor payment for care coordinators</li> </ul>	<ul style="list-style-type: none"> <li>The findings failed to show evidence of the sustainability or generalizability of various integrated models</li> </ul>	<ul style="list-style-type: none"> <li>More models of integrated payment needed</li> <li>How generalizable is this practice?</li> <li>Can consistent patterns of care be sustained?</li> </ul>
4. To what extent did successful integration programs make use of health information technology (IT)?	<ul style="list-style-type: none"> <li>Minimum use of IT</li> </ul>	<ul style="list-style-type: none"> <li>Little is known about the use of IT in integrated models of care</li> </ul>	<ul style="list-style-type: none"> <li>How can IT be better used to support integrated care?</li> <li>Does the use of IT improve outcomes in integrated care?</li> <li>Could telephonic mental health consultations be enhanced with integrated IT systems</li> </ul>
5. What financial and/or reimbursement structure was employed in successful integration programs? Is any specific financial/reimbursement strategy superior to another?	<ul style="list-style-type: none"> <li>See KQ 3</li> </ul>	<ul style="list-style-type: none"> <li>Little was found on financial models for integrated care</li> </ul>	<ul style="list-style-type: none"> <li>What is the business case for integration?</li> </ul>

**Table 1. Summary of findings, limitations and recommendations from the 2008 AHRQ Review (modified using Table 19 of the original report<sup>2</sup>) (continued)**

<b>Key Question</b>	<b>Results of Literature Review</b>	<b>Limitations</b>	<b>Future Research Recommendation</b>
6. What are the key elements of programs that have been successfully implemented and sustained in large health systems?	<ul style="list-style-type: none"> <li>• VA offers a good model of sustained program</li> <li>• Active support at all levels</li> <li>• Special funding</li> </ul>	<ul style="list-style-type: none"> <li>• While the research found overall improvement in health outcomes with integrated care, few studies examined key elements for success</li> </ul>	<ul style="list-style-type: none"> <li>• What elements of integration are vital?</li> <li>• Do the standard elements of successful continuous quality improvement (CQI) implementation pertain here?</li> </ul>

The authors of the 2008 AHRQ review reported on a number of gaps/limitations (summarized in Table 1, reproduced from the original report). Several gaps identified little prior research in conditions other than depression or examined care integration in younger populations. Other gaps included little research in rural areas, little examination of the use of information technology, or little development of financial models. One of the largest gaps was the paucity of research on integrating medical care into mental health care for patients with serious and persistent mental illness.

In February 2010, AHRQ commissioned the RTI International–University of North Carolina at Chapel Hill Evidence-based Practice Center (RTI-UNC EPC) to work with stakeholders to develop a prioritized list of future research needs in this area that would inform researchers, funders, practitioners, advocacy groups, patients, and family members. A structured approach, including the AHRQ population, intervention, comparator, outcome, timeframe, setting (PICOTS) framework, to future research needs prioritization is new: this project therefore also served as a pilot for development and testing of methods to conduct such an evaluation. In the future, we anticipate that all AHRQ-sponsored comparative effectiveness research systematic reviews will contain a documentation of future research needs. In this report, we use the term “research gap” to indicate gaps from the report, the work with the stakeholders, and the RTI-UNC team review of the report; we used the identified gaps to generate “research needs,” including definitions of key study design issues such as PICOTS, and methods considerations such as feasibility and sample size.

# Methods

## Identifying Research Gaps from the 2008 AHRQ Review

Investigators from the RTI–UNC EPC initially examined the original 2008 AHRQ systematic review and contacted the authors for collaboration and advice. The original table of research gaps contained in the 2008 report was supplemented with research gaps identified in the text of the original report.

## Identifying Recently Published and Ongoing Studies

We conducted a scan of the literature published on integrating mental health with primary care since 2008 (search strategy in Appendix C) and found an active research area, with 942 relevant citations, 70 of which were found to be relevant publications likely to have met inclusion criteria for the original report (Appendix D). Publications were identified through searches of Medline, Cochrane, CINAHL, and PsycINFO. We used the literature scan to demonstrate activity in the field within the research gaps identified by the 2008 report. Titles and abstracts identified were dually reviewed, and each eligible study was assigned to a research gap from the 2008 report.

Ongoing research projects were identified through searches of clinicaltrials.gov, NIH REPORTER, HSR PROJ, and the Public Welfare Foundation grants database. In addition, as part of the US Department of Health and Human Services, the Health Resources and Services Administration (HRSA) Web site was searched for relevant ongoing studies, as were the following National Institutes of Health (NIH) Web sites: National Institute of Mental Health (NIMH), National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Cancer Institute (NCI), National Institute on Drug Abuse (NIDA), and the Clinical and Translational Science Awards (CTSA) consortium. Each research abstract was dually reviewed by the RTI-UNC EPC investigators and staff to determine relevance to the area of integrated care in mental health and subsequently mapped to the research gap it might fill.

We did not present the stakeholders with the results of the literature search prior to the priority-setting exercises, since we had not assessed the quality of individual studies and the strength of the new evidence and were not therefore in a position to determine if recent evidence has filled research gaps identified in the 2008 report.

## Prioritizing Research

We used several methods to prioritize research gaps: a combination of teleconference, online web meetings, email, and web-based prioritization exercises (Appendix E). We convened stakeholders during two meetings, conducted two online prioritization exercises, and received additional feedback by email.

We provided stakeholders with the 2008 report and asked them to focus on the 19 identified gaps from that report. During this process of prioritization, we asked the stakeholders to consider their knowledge of the field, the original 2008 AHRQ review, AHRQ's Effective Health Care Program selection criteria for new research proposed by the AHRQ Scientific Resource Center (Appendix F),<sup>6</sup> and the matrix of integration levels outlined in Appendix G. For additional consideration, we also provided stakeholders with a list of ongoing research projects

in the area of mental health and integrated care, identified by the initial research gap the study might be able to fill (Appendix D). During an initial conference call discussing the purpose of the project, the stakeholder group discussed the initial list of research gaps. The EPC had also identified additional gaps from the text of the report that were not fully reflected in the table. The stakeholder group recommended several additional gaps for consideration that we subsequently added to the list, bringing the total number of gaps to 40 (Appendix H). We felt that this number was too many to be useful as a “priority list,” because of potential overlap in topics that might have led to vote-splitting, variation in types of priorities, and magnitude of topics. We conducted an online priority-setting exercise where we presented the stakeholder panel with the 40 non-rank-ordered research gaps and asked them to rate the gaps twice, using different methods. First, we asked stakeholders to use a 5-point Likert scale of “importance” to determine whether each gap was of low or high priority for future research, and second, we provided an online forced prioritization exercise where we assigned each stakeholder a total of “20 chits,” of which a maximum of 5 chits could be assigned to any one gap.

We held a second call/Web meeting (using GoToMeeting<sup>®</sup> technology) to review the initial findings and refine the original list. Based on results from the first prioritization exercise and discussions from the second call, we refined the list of 40 gaps further and reduced it to a total of 20 gaps. We eliminated some gaps that had received zero or only one vote as low priority areas, and combined and reworded others for greater clarity. We shared these modifications with the stakeholders. Appendix F lists the final list of 20 gaps that were carried forward for stakeholder prioritization.

The second round of prioritization also utilized an online exercise. The Likert scale exercise was found to have minimal usefulness in prioritizing gaps; the stakeholders indicated that almost all of the gaps were of moderate or high importance. Although this finding did reassure us that we had identified important gaps, the Likert scale was not useful in distinguishing among the gaps and was not employed for this second round of prioritization. Instead, stakeholders were presented with an online, nonranked list of 20 gaps and provided a total of 12 chits to assign to gaps, 4 of which could be used for any one gap.

The results from the second exercise formed the basis of the final prioritized list for development as future research needs. The final list of 13 gaps incorporated all gaps chosen two or more times by stakeholders. Each was developed as a potential future study with PICOTS and an outline of study design considerations.

## **Engaging Stakeholders, Researchers, and Funders**

The RTI–UNC team worked with AHRQ and the authors of the 2008 review in the identification and recruitment of stakeholders, including advocacy groups, researchers, providers of care, federal government funders of research, and professional organizations. We developed and refined a list of stakeholders and recruited them in the first two months of the project. A variety of methods were employed to select stakeholders. These included ensuring representation from a broad spectrum of organizations and interest groups, and engaging stakeholders with a range of perspectives. One major innovation with this effort of stakeholder engagement is the presence on the stakeholder panel of federal agencies as research funders. On two occasions, the first individual contacted had time constraints or felt they were not the best choice and worked with us to recruit a panel representative elsewhere in their organization. One organization did not respond to several invitations. Several levels of approval needed to take place prior to the federal stakeholders joining the project, perhaps owing to the newness of the initiative.

## **Role of Stakeholders**

The primary role of the 10 stakeholders for this project was to rank order or prioritize research gaps in the area of integration of mental health and substance abuse and primary care from the many gaps identified in the 2008 AHRQ report. Stakeholders informed the original list of gaps, refined the list through a series of discussions and online exercises, and prioritized the final list. To provide the opportunity for input at multiple times and through several mechanisms, we used moderated group discussions, email, and anonymous online prioritization exercises to solicit input.

This working document will be made available by AHRQ for public comment and input.

## **Handling Conflicts of Interest**

Each potential stakeholder completed a conflict of interest form. Forms were reviewed by both the RTI–UNC EPC and AHRQ for potential conflicts of interest. Had a substantial conflict of interest been discovered, the stakeholder would have been considered ineligible for participation on the panel and another stakeholder would have been approached in his/her place. To avoid any unfair advantage resulting from potential future RFAs arising from this report, the stakeholders prioritized the final list of gaps individually and were not privy to the final rank order prior to publication of the report for public comment.

## **Determining Appropriate and Feasible Study Design**

After the stakeholders prioritized the research gaps, the study team developed the future research needs through elaboration of PICOTS (population, intervention, comparator, outcome, timeframe, setting) for each of the 13 prioritized areas. We evaluated potential study design considerations for each of the prioritized future research needs against specific criteria such as stage of research, generalizability, feasibility, cost-effectiveness, and ethics. Study design options were generated and refined over several rounds by the multidisciplinary study team, which included methodologists, analysts, and mental health service researchers, drawing on the expressed priorities generated by the stakeholder group. For instance, we suggested demonstration pilots for studies that require preliminary data on acceptability and feasibility before considering large studies or trials. We considered case studies where testing is necessary across multiple settings. When outcomes are available from claims data, we suggest secondary data analysis as a cost-effective method of using existing data to study identified outcomes. When controlled trials may be unethical or infeasible due to high costs and difficulty enrolling patients we suggested observational studies. We suggested randomized trials when practical and feasible for studies looking at the efficacy of one treatment or system compared with another. Several future research needs could be addressed by more than one study design; we anticipate that the study design implemented could in part depend on study setting, administrative feasibility, and funding availability. Choice of clinical and organizational outcome was derived from the team's knowledge of the literature, experience with similar studies, and judgment as to the most efficient way of addressing the research need. The timeframe chosen for the study was also generated from the team's research experience and knowledge of organizational change in practices. We determined trial feasibility by conducting power analysis and examining the practicalities of clustered randomization, contamination, setting, and timeframe. Meta-analysis was considered where it might be appropriate to combine trials, which would provide a way to perform subgroup analysis on a large sample.

We conducted power analyses based on several hypothetical designs for cluster randomized trials that would fit one or more of the research needs outlined in this report. The objective was to determine the approximate numbers of practices and patients needed in order to have power of 0.80 to detect a clinically meaningful difference in outcomes with a two-tailed test at a significance level of 0.05. Separate analyses were conducted for hypothetical trials with 40, 60, and 80 clusters (i.e., 20, 30, and 40 practices in each treatment arm).

We used various assumptions for the treatment effect size and the amount of variation between sites in the treatment effect. With regard to treatment effect sizes for mental health outcomes in primary care practices, we used the Re-Engineering Systems for Primary Care Treatment of Depression (RESPECT-D) study as a reference point because it used a cluster-randomized design, the study population was similar to the general population of patients with depression, and the intervention was relatively modest in scope.<sup>7,8</sup> In that study, the power analysis was based on an effect size of 0.3, and in fact the authors found 6-month effect sizes of 0.31, 0.29, and 0.35 for depression severity, response, and remission, respectively. (For response and remission, both dichotomous outcomes, odds ratios [ORs] were converted to standardized effect sizes [ESs] using  $ES = \ln(OR)/1.81$ .<sup>9</sup>) Therefore an effect size of 0.3 was assumed for cluster randomized trials comparing the mental health outcomes of integration to those of usual care in primary care practices. This effect size is similar in magnitude to the lower bounds of the 95% confidence intervals for the 3-month and 6-month effects measured in the IMPACT study.<sup>2</sup> It is also smaller than the 12-month effect size of 0.51 reported by Druss and colleagues on the Short Form-36 Physical Component Summary (SF-36 PCS) in their study of integration in mental health specialty practices.<sup>2</sup> Therefore the more conservative effect size estimate of 0.3 was used for medical outcomes in specialty mental health practices as well as for mental health outcomes in primary care practices. A smaller effect size of 0.15 was also used, in order to project the effect on required sample size when the treatment is expected to have lower impact (e.g., when individual components of integration are tested, as in research needs #3 and #7).

In a cluster randomized trial, assumptions about the amount of between-site variation in the treatment effect also influence projections of the required sample size. (Between-site variation in the treatment effect reduces statistical power.) Neither the RESPECT-D trial nor the study by Druss and colleagues reported intraclass correlations (ICCs).<sup>7,8,10</sup> However, unpublished analyses by this study team of secondary data from the Sequenced Treatment Alternatives to Relieve Depression (STAR\*D) study<sup>11</sup> (N=4,041) resulted in ICCs of 0.053 and 0.042, respectively, for baseline Quick Inventory of Depressive Symptomatology-Self Report (QIDS-SR-16) and Hamilton Rating Scale for Depression (HAM-D) scores among patients in primary care clinics, and an ICC of 0.12 for baseline PCS-12 scores among patients in mental health specialty clinics. Therefore, ICCs of 0.05 and 0.12 were used for the power analyses. The ICC of 0.05 represents a small amount of between-site variation, and the ICC of 0.12 is between medium (0.10) and large (0.15).<sup>12</sup> Based on the power analysis findings, we added general notes on sample size to multiple discussions of design considerations in Appendix A. We concluded that several prioritized future research need projects required substantial numbers of both clinics and patients because the intervention effect sizes for those projects were expected to be modest.

# Results

## Prioritization of Research

Interim results, from the two prioritization exercises, are presented in Appendix H. Only research gaps prioritized by the stakeholders two or more times (n=13) were included in the final list. The following is the final prioritized list of potential research studies. We present PICOTS and a summary of study design considerations here; detailed rationales can be found in Appendix A. Although the research priorities are listed from 1 to 13, numbers 1, 2, and 3 had identical levels of enthusiasm from the stakeholders.

**Research Need #1.** What are effective methods of integrating primary care into specialty mental health practice settings? Studies would include both mental and general health outcome(s) (e.g., obesity and depression).

**Population.** Adults with serious mental illness. This may include people with psychotic disorders such as schizophrenia, major depressive disorder, bipolar disorder, and serious anxiety disorders.

**Intervention.** Delivery of primary medical care in the mental health setting, which could include on-site services by a physician's assistant, nurse practitioner, or primary care physician, or a systematic collaborative effort such as case identification through screening, treatment plans developed jointly between providers, and joint decisionmaking in defined roles. An alternative intervention would be provision of some services through health IT, such as telemedicine interventions.

**Comparator.** Usual care, with referral of patients to primary care providers in the local medical community, including referrals to local community health centers.

**Outcome.** Process measures of care including proportion of patients who receive appropriate preventive interventions such as hypertension screening, colorectal cancer screening, lipid screening, and women's health screening. Additional measures include dietary counseling and diabetes screening for people with obesity. Chronic disease process measures include diabetes care management among those with adult onset diabetes mellitus. Process measures should also include evidence of care coordination and specialty referral when appropriate. Patient-centered outcomes could include control of blood pressure in those who have identified hypertension and control of hyperlipidemia among those with severely elevated lipids or diabetes. Health care utilization outcomes include measures such as emergency department visits. Health care quality of life would of course be the most patient-centered outcome and would measure outcomes of both mental health and general medical care. Patient and mental health clinic satisfaction would be secondary outcomes.

**Timeframe.** To evaluate success, a minimum of 1 year of intervention time would be required.

**Setting.** Mental health practices with large numbers of patients with serious mental illness, and with sufficient numbers of patients to justify such on-site care.

**Study Design Considerations.** We could envision several study designs to enhance understanding of integration of primary care into mental health.

- Demonstration pilots may well be needed to determine the acceptability and feasibility of this type of integrated care.
- Use of claims data with propensity matched controls and difference-in-difference models are a relatively low-cost approach to assessing patient-level outcomes.
- Prospective observational studies with control for clinic and patient characteristics are another option, although with the expected challenges of the need to control for case mix and practice environmental differences between settings.
- Randomized trials of integration of primary care into specialty mental health practice will require randomization at the level of the practice, with analysis using clustered methods. Randomization at the level of the individual would likely be administratively infeasible. The primary unit of analysis in such studies would be at the level of the patient. Sample size would depend on the size of any practice effects, because patients are clustered within practices. Sample size would also depend on the outcome measure used.

**Research Need #2. Effectiveness of cross-cutting models/strategies for integration of mental health into primary care.**

**Note:** "Cross-cutting" here indicates care across multiple mental health diagnostic categories (e.g., depression or anxiety disorder), as opposed to a separate strategy for each diagnostic category.

**Population.** Individuals with mental health diagnoses such as anxiety disorder, somatization disorder, problem drinking, or depression, seen in primary care settings using integrated care.

**Intervention.** An integrated approach to mental health care delivery. The same personnel would address multiple mental health diagnoses. The diagnostic and treatment protocols would be specific to each diagnosis, but the systems of screening, case identification, followup, and communication among the members of the care team would be similar across the mental health diagnoses.

**Comparator.**

- A. Feasibility and fidelity studies would not require a comparison group.
- B. Tests of the efficacy of the cross-cutting approach could be conducted with two potential comparison conditions:
  - Use of different personnel for each mental health diagnosis, for example, a separate program, with separate personnel for each diagnosis (depression, problem drinking). This could be called “diagnosis-specific care,” which may not emulate actual practice. Specifically trained non-MD/PhD personnel may have specialized expertise, although the efficiency of the care integration may be an issue.
  - Care as usual, without integration.

**Outcomes.** An initial outcome would be the feasibility of such cross-cutting care. Is it acceptable to the mental health and primary care providers? If the intervention is feasible, next steps would

be assessment of process measures of quality of care. For tests of efficacy, outcomes would include condition-specific clinical outcomes similar to those considered for other integrated care intervention studies. An additional outcome would be an assessment of the costs of cross-cutting integrated care compared to diagnosis-specific care. Costs might be lower when the same personnel are used across diagnoses. Provider and patient satisfaction could also be assessed.

**Timeframe.** Practices would need at least 1 year in order to assess such a cross-cutting care system. For some research questions, such as the feasibility of the cross-cutting care, no run-in period would be appropriate, since the study is intended to evaluate such implementation issues. Studies of cost, however, would be more appropriate after the care systems are established and shown to be effective.

**Setting.** Primary care clinics implementing mental health integration practices.

**Study Design Considerations.**

- Studies of the feasibility and fidelity of cross-cutting integrated care will be case studies. Are integrated care principles in a cross-cutting framework acceptable and feasible for practices, providers, and patients? Testing in several primary care settings would be needed, including large practices such as the VA or closed-panel health maintenance organizations, public settings such as community health centers, and private practices.
- Once feasibility is established, studies of the efficacy of the cross-cutting approach can employ randomized trials, with the practice site as the unit of randomization. Depending on the comparator used (usual care vs. diagnosis-specific care), the required sample size would be either moderate or very large (see section on power analysis below).

**Research Need #3.** Studies examining the use of information technology (IT) including text messaging, use of the Internet, and effective use of electronic health records for integrated mental and general medical health care.

**Note.** These would focus on true interoperability and sharing of information between the primary care and the mental health professionals.

**Population.** Individuals with mental health diagnoses seen in primary care settings using integrated care.

**Intervention.** Use of IT to deliver mental health care to patients seen in primary care settings. Mental health providers would need to be involved in the delivery of care. Sharing of queries among providers and movement of text-based data by the mental health provider into the primary care electronic health record will be an important component of “meaningful use.”

**Comparator.** Integrated care that does not utilize electronic IT.

**Outcome.** Both process and patient-centered measures could be used. Process measures would include the number of patients treated through the intervention per mental health professional, the quality of care provided using standard metrics, the costs of the intervention, and the

satisfaction of providers and staff with the IT intervention. Outcome measures would include the proportion of patients who respond to treatment and the satisfaction of patients with the IT intervention. The precise metrics used would depend on the mental health diagnoses addressed.

**Timeframe.** IT interventions have a substantial learning curve. A minimum of 6 months is generally used prior to examination of the effect of an IT intervention. The duration of the observation should be at least 1 year.

**Setting.** Primary care clinics wishing to utilize integrated care for mental health problems.

**Study Design Considerations.** We could envision several study designs to enhance understanding of the use of information technology in the integration of mental health into primary care.

- Demonstration projects at a limited number of sites could be used to assess the feasibility of such interventions.
- Randomized trials or observational studies with a contemporaneous control group. The practice would need to be the unit of randomization. Randomizing patients within a practice would likely not be possible due to administrative complexity and possible contamination of the control patients.
- If the comparison arm is integrated care without health IT components, the effect on outcomes would likely be modest. This would necessitate a very large sample size on the order of 12,000 patients (see power analysis below).

**Research Need #4.** Studies examining the sustainability of integrated care without external support such as grant funding. Integrated care can be delivered with special grant funding but are there ways of supporting it following or in lieu of grant funding?

**Population.** The unit of intervention and analysis is the integrated care organization, not the patient or the provider. The populations cared for could be either adults or children and the clinics either primary care or specialty mental health in public or private settings.

**Intervention.** Integrated care, either in primary care or mental health settings. It is important that the specifics of the integrated care system be described in order to assess applicability to the user community. The systems of interest would be those that had been able to successfully deliver services for at least 1 year without external grant support. Cost-sharing across settings would be important to document.

**Comparator.** Integrated care systems that after a period of time do not make the transition to sustainability either by continuing to require grant subsidies or by ceasing integrated care operations.

**Outcome.** Successful functioning of the integrated care system. Identification of the organizational characteristics of health care systems and integrated care organizations that successfully deliver services without funding external to the health care system. Specific outcomes might include the percentage of patients continuing to receive integrated care at 1, 3,

and 5 years after funding has ceased; the number of co-located specialists at 1, 3, and 5 years; and patient and provider satisfaction at 1, 3, and 5 years.

**Timeframe.** At least 1 year, but longer-term sustainability will necessitate following practices and programs through several budget cycles, up to 5 years.

**Setting.** Public or private settings.

**Study Design Considerations.** Case studies of both successes and failures to sustain integrated care.

- Both qualitative and quantitative information could be used. Qualitative information might include interviews with practitioners, administrators, and payers. What led them to continue with the program after the end of the initial grant or contract? Which components were sustained and why? Quantitative information needed includes the financial aspects of the grant that the integrated care system started with, as well as documentation of any internal transfers that are occurring after the end of the grant. Such transfers sometimes occur through use of health care organization quality improvement funds.
- If data were available, larger secondary analyses could be conducted of integrated care systems. An example might be examination of VA systems or state mental health systems if they had sufficient variability across practices.

**Research Need #5.** Studies examining the dissemination of successful models/strategies into community settings. How can efficacious interventions be incorporated into everyday practice in the face of weak incentives and competing medical priorities?

**Population.** The unit of analysis is the integrated care practice, not the patient or the provider. The populations cared for could be either adults or children and the clinics either primary care or specialty mental health, in either public or private settings.

**Intervention.** Implementation of integrated care in community settings. The level of integrated care and incentives used to motivate clinicians will need to be documented using a standardized format such as that outlined in Appendix H as derived from the 2008 AHRQ report.

**Comparator.** Any efficacy study including implementation of integrated care in the larger settings of VA facilities and academic practices where most of the published studies have been based. The comparator does not necessarily need to be contemporaneous.

**Outcome.** Fidelity of the intervention to integrated care as developed and implemented in published studies.

**Timeframe.** Implementation for at least 1 year to determine if it is sustainable.

**Setting.** The practices would be community settings such as VA or federally qualified health centers (FQHCs) and private practices that have adopted integrated care.

### **Study Design Considerations.**

- One approach would be to re-conduct randomized trials of integrated care in community settings including smaller practices, private practices, and rural practices. Such study replication would be expensive, and integrated care has already been demonstrated to be effective in multiple trials. Examination of fidelity of implementation in community practices would be substantially less expensive.
- Studies examining the fidelity of the integrated care intervention would be qualitative and organizational.
- Given that relatively little research has been conducted to date on integration of primary care into specialty mental health practice, studies examining the generalizability of those models may be premature pending additional efficacy studies.
- Since the studies are largely qualitative and organizational, the main focus will be on lessons learned from implementation in community settings. What are the common adaptations necessary for successfully implementing integration practices in the community setting? Sample sizes will not need to be large, but different types of interventions will need to be examined: private practices as well as VA/ FQHCs, rural as well as urban, etc. Several case studies will be needed for each type of practice. Given the variety of settings and populations, at least 8-12 practices will need to be examined. Small or rural practices may need to adapt integrated care interventions to their circumstances, and documentation regarding how interventions change will be useful to the practitioner community.

**Research Need #6. Studies examining effective models/strategies of integrated or “bundled” payment for integrated care. Are there effective ways of combining primary care reimbursement mechanisms with reimbursements for mental health care services?**

**Population.** The main unit of intervention would be the organization delivering the integrated care. These could be either mental health services delivered in primary care settings or primary care services delivered in mental health settings. Specialty services such as outpatient cardiology or orthopedic surgery would presumably be excluded.

**Intervention.** Bundled payment for services across mental health and primary care. This may or may not include hospital services.

**Comparator.** Similar organizations using fee-for-service reimbursement. As noted in the 2008 AHRQ review,<sup>2</sup> there is substantial variability in the current payment systems, so adequate characterization of the payment system in the comparator practices will be important.

**Outcome.** Costs of combined services between the intervention and comparator organizations. Ideally, this will include costs to the practice, as well as costs to the organization. This would need to include both the cost per unit of service delivered and the overall costs per patient. Such “bundling” may or may not include inpatient care. The evaluation would also need to examine the quality of the services delivered in order to reassure providers and policymakers that payment bundling did not result in diminished care delivery. Patient and provider satisfaction would be a secondary outcome.

**Timeframe.** Presumably would need at least a 6 month run-in of the bundled payment system prior to initiating the evaluation of the services delivered. Time of evaluation would need to be at least 1 year.

**Setting.** Organizations utilizing integrated care. Given the unique characteristics of payment within the VA, this setting might be problematic, so community mental health settings would be optimal.

**Study Design Considerations.**

- Randomization at the level of the practice would be ideal, but may be organizationally difficult.
- The most feasible study design will be an observational study comparing organizations that are using bundled payment with those that are not. Organizations that are early adopters of bundled payment may be systematically different from later adopters. These factors would need to be addressed in data collection and analyses.
- Description of types of payment could be based on figure 13 from the 2008 AHRQ review<sup>2</sup> (Appendix B), although this framework may need to be modified as new payment systems are developed.

**Research Need #7.** Studies identifying the effectiveness of various components of integrated care, and determining the value added by each component individually and synergistically. What are the efficacious elements of integrated care?

**Population.** Individuals with mental health diagnoses seen in primary care settings using integrated care.

**Intervention.** An integrated approach to mental health care delivery. This should include some communication or coordination between providers to meet both the mental and general health needs of the patient. Each component of the integrated care system should be described in detail and might include such things as case identification through screening and referral, regular team meetings among providers (formal or informal), treatment plan consensus, co-location, joint decisionmaking, and electronic communication between providers.

**Comparator.**

- A. Usual or routine care likely including simple referral of mental health patients to specialty mental health settings.
- B. A similar integrated approach but with one of the key components removed. For example, the intervention might include case identification, co-location, and regular team meetings between providers and the comparator may include just case identification and co-location without regular team meetings.

**Outcomes.** To identify the key components of successful integrated programs, the outcomes of interest should reflect the various components under investigation. In the example above, the importance of team meetings for successful integration could be assessed relative to usual care by comparing the number of patients screened and subsequently treated within the program, as

well as patient-centered health outcomes such as symptom severity, response and remission rates, health-related quality of life, and patient as well as provider satisfaction.

**Timeframe.** This study question requires examining established programs in place for at least 12 months and preferably 3 years or longer.

**Setting.** Primary care clinics implementing mental health integration practices.

**Study Design Considerations.** A number of study designs could be considered to answer this question.

- In theory a randomized trial could be designed to test various components in a four-cell matrix of integrated care but this would likely be expensive given the variety of approaches and individual components in question. The differences between the intervention and comparison groups are likely to be modest, necessitating large sample size, up to 80 practices and 12,000 patients (see power analysis). Descriptive case studies may be a more feasible option to identify program components included/excluded in successful and unsuccessful integration programs. Both qualitative and quantitative information could be used. Qualitative information would include interviews with practitioners, patients, and administrative staff to discern which program elements were vital to success and which were incidental. Cost and administrative complexity of the intervention components are also considerations.
- As with research need #5, the main focus will be on lessons learned from successful implementation. Sample sizes will not need to be large but different types of interventions will need to be examined.

### **Research Need #8. Cost-effectiveness of integrated models from the societal perspective.**

**Population.** Either (a) individuals with mental health diagnoses seen in primary care settings or (b) individuals with medical comorbidities seen in specialty mental health settings. These could include both adults and children, although studies addressing those two populations would likely be conducted separately in each setting.

**Intervention.** An integrated approach to mental and general health care delivery.

**Comparator.** Usual care likely including simple referral of (a) primary care patients with mental health needs to a specialty mental health setting or (b) specialty mental health patients with medical comorbidities to a primary care setting.

**Outcomes.** Costs and clinical outcomes including benefits and harms could be assessed using disease-specific measures such as the cost per depression-free day or the cost per emergency department visit or hospitalization avoided.

**Timeframe.** To adequately evaluate costs, benefits, and harms a minimum of 6 months would be required, but longer time horizons would be preferred. A lifetime horizon is optimal to evaluate all costs, benefits, and harms.

**Setting.** Primary care practices with the capacity to deliver an integrated model of care. As noted above, studies of practices treating adults and children would likely be separate.

**Study Design Considerations.**

- A cost-effectiveness analysis conducted from the societal perspective using the cost per quality-adjusted life year (QALY) as the outcome measure. Depression-free days (or its counterpart for other conditions) can be cross-walked to QALYs. Cost per QALY could be assessed using incremental cost-effectiveness ratios, the net benefits framework, cost-effectiveness planes, and acceptability curves. Clinical characteristics of the patients should extend beyond depression, which has formed the basis of most of the studies in the past. The clinical characteristics of the patients should be assessed, since the cost-effectiveness of the integrated care intervention may vary depending on the case mix and severity of the mental health problems addressed.
- The “societal perspective” in this case may be close to the perspective of the insurer, but a true societal perspective will also include assessments of indirect costs, such as cost of time off work and disability payments.

**Research Need #9.** Studies examining the business case for integration. When a practice or system invests in integrated care staffing and services, what are the revenues generated, and what are the effects on downstream costs such as hospitalization?

**Note.** Studies could take the perspective of the practice, the health care system, or the payer.

**Population.** Practices implementing integrated care. The clinical population could be either single diagnosis, such as depression, or be composed of care for multiple diagnoses such as depression and asthma, diabetes, or congestive heart failure. The population could include adults or children. However, it is important that the population be described in terms of demographics and clinical characteristics so that the generalizability of the research can be assessed.

**Intervention.** Integrated care of patients with mental health diagnoses in primary care, or primary care for patients with mental health diagnoses in specialty mental health clinics.

**Comparator.** No specific comparator needed for this “business case” study, since it is descriptive of how integrated care functions.

**Outcome.** Revenues generated from conducting integrated care minus the expenditures of that care. The revenues generated could be fee-for-service, or could be partial capitation or “gainsharing,” in which a portion of funds saved from reduced hospitalization or emergency department use is returned to the practice.

**Timeframe.** At least 1 year of run in of the integrated care intervention with duration of observation of at least 1 year.

**Setting.** Practices conducting integrated care.

### **Study Design Considerations.**

- As noted above, these are observational studies. Given the variability in integrated care and the patient populations treated, adequate description of the intervention and patient case mix will be critical. The business case may be more readily achieved among patient populations who are more severely mentally ill, since they are the highest-cost patients.
- The number of cases for study will likely need to be at least 8, in order to assess variability across practice size, patient case mix, and type of organization. If great variation in business case results is found, more case studies may be needed.

**Research Need #10. Effectiveness of measurement-based integrated care for case identification, treatment, and monitoring, focusing on mental health conditions other than depression.**

**Population.** Patients with common mental health diagnoses other than depression seen in primary care practices. These might include anxiety disorders (including posttraumatic stress disorder [PTSD]), general/social phobias, and substance dependence (or substance use disorders).

**Intervention.** Identification of the patients and assessment of response to treatment using valid short instruments. Developmental work may be needed to test systems for care managers or others to identify patients. One approach would be to conduct a general mental health screening followed by more condition-specific use of diagnostic instruments.

**Comparator.** Integrated care models that do not use these instruments, in which the primary care clinicians and mental health professionals are reaching diagnoses and assessing progress using clinical judgment.

**Outcome.** Number of patients with the disorders of interest identified. The ability of the practice to monitor their progress, assessed through provider interviews. Valid tools to assess the response of patients to treatment will be needed.

**Timeframe.** At least 1 year. As with most organizational interventions, one would need at least a 6 month run-in time for the practice to gain familiarity with integrated care.

**Setting.** Primary care practices in both the intervention and comparator groups that have already established integrated care programs. The test here is of measurement-based care for these diagnoses when treated in an integrated care practice, not integrated care itself.

### **Study Design Considerations.**

- These studies presuppose that short screening and measurement tools exist for diagnoses such as anxiety disorders, posttraumatic stress, and others. As such tools are developed, integrated care settings are obvious settings for testing.
- Clinical outcomes for the patients would need to be assessed using valid instruments, but the treating clinician would need to remain masked to the study instrument outcomes in order to prevent contamination of the comparator group. Ethical and practical issues of such masking will be significant design issues.

- Intervention would need to be at the level of the practice, not the provider, in order to avoid contamination of the comparator group.
- Randomized trial design, with the randomization occurring by practice, would be optimal.

## Research Need #11. Effectiveness of integrated care for patients with dual Medicaid and Medicare.

**Population.** Dual Medicaid and Medicare patients with mental health diagnoses.

**Intervention.** An integrated approach to mental health care delivery. This should include communication or coordination between providers to meet both the mental and general health needs of the patient.

### **Comparator.**

- A. Usual care likely including simple referral of mental health patients to specialty mental health settings for mental health treatment or from mental health settings to primary care for general medical health treatment.
- B. Nondual eligibles receiving the same integrated approach to mental and general health care delivery. Such patients are likely to be higher socioeconomic status, even if Medicare recipients, and measures to control for these differences will be needed.

**Outcomes.** Process of care outcomes might include number of patients screened for common mental health disorders, number of patients receiving some form of guideline-concordant psychological and/or pharmacologic treatment, number of patients receiving disease-specific mental health education and/or self-management advice, and availability of mental health providers.

Patient-centered outcomes could include symptom severity, response and remission rates, quality of life measures, adherence, and patient satisfaction.

**Timeframe.** To evaluate effectiveness, a minimum of 6 months of intervention time would be required.

**Setting.** Primary care clinics treating dual Medicare and Medicaid patients with mental health diagnoses.

### **Study Design Considerations.**

- There could be several study designs to enhance understanding of integrated care for patients with dual Medicaid and Medicare eligibility. Subgroup analysis of dual eligibles could be conducted within a larger trial or observational study. Ideally the population of dual eligibles would be defined in advance and intended as a subgroup question. The difficulty with such studies is having enough power to answer a secondary question.
- A meta-analysis of subgroup data across existing trials has the advantage of providing adequate power by pooling data from different sources including small inadequately powered studies.

- Secondary data analysis of large datasets offers a potentially efficient and cost-effective method of studying integrated care for patients with dual Medicaid and Medicare eligibility. Datasets might include national comorbidity data, Substance Abuse and Mental Health Data Archive (SAMHDA), and linked Medicare and state Medicaid data sets.

**Research Need #12. Effectiveness of integrated care in the presence of both general medical comorbidities such as diabetes or chronic pain, as well as mental health comorbidities, such as depression and anxiety.**

**Population.** Patients with comorbid serious mental health and general medical conditions seen in primary care. Serious mental illnesses might include schizophrenia and bipolar disorders as well as other psychotic disorders. General medical conditions might include obesity, diabetes, hepatitis C, coronary heart disease, arthritis, hypertension, and chronic obstructive pulmonary disease as some of the more common co-occurring general medical conditions seen in this population.

**Intervention.** An integrated approach to mental health care delivery. This should include communication or coordination between providers to meet both the mental and general health needs of the patient.

**Comparator.** Usual or routine care likely including simple referral of serious mental health patients to specialty mental health settings.

**Outcomes.** Both the mental and general health outcomes would be of interest. Process of care outcomes might include number of patients with chronic conditions screened for common mental health disorders, number of patients receiving some form of psychological and/or pharmacologic treatment, number of patients receiving disease-specific mental health education and/or self-management advice, proportion of NQF quality measures for those conditions achieved, and availability of mental health providers.

Patient-centered outcomes could include symptom severity, response, and remission rates for both the mental and general medical conditions, quality of life measures, adherence, and patient satisfaction. For diabetes, for example, measures would include hemoglobin A1C, blood pressure control to a level of systolic less than 140, and control of low-density lipoprotein levels.

**Timeframe.** To evaluate effectiveness, a minimum of 6 months of intervention time would be required.

**Setting.** Primary care clinics treating patients with co-occurring mental and general medical diagnoses.

#### **Study Design Considerations.**

- There could be several study designs to enhance understanding of integrated care for patients with comorbid mental and general medical conditions. An obvious design would be subgroup analysis within a larger trial or observational study, ideally powered to answer the secondary question.

- A meta-analysis of subgroup data across several trials could answer this question and has the advantage of providing adequate power by pooling data from different sources including small studies. Whether the component studies could support such a meta-analysis would need to be assessed.
- Secondary data analysis of large datasets offers a potentially efficient and relatively low-cost method of studying integrated care for patients with dual comorbid mental and general medical conditions. Drawing information on medical conditions from an electronic medical record would also have efficiency advantages.

Randomized trials would require randomization at the level of the practice, with analysis using clustered methods. Randomization at the level of the individual would likely be administratively infeasible and place the study at risk of contamination. The primary unit of analysis in such studies would be at the level of the patient. Sample size would depend on the size of any practice effects, since patients are clustered within practices. Sample size would also depend on the outcome measure used. Observational studies with control for clinic and patient characteristics are another option, but with the challenge of case mix adjustment and assessment of comorbidity between practice settings.

### Research Need #13. Effectiveness of the medical home as a model/strategy for integrated care.

**Note.** The “medical home” could be a primary care office for many patients, but could also be a specialty mental health practice with elements of primary care integrated to form the medical home.

**Population.** Patients with mental health conditions including depression and anxiety disorder treated in patient-centered medical home (PCMH) practices. Some specialty mental health practices might have characteristics of a PCMH if they are integrating components of comprehensive medical care with the mental health care provided. Patients in specialty mental health practices will be much more likely to have serious mental disorders such as schizophrenia and bipolar disorder.

**Intervention.** The patient-centered medical home. While multiple definitions exist, the NCQA “level 3” certification is commonly accepted as representing an advanced level of care delivery and coordination.

**Comparator.** Two comparator groups could be considered:

- A. Primary care practices that do not consider themselves “patient-centered medical homes” or that are not NCQA-certified as PCMHs. It is highly unlikely that specialty mental health settings currently consider themselves “medical homes;” studies of those settings are most likely to be descriptive.
- B. Usual care in either the primary care or the specialty mental health setting.

**Outcomes.** Determination of the extent to which the PCMH incorporates the principles of integrated care for mental health conditions. Determination of the extent to which specialty mental health practices incorporate PCMH principles into their care. The extent to which quality of care measures are met. Remission of symptoms among patients with mental health diagnoses.

**Timeframe.** An initial study would be cross-sectional, determining whether PCMH practices are in fact delivering integrated care for patients with mental health diagnoses. Studies to determine the effectiveness of PCMHs in treating mental health conditions would need to be conducted for at least 1 year.

**Setting:** Primary care practices that are NCQA PCMH level 3 accredited. Specialty mental health practices that are integrating general medical care into their practices.

**Study Design Considerations:**

- A scan of gray literature on the topic might be helpful since the concept of medical home is relatively new as a model for integrated care.
- Surveys of current PCMH accredited practices could be conducted, comparing their activities with those of primary care practices using integrated mental health care principles. If the PCMH practices are not addressing mental health issues, then conducting a study comparing the outcomes would likely not be very productive. Assuming that they are addressing mental health issues, cross-walking the principles of care management will be very useful, since similar practices may use different terminology.
- Only after the first several steps are taken will it be wise to conduct cohort studies comparing the outcomes of patients with depression or other mental health diagnoses seen in PCMH to those of patients seen in integrated care practices that do not consider themselves PCMH. The initial steps will assist in refining the data elements to be collected and analyzed. Randomization would very difficult given the complexity of PCMH accreditation.

## **Dissemination Gap**

We note one topic that stakeholders ranked as high priority in the initial round of voting but that is not included in the above list: the need for a resource where researchers and policymakers can go to identify existing programs that already show return on investment related to different levels of integration. We excluded this topic from the second round of prioritization because it is not a research topic per se, but we consider the issue to be noteworthy and needed.

## **Power Analysis**

The table below shows the results of power analyses that were conducted based on the assumptions described in the Methods section, using the formulas proposed by Spybrook and colleagues<sup>13</sup> for cluster randomized trials. Where the projected number of patients per practice is greater than 1,000, the number of clusters and the cluster size are omitted from the table.

Between-site variation in effect size	Effect Size	Clusters	Approx. n per cluster	N
0.05	0.3	40	17	680
0.05	0.3	60	9	540
0.05	0.3	80	6	480
0.05	0.15	40	---	---
0.05	0.15	60	---	---
0.05	0.15	80	161	12,880
0.12	0.3	40	---	---
0.12	0.3	60	19	1,140
0.12	0.3	80	9	720
0.12	0.15	40	---	---
0.12	0.15	60	---	---
0.12	0.15	80	---	---

For a comparison of mental health outcomes in primary care practices, assuming  $ES=0.3$  and  $ICC=0.05$ , the required sample size would be about 500-700 patients and 40-80 practices, with at least 6-17 patients per practice (depending on the number of practices). Assuming a smaller effect size ( $ES=0.15$ ,  $ICC=0.05$ ), it would be impractical to conduct a trial (e.g., with 80 practices, such a study would require 161 patients per practice, or a total sample size of 12,880). This is relevant especially for research needs #3 and #7, which could be expected to involve small treatment effects. Power could be increased by adding practice-level covariates or by reducing the between-site variation in the treatment effect. However, a more detailed power analysis would be required, and it would be very important to meet the assumptions specified in the research design phase.

Assuming greater between-site variation in the treatment effect ( $ES=0.3$ ,  $ICC=0.12$ ) also reduces power, but it would still be practical to conduct a trial with about 700-1,200 patients and 60-80 practices, with at least 9-19 patients per practice (depending on the number of practices).

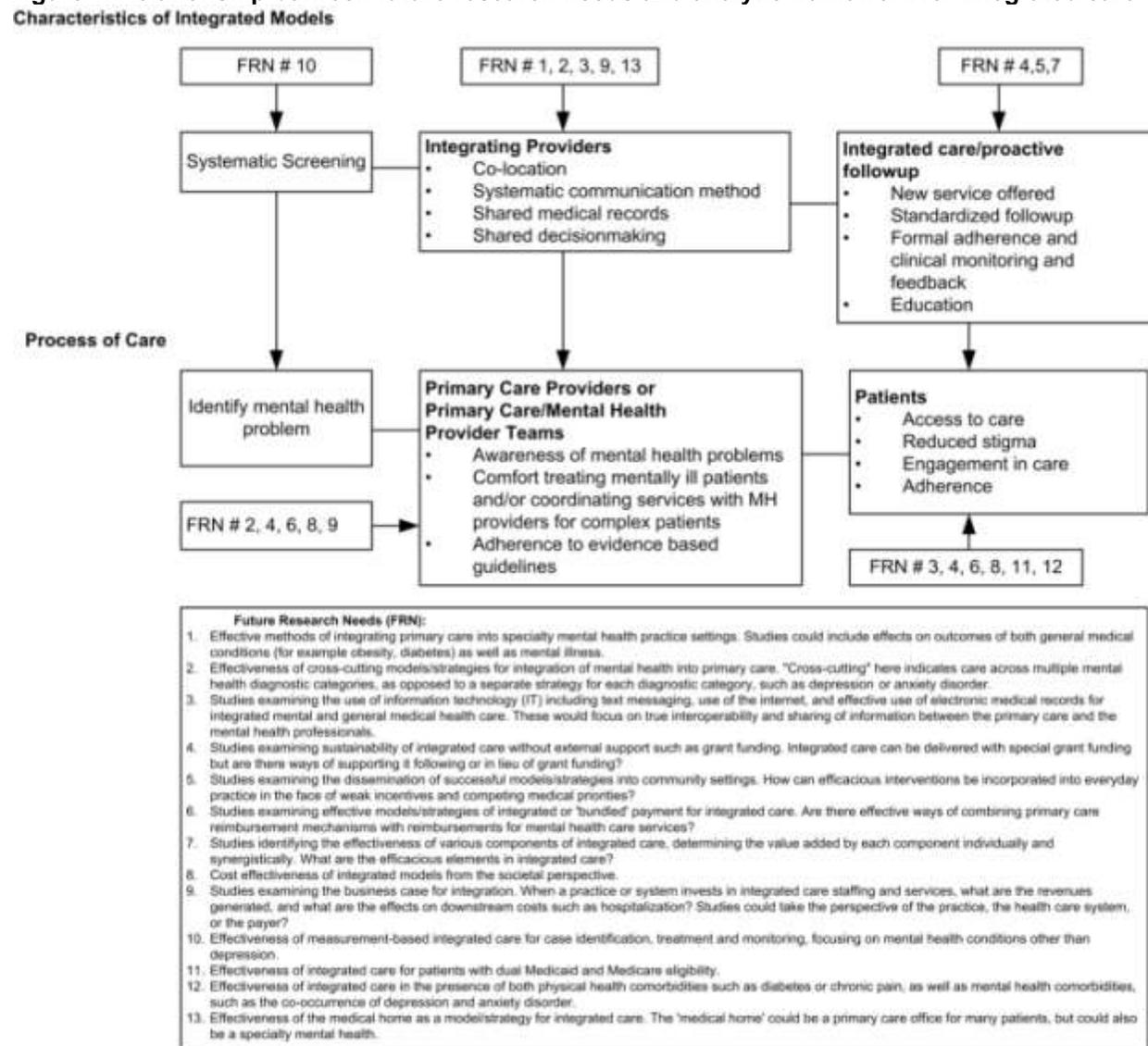
Given the possibility that assumptions may be incorrect, it would be wise for a cluster randomized trial to include at least 60-80 practices if possible, to measure relevant practice-level covariates, and to make every effort to reduce between-site variation in the treatment effect.

The results reported above are intended to convey only general information about the types of study designs that could (or could not) be used to meet research needs. For example, these power analyses do not take into account the testing of interaction effects. For trials designed to test the effects of interactions between person-level characteristics and the treatment effect (as in research need #11 on dual eligibles), the required sample sizes may be larger than those reported above. Because the power calculations for multilevel models involve complicated formulas, simulation may be a preferred method of power analysis for models that include interaction terms or have other complex features. The study team recommends that for any new trial being contemplated, the investigators conduct a separate, detailed power analysis specific to the proposed study.

## Modified Analytic Framework

Using figure 1 from the 2008 AHRQ review (Appendix I) as an analytic framework, we developed a modified framework linking the identified future research needs to specific characteristics and processes of care (Figure 1) Some future research needs related to more than one area.

**Figure 1. Relationship between future research needs and analytic framework for integrated care**



## Discussion

Systematic reviews can rarely answer all aspects of the key questions asked because of gaps in the reviewed research. Traditionally, future research needs are briefly summarized within a review with few concrete recommendations to inform researchers, funders, or policymakers. This pilot project sought to develop a structured approach to future research needs. The primary objective was to clearly identify gaps in a recent AHRQ review and to work with stakeholders to develop a prioritized list of potential future research, develop PICOTS, and discuss study designs for future consideration. The secondary objective was to work through the methods and processes of this pilot task as a means of identifying best practices for subsequent future research needs projects.

Regarding our primary objective, our findings suggest that future research in the area of integration of mental health and primary care should first focus on (a) identifying methods of integrating primary care into specialty mental health settings; (b) identifying cross-cutting strategies of integration across multiple mental health diagnostic categories as opposed to a separate strategy for each diagnostic category; and (c) examining the use of information technology for integrating mental and general medical health care. Other important priorities for future consideration include the sustainability of successful integration models, methods of disseminating integration programs into various settings, the business case for integration as well as methods of payment, the cost-effectiveness of integration, and the key components of successful strategies. The importance of sustainability and economic justification for integrated care strategies emerged as a theme throughout the prioritization process and during our conference calls with the stakeholders. The literature and the stakeholders indicated that the efficacy of integrated care was established; but that its ability to be sustained in everyday practice remains to be proved, and will in part depend on the level of incentives and support provided through payment system reform, as well as the ability of the practices to provide the care efficiently.

Regarding the methods and processes of this pilot project, we specifically focus on the value of processes: stakeholder engagement and sample size analysis. We were gratified by the engagement of the stakeholders, their practical knowledge of the field, and their enthusiasm to advance the science and service delivery to this at-risk population. The stakeholder group was diverse, including advocates, professional representatives, researchers, and funders. They were quite collegial and through their voting indicated a clear ability to set priorities when presented with a large number of options. All stakeholders were sent a copy of the draft report at the same time as it was released for public comment. One possible modification for future projects of this type would be a third set of rankings after the full PICOTS elaboration of the future research needs. This would allow the stakeholders to make more informed choices resulting in a more refined set of priorities, but it would also significantly prolong the project.

Although our initial list of research gaps included lack of information on diagnosis-specific integrated care (such as a specific study on anxiety disorders or problem drinking), the stakeholders did not consider such studies to be priorities. In discussion, they indicated that although the burden of illness caused by anxiety disorders (as an example) is large, the impracticality of implementing multiple condition-specific integration interventions in a single practice decreased the value of conducting such studies. Similarly, the stakeholders highly ranked cross-cutting integrated care interventions, by which multiple types of conditions could

be managed in a practice using the same personnel and procedures. This finding underscores the utility of stakeholder involvement.

Although our final list of 13 research need statements was substantially reduced from the original list, the questions posed related to essentially all components of integrated care in mental health as described in the 2008 AHRQ report (Appendix I), including screening, integration of providers, formation of teams, followup, and patient issues. This distribution was not by design, and the analytic framework was not discussed during the stakeholder conference calls. We were impressed that the stakeholders identified a variety of topics, addressing multiple components of systems of integrated care, as priorities for future research. Because many of the future research need topics can be addressed through use of more than one study design, many studies could be derived from this priority list. We have illustrated the advantages and disadvantages of approaches in the sections on study design considerations. Final choice of study design by a researcher will likely include knowledge of the specific potential study settings, issues of administrative feasibility, time constraints, funds available, and expertise.

Our examination of sample size as one of the key study design considerations was useful. Some of the research gaps could be addressed relatively inexpensively through secondary data analysis or through case studies of 8-16 practices. Other questions, however, will require prospective data collection. At least two research gaps would necessitate comparing interventions which may have only a modest effect size difference between them, such as #3 comparing the addition of information technology to integrated care, or #7 comparing the various components of integrated care. When comparing two active interventions, each better than “usual care,” the effect size found between the two active interventions will generally be smaller than the effect size between the active intervention and usual care. This is a generalizable issue in comparative effectiveness research. When sample size calculations indicate the need for very large samples, a critical question that must be addressed is whether the importance of the question is worth the large investment in research funding and effort.

The following challenges and limitations of this pilot project are worth noting. Initial selection and engagement of stakeholders was often time-consuming, particularly in the case of federal stakeholders for whom several layers of approval were required. This may be a product of the fact that this was a new initiative and now that a process has been established may be less of a factor for future reports. Despite a fairly significant time commitment, stakeholders were not compensated because of concerns regarding conflict of interest. The absence of even modest compensation may become a problem if we need to engage the same stakeholders long-term for a variety of projects. Focusing stakeholders on the specific gaps identified in the report under review was sometimes challenging; there was a tendency to redefine the questions asked in the report or to pose questions that might be out of scope of the systematic review. Agreeing upon an initial list of research needs was also challenging; some needs were very broadly defined while others were quite specific. The decision to split or group research needs required much thought and is a potential limitation to the exercise. The risk, on one hand, is losing important research needs by combining gaps under broad headings; on the other hand, splitting may result in a list too long to be useful for the purpose of prioritizing. We felt that a relatively specific description of research gaps was best; broad research aims or goals may be difficult to operationalize. Nesting specific gaps under broad headings may be an alternative approach but this presents technological challenges for online voting, since stakeholders may interpret such nested lists differently. We began the process of prioritization with a large number (N= 40) of identified research gaps. Although we were able to significantly refine the questions posed by the gaps and

reduce the number of questions through the prioritization process, we still had a large number of identified priorities which we elaborated in a PICOTS framework and discussion of sample size considerations. Given this large number of potential projects, we did not develop any “value of information” analyses; this would have substantially lengthened the project and probably not have provided substantial new information. We did, however, find the evaluations of effect size and sample size to be very useful.

The full report will be posted on the AHRQ Web site and public comments will be collected, including comments from the stakeholders.

## Conclusions

As a pilot project, we engaged stakeholders, developed a process for prioritizing future research, elicited priorities from the stakeholders through an iterative process, and developed a framework for considering the most feasible study designs to employ for each identified research need. We were able to identify 13 potential future research projects in the area of integrated care, with details regarding the study design options within the PICOTS framework. We found that the stakeholders were able to prioritize, but the number of research needs was quite large, leading to limitations in the level of study design detail in this report. The research needs of integrated care in mental health has moved past demonstration of efficacy to address issues of implementation, effectiveness, sustainability, utilization of technology to reduce costs, extension of the successful integrated care models to specialty mental health settings, and to clinical conditions beyond depression. Many of the studies discussed in the research need priority areas, such as the examination of cost-effectiveness and sustainability, can be implemented at modest cost. Key will be conducting the studies in generalizable settings and with early communication with the user community. The level of public and policy interest in this area will necessitate continued relatively rapid translation of these research gaps into studies and then to policy implementation.

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## Abbreviations

AHRQ	Agency for Healthcare Research and Quality
CQI	continuous quality improvement
CTSA	Clinical and Translational Science Awards
EPC	Evidence-based Practice Center
ES	effect size
FQHC	federally qualified health center
FRN	future research need
HAM-D	Hamilton Rating Scale for Depression
HRSA	Health Resources and Services Administration
HSR PROJ	Health Services Research Projects in Progress
ICC	intraclass correlation
IMPACT	Improving Mood Promoting Access to Collaborative Care Treatment
IT	information technology
NCI	National Cancer Institute
NCQA	National Committee for Quality Assurance
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases
NIDA	National Institute on Drug Abuse
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NQF	National Quality Forum
OR	odds ratio
PCMH	patient-centered medical home
PICOTS	population, intervention, comparator, outcome, timeframe, setting
PTSD	posttraumatic stress disorder
QALY	quality-adjusted life year
QIDS-SR-16	Quick Inventory of Depressive Symptomatology - Self Report
RePORTER	Research Portfolio Online Reporting Tools—Expenditures and Results
RESPECT-D	Re-Engineering Systems for Primary Care Treatment of Depression
RFA	request for application
SAMHDA	Substance Abuse and Mental Health Data Archive
STAR*D	Sequenced Treatment Alternatives to Relieve Depression
UNC	University of North Carolina
VA	U.S. Department of Veterans Affairs

## Appendix A. Rationale for Final Prioritized List of Potential Research Studies (Detailing Rationale, PICOTS, and Study Design Considerations)

Research Need #1. What are effective methods of integrating primary care into specialty mental health practice settings? Studies would include both the mental and general health outcome(s) (e.g., obesity and depression).

**Rationale.** This research need was nominated by our stakeholders and also proposed in the 2008 AHRQ review<sup>2</sup> conducted by the Minnesota EPC, which had found few studies addressing integration of primary care into the specialty mental health setting. Our literature scan in the first months of our project also found few such studies published since 2008. The burden of general medical illness in people with serious mental illness is substantial. People with serious mental illness are at greater risk for hypertension, diabetes with complications, hepatitis C, fluid/electrolyte disorders, obesity and early mortality related to cardiovascular disease, and nicotine abuse/dependence. They are also less likely to utilize indicated preventive interventions. Patients with serious mental illness may have difficulty accessing primary care.<sup>3</sup>

Research Need #2. Effectiveness of cross-cutting models/strategies for integration of mental health into primary care. “Cross-cutting” here indicates care across multiple mental health diagnostic categories, as opposed to a separate strategy for each diagnostic category, such as depression or anxiety disorder.

**Rationale.** The 2008 AHRQ report indicated that most of the evidence regarding integrated care had examined treatment of patients with depressive disorders in primary care. Diagnostic and treatment strategies evaluated in the 2008 report were often quite specific to depressive disorders. Other common mental health conditions, such as anxiety disorder, problem drinking, and somatization disorder have been much less studied. The stakeholder group felt that interventions requiring separate therapists or care managers for each of the common mental health disorders seen in primary care would likely be both administratively and financially unfeasible. An alternative strategy would be for the same personnel (M.S.W., Ph.D. psychologist, M.D. psychiatrist, care managers) to treat multiple conditions. Where available, specific evidence-based treatments would be tailored to specific conditions but a common approach would allow for treatment of patients who have more than one mental health diagnosis, such as anxiety and depression. In addition, the practice could gain efficiency through use of common processes for screening, case identification, communication with the mental health professionals, etc. Note that there is a connection between this question and research question #10 on measurement-based care. Valid and brief measures are needed for case identification and assessment of progress for each condition. The components of the cross-cutting strategies would also relate to research question #7 on the utility of components of integrated care.

**Research Need #3.** Studies examining the use of information technology (IT) including text messaging, use of the Internet, and effective use of electronic medical records for integrated mental and general medical health care. These would focus on true interoperability and sharing of information between the primary care and the mental health professionals.

**Rationale.** Our literature scan identified a number of ongoing studies, including the following, using various forms of health information technology in integrated care for mental health problems.

- Telemental Health to Improve Mental Health Care and Outcomes for Children in Underserved Areas<sup>14</sup>
- Effectiveness of a Technology-Assisted Behavioral Intervention in Assisting People With Major Depressive Disorder. Integrated Telemental Health Intervention for Depression in Primary Care<sup>15</sup>
- Feasibility of Depression Care Management by Email. Pilot Trial of Depression Care Management by Electronic Secure Messaging<sup>16</sup>
- Telemedicine Outreach for Post Traumatic Stress in CBOCs (TOP)<sup>17</sup>
- Effectiveness of Telepsychiatry-based Culturally Sensitive Collaborative Treatment of Depressed Chinese Americans<sup>18</sup>
- Adapting and testing telephone-based depression care management intervention for adolescent mothers<sup>19</sup>

The health IT area is rapidly progressing due to enhancements in technology and, especially, Office of the National Coordinator (ONC) initiatives providing substantial financial incentives for providers to install electronic health records and use them to care for patients through “meaningful use.” IT provides an opportunity for integrated care initiatives. This research need is specific to the use of IT as part of integrated care. Interventions by primary care or mental health providers to give IT support to patients through technology would not be considered in this area unless the mental health provider were providing the IT support linked and integrated with the primary care practice. This research question is related to research question #13, which examines the role of the medical home as a model for integrated care. Many medical home models make extensive use of health IT.

**Research Need #4.** Studies examining sustainability of integrated care without external support such as grant funding. Integrated care can be delivered with special grant funding but are there ways of supporting it following or in lieu of grant funding?

**Rationale.** This question is related to research question # 9 on the “business case for integration,” but the study designs and analyses involved may be quite different. Are health care systems willing to support integrated care systems without grant support? What are the characteristics of the integrated care systems that are self-supporting? What are the characteristics of the health care systems that support them? By identifying the characteristics associated with self-sustaining, high-quality integrated care organizations, such efforts may be used to replicate successful integrated care organizations. What distinguishes this question from

the purely financial “business case” question is the recognition that some organizations may value integrated care in mental health sufficiently to support such care even when the business case is not positive. Similarly, some organizations will likely not value integration even when a business case exists.

**Research Need #5: Studies examining the dissemination of successful models/strategies into community settings. How can efficacious interventions be incorporated into everyday practice in the face of weak incentives and competing medical priorities?**

**Rationale.** A critical issue in moving from treatment efficacy to treatment effectiveness is whether the intervention can be applied to the average patient in the average practice. This is a particular issue for integrated care since there may be special challenges in implementing integrated care in many types of practices, such as smaller or more rural practices. Much of the literature has been conducted in larger practices, often in urban areas, or in well-developed health care systems such as the Veteran’s Administration or large HMOs. Integrated care practices may need to be adapted for these other settings, and research is needed to determine the fidelity and effectiveness of these adaptations.

**Research Need #6. Studies examining effective models/strategies of integrated or “bundled” payment for integrated care. Are there effective ways of combining primary care reimbursement mechanisms with reimbursements for mental health care services?**

**Rationale.** According to the 2008 AHRQ report, no reimbursement system has been subjected to experiment so no evidence exists as to which reimbursement system may most effectively support integrated care. However, the recent Affordable Care Act (ACA) will generate multiple policy initiatives involving payment “bundling,” and it encouraged the Centers for Medicare and Medicaid Services to conduct demonstrations as to whether care could be delivered at lower cost with the same improved quality through combined payment across services or over time. Currently, the mechanisms of payment for mental health care are generally fee-for-service, so such bundling would be a significant change for both primary care and mental health practices and practitioners. Policymakers sometimes discuss such payment bundling as one component in the development of “accountable care organizations” (ACOs).

**Research Need #7. Studies identifying the effectiveness of various components of integrated care, and determining the value added by each component individually and synergistically. What are the efficacious elements of integrated care?**

**Rationale.** By definition, integration strategies include multiple components and while integration at large appears to show positive results for symptom severity, treatment response, and remission when compared to usual care, the key elements required for a successful integration program remain elusive. The 2008 AHRQ report found no discernable effect of integration level, processes of care, or combination, on patient outcomes from mental health services in primary care settings. Moreover, on the basis of current evidence, it is not possible to distinguish the effects of increased attention to mental health problems from the effects of specific intervention strategies. This situation calls for studies that assess the efficacy and effectiveness of individual integration components as well as “packages” of components.

Systematic dismantling of successful multi-component interventions would help to isolate efficacious elements. If some components are more expensive or administratively cumbersome to implement, but not essential to the effectiveness of integrated care interventions, then dissemination of integrated care could be simpler and more streamlined.

### **Research Need #8. Cost-effectiveness of integrated models from the societal perspective.**

**Rationale.** The cost-effectiveness of integrated mental and general health care was nominated by our stakeholders as a priority question for future research. The 2008 AHRQ review did not specifically address cost-effectiveness as a key question but reported on its implications in relation to the business case for integration (see research question #9). The Department of Veterans Affairs, used as a case study in the AHRQ report, found collaborative care interventions to be cost-effective based on a meta-analysis of over ten cost-effectiveness analyses. The AHRQ report however, did not look at this question across populations or settings and suggested that questions remain unanswered regarding whether targeting high-risk cases (based on medical comorbidities and/or the presence of medical complexity) produces greater cost-effectiveness.

There is good reason to consider cost-effectiveness from a variety of perspectives including payer and patient. In addition, a societal perspective estimates all gains and losses, reflecting the effectiveness and potential harms of an intervention as well as its direct and indirect costs.

**Research Need # 9. Studies examining the business case for integration.** When a practice or system invests in integrated care staffing and services, what are the revenues generated, and what are the effects on downstream costs such as hospitalization? Studies could take the perspective of the practice, the health care system, or the payer.

**Rationale.** The “business case” for integration focuses on the operational costs of the integrated care at the practice or the health care organization level. The business case analysis is financial and does not examine patient health status, functioning, or employment status. Such patient-centered outcomes are considered in cost-effectiveness analyses.

Many of these business case issues are highly dependent on local practices and financial arrangements. For example, if a practice implements integrated care and reduces ER and hospital costs, but receives little or no increase in fee-for-service or bundled compensation for this effort, the practice will have no “business case” if it is the business entity at risk. The business case for the practice will be dependent on the amount of fee-for-service or case-based reimbursement for the mental health services provided, minus the cost to the practice of providing those services. A practice might not receive any savings from the avoided ED visit, specialty visits, and hospitalizations. A somewhat different perspective would be to conduct a business case analysis for the overall care organization: primary care practice, hospital, and specialists considered as a single entity. These analyses could be conducted in coordination with study question #4 on sustainability of integrated care. The focus in that question is on organizational factors, but examination of financial “business case” factors could be conducted at the same time and in the same practices.

**Research Need #10. Effectiveness of measurement-based integrated care for case identification, treatment, and monitoring, focusing on mental health conditions other than depression.**

**Rationale.** A significant aid to integrated care in depression has been the availability of brief instruments (e.g., Patient Health Questionnaire) to screen for depression and assess progress over time. Short instruments which can be administered by nonspecialist personnel are critical given the time- and resource-constrained environment of primary care practice. The stakeholder panel emphasized the importance of integrated care models that treated the multiple mental health problems seen in primary care practices; a different system for each diagnosis was felt to be impractical for most primary care settings. The use of short diagnostic and assessment instruments may seem intuitive, but each instrument must be validated as well as assessed for its usability in daily practice.

**Research Need #11. Effectiveness of integrated care for patients with dual Medicaid and Medicare eligibility.**

**Rationale.** The 2008 AHRQ review asked to what extent the impact of integrated care programs on outcomes varies for different populations.<sup>2</sup> They found that most work had been done with older patients and found some positive results with minority populations. The review concluded that existing literature remains unclear as to who is most likely to benefit from integrated care. Our stakeholders highlighted patients with dual Medicaid and Medicare eligibility (dual eligibles) as a population for whom research is needed to determine whether integrated care is effective.

The nine million dual eligibles nationwide are a vulnerable and costly group. They tend to be poor and report lower health status than other beneficiaries, and cost Medicare about 60% more than nondual eligibles.<sup>20</sup> Among dual eligibles, approximately 60% of the disabled and 20% of the elderly have mental disorders.<sup>21</sup> In addition, dual eligibles are three times more likely to be disabled and have higher rates of diabetes, pulmonary disease, stroke, and Alzheimer's disease.

**Research Need #12. Effectiveness of integrated care in the presence of both general medical comorbidities such as diabetes or chronic pain, as well as mental health comorbidities, such as depression and anxiety.**

**Rationale.** This question was addressed in the 2008 AHRQ review under their key question 2: To what extent does the impact of integrated care programs on outcomes vary for different populations?<sup>2</sup> The review found that only depression research had examined the possibility of improved medical condition outcomes as a result of integrated care and proposed randomized controlled trials, demonstrations, and qualitative studies to examine which groups of patients are most likely to benefit from integrated care. Our stakeholders highlighted the population of mental health patients with comorbid general medical conditions as a population of particular interest in primary care. A recent AHRQ topic development project explored this question as part of a larger treatment review for patients with comorbid general medical and mental health diagnoses and has been put forward by AHRQ for topic refinement. Given the upcoming AHRQ review, future research should perhaps focus on other, less common, mental health conditions also seen in primary care. Patients with serious mental illness such as schizophrenia and bipolar disorders may present first in primary care. This population typically has comorbid general

medical conditions. There is currently very little research on the effectiveness of integrated care for these individuals.

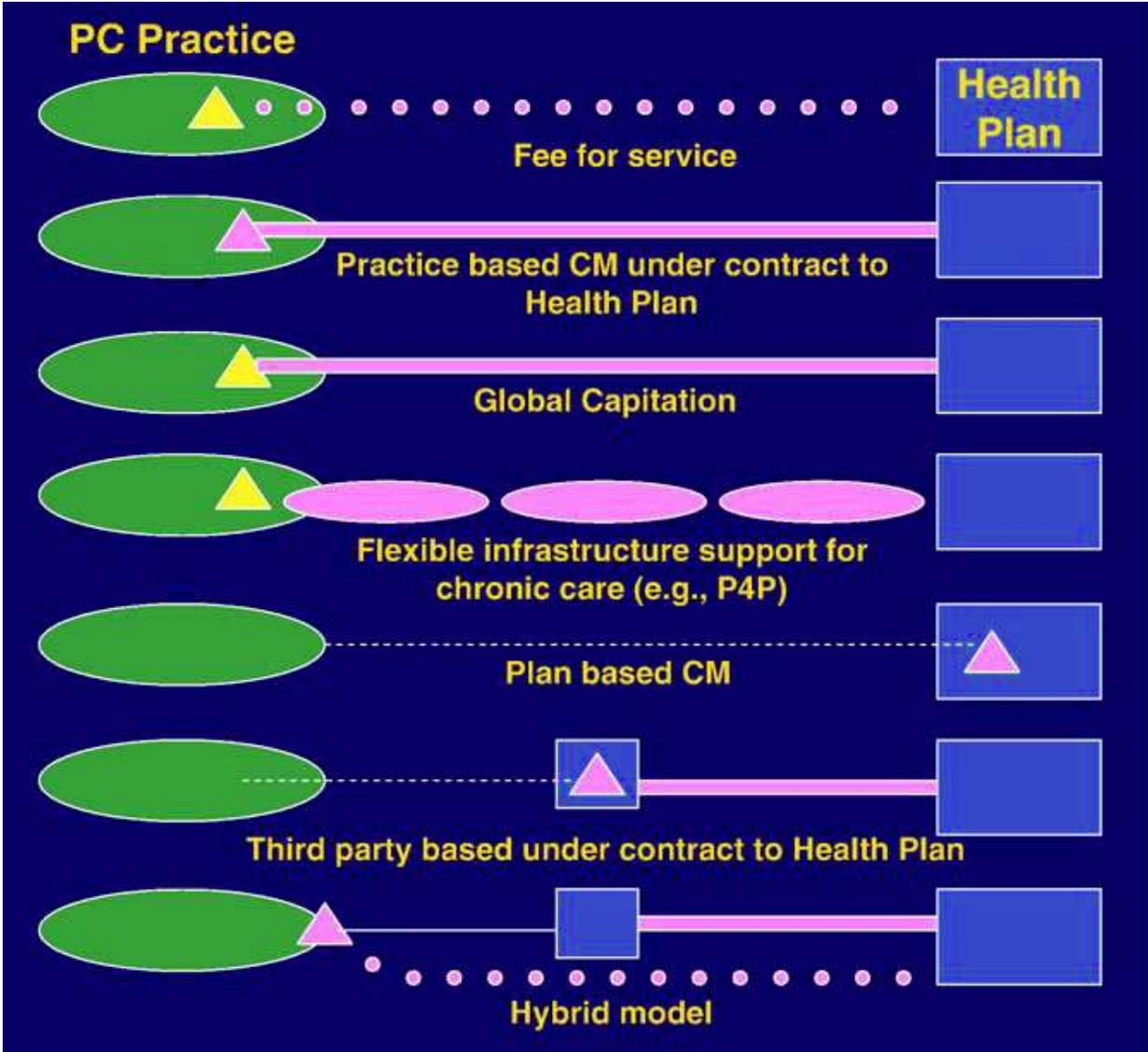
**Research Need #13. Effectiveness of the medical home as a model/strategy for integrated care.** The “medical home” could be a primary care office for many patients, but could also be a specialty mental health practice with elements of primary care integrated to form the “medical home.”

**Rationale.** This research need was nominated by our stakeholders and is also present in the 2008 AHRQ review.<sup>2</sup> The AHRQ review found that most models integrate mental health into primary care; fewer do the opposite. Our literature scan in the first months of the project also found few studies published since 2008 on the topic of integrated care in specialty mental health practices. A number of states have adopted the concept of the medical home and Medicare has proposed demonstration projects to test the effectiveness of the medical home concept. Under the terms of a Medicare demonstration project, volunteer practices would receive a special payment to serve as a medical home.

A number of definitional issues need to be considered in relation to the idea of the medical home, particularly in terms of the overlap with integrated care, co-location, collaboration, care management, and patient-centered care.

“Medical home” (often called the “patient-centered medical home,” or PCMH) as a model for integrated care is in the early stages of definition and implementation. First steps could involve an environmental scan to identify (a) the key elements of “medical home” as a strategy for integrated care, (b) primary care where “medical home” has been implemented through integration of mental health care into primary care, and (c) mental health specialty practices where “medical home” has been implemented through integration of primary care into mental health specialty practice and sustained as a model for integrated care. Additionally, an examination of the evidence on “medical home” as a strategy for integrated care would identify answers to questions such as (1) who is most likely to use this type of care, (2) who is most likely to benefit from this type of care, (3) should “medical home” as a strategy be directed at all persons with identified mental illness (or are certain mental illness diagnoses like depression more effectively addressed in this manner compared to other diagnoses such as schizophrenia or bipolar disorder), (4) how does “medical home” as a strategy for integrated care vary by patient severity, (5) how does “medical home” as a strategy for integrated care vary by setting, and (6) what is the evidence for feasibility of integrated care models and medical home models in rural areas, where there is lack of or limited availability of mental health and primary care professionals? We recognize that the answers to many of these targeted questions above may not be known, but they would further inform the refinement of the PICOTS.

**Appendix B. Methods for Paying for Care Management**  
 (figure 13 from Bachman et al., 2006<sup>22</sup>)



## Appendix C. Search Strategy for Ongoing Trials and Publications Since Release of the Original 2008 Report

**Search for new publications.** We began by updating the search strategy recorded in the original AHRQ review. This was translated from OVID-Medline to PubMed. We created an EndNote library with the main literature search topic—the intersection of integrated health care, primary health care concepts, and mental health concepts—to determine how many of the 61 references selected by the authors of the 2008 review were retrieved with the converted strategy. It should be noted that the investigators manually searched the references of all systematic reviews, which we did not replicate. The converted search was performed on February 7, 2010, in PubMed with the following results:

The total for the main topic (the intersection of integrated health care, primary health care concepts, and mental health/disorder concepts) (“Main Topic”): 6,863 references

- a. Main Topic, limited to quantitative study types: 2,744
- b. Main Topic, limited to qualitative study types: 223
- c. Main Topic, limited to quantitative study types, and English language: 2,500
- d. Main Topic, limited to qualitative study types, and English language: 213
- e. Main Topic (6,852), limited to English language: 6,085
- f. Main Topic, limited to “systematic reviews” subset in PubMed, OR Review publication type: 1,099
- g. Main Topic, NOT one of the qualitative or quantitative study types searched above (“The Rest”): 3,469

These 3,469 remainder articles (g) were combined with sets c, d, and f, and duplicates removed, for a grand total of 6,085.

When limited to publication dates from October 2007 to the present, the totals were:

- h. Main Topic, limited to quantitative study types, English language, and publication date limit: 510
- i. Main Topic, limited to qualitative study types, English language, and publication date limit: 70
- j. Main Topic, limited to “systematic reviews” subset in PubMed, OR Review publication type, and publication date limit: 210
- k. Main Topic, NOT one of the qualitative or quantitative study types searched above (“The Rest”), and publication date limit: 488

Results in sets h, i, j, and k were combined for a total of **1,030** citations. We remodeled the search to take advantage of appropriate MeSH and minimize the use of keywords. This should result in a lower-yield and more targeted search. The converted search, using MeSH when available, was performed on February 4, 2010, with the following results:

The total for the main topic (the intersection of integrated health care, primary health care concepts, and mental health concepts) (Main Topic): 3,387 references

- a. Main Topic, limited to quantitative study types: 983
- b. Main Topic, limited to qualitative study types: 428
- c. Main Topic, limited to quantitative study types, and English language: 935
- d. Main Topic, limited to qualitative study types, and English language: 409
- e. Main Topic (3,387), limited to English language: 3,101
- f. Main Topic, limited to “systematic reviews” subset in PubMed, OR review publication type, and English language: 501
- g. Main Topic, English language, NOT one of the qualitative or quantitative study types searched above (“The Rest”): 1,945
- h. Main Topic, limited to quantitative study types, English language, and published 2007-present: 272
- i. Main Topic, limited to qualitative study types, English language, and published 2007-present: 154
- j. Main Topic, limited to “systematic reviews” subset in PubMed, OR review publication type, English language, and published 2007-present: 137
- k. Main Topic, English language, NOT one of the qualitative or quantitative study types searched above (“The Rest”), and published 2007-present: 298

Results from e (Main Topic, limited to English language) were rerun in PubMed on February 8, 2010, and the results increased by two citations for a total of **3,103**.

Results from h, i, j, and k were combined and duplicates removed, for a grand total of **652**.

Analogous searches were run in the following databases with the following results:

- CINAHL = 276 retrieved, 165 added unique citations
- PsycINFO = 149 retrieved, 87 added unique citations
- Cochrane Library = 130 retrieved, 38 added unique citations

These additional searches contributed 290 new citations, for a new total in of 942 citations.

The translated search (1,030 citations) was initially imported into the new search (652) and duplicates (overlap) removed. There were 675 overlapping citations, leaving **297** that were identified by the new search but not by the old one, for a combined total of 1,327. We concluded that substantial activity has taken place since the publication of the AHRQ review in 2008. Although we did screen the titles and abstracts for relevance to the future research needs gap areas with dual review, we did not perform article abstraction nor did we perform quality assessment, since those activities would have represented a full update of the 2008 AHRQ review and were beyond the scope of this report.

#### **Search for ongoing trials.**

Clinical Trials.gov, searched February 8, 2010: (("integrated care" OR "Cooperative Behavior" OR "Case Management" OR "Disease Management" OR consultation) AND ("Primary Health Care" OR "primary care")) AND (mental disorder\* OR "Mental Health" OR

Psychiatry OR Depression OR "Depressive Disorder")). Limited to studies received between October 2007 to the present:

80 results

HSRProj, searched February 8, 2010: search same as ClinicalTrials.gov, limited to ongoing projects:

27 projects

NIH Research Portfolio (RePORTER)

Searched: "integrated care,primary care,mental" OR "integrated care,primary health care,mental" limited to active projects, 2010, 2009:

4 results

Searched: "integrated health care,primary health care,mental" limited to active projects, 2010, 2009:

1 result

# Appendix D. Ongoing Trials and Recent Publications

## Ongoing Trials

### Source: Clinical trials.gov

Baylor College of Medicine. Cognitive behavior treatment of older adults with generalized anxiety disorder in primary care. 2009. Accessed August 18, 2010]. Available at <http://clinicaltrials.gov/ct2/show/NCT00765219>.

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#### **Ongoing Trials Presented to Stakeholders for the First Conference Call**

<b>Key Question</b>	<b>Research gaps</b>	<b>Ongoing Studies that may address gaps (N=41)</b>
1. What models of integration have been used? What is the evidence that integrated care leads to better outcomes	<b>Population</b>	<b>Population: A</b>
	A. Models of integration for anxiety disorder	NCT00765219 NCT00769925 NCT00669526 U01MH070022-01A2
	B. Models of integration for Somatization	<b>Population: B</b>
	C. Models of integration for alcohol abuse	<b>Population: C</b>
		NCT00996775 NCT00619255
	D. Models of integration for ADHD	<b>Population: D</b>
	NCT00830700 NCT00644566 NCT00600470 R01MH063272-06A1	
E. Models of integration for PTSD		<b>Population: E</b>
	F. Models of integration for severe mental illness	NCT00974402 R01MH073613-04

<b>Key Question</b>	<b>Research gaps</b>	<b>Ongoing Studies that may address gaps (N=41)</b>
	G. Models of integration for mood disorders	<b>Population: F</b> 2R01MH070437-06A1
	H. Models of integration for postpartum depression	<b>Population: G</b>
	I. Models on integration for bipolar disorder	<b>Population: H</b>
	J. Models of integration (cross-cutting)	<b>Population: I</b>
	<b>Intervention/ Comparator</b>	<b>Population: J</b>
	A. Studies testing explicit variations of integration	<b>Population: J</b>
	B. Studies examining the fidelity of integration principles (evidence-based intervention, communication among clinicians, followup) to what is delivered	<b>Intervention/ Comparator: A</b>
	C. Methods of integrating primary care into specialty mental health	NCT00676962
	D. Studies comparing integrated care to systematic practice (i.e. some variation of usual care)	<b>Intervention/ Comparator: B</b> 5R37DA010572-14
		<b>Intervention/ Comparator: C</b>
		<b>Intervention/ Comparator: D</b>
2. To what extent does the impact of integrated care programs on outcomes vary for different populations?	<b>Population</b>	<b>Population: A</b>
	A. Populations most likely to benefit from this type of integrated care	NCT00765219 NCT00854542 NCT00805532 NCT01014312 NCT00560027 1R34MH085881-01A1 K23MH073008-01
	B. Integrated care for children and adolescents	<b>Population: B</b> NCT00560027 NCT00769925 NCT00669526 NCT00830700 NCT00644566 NCT00619255 NCT00600470 NCT006040971 1R01MH085645-01A1 ROIMH073918-01A1 R01MH063272-06A1 R01MH081997-01A1
	C. Integrated care and consistency with cultural values of various minority groups	<b>Population: C</b> NCT00854542 NCT00709150 NCT00570427

<b>Key Question</b>	<b>Research gaps</b>	<b>Ongoing Studies that may address gaps (N=41)</b>
		U01MH070022-01A2 R01MH068468-01A2 R01MH079831-01A2
	D. Effects of integrated care on health disparities	<b><u>Population: D</u></b>
	E. Effects of integrated care in the presence of comorbidities	<b><u>Population: E</u></b> NCT00805532 NCT00709150 1R34MH085880-01A1 5R24MH080827-02 2R01MH070437-06A1 5R01MH041739-20 5R21AA017252-02 IIR06-082 K23MH073008-01 R01MH073613-04 R21HS017635-01 R01MH068468-01A2
	F. Effects of integrated care for minor depression versus major depression	<b><u>Population: F</u></b>
	<b>Setting</b> A. Integrated care in rural settings	<b><u>Setting: A</u></b> MHI08-098 R01MH081997-01A1
3. What are the identified barriers to successful integration and sustainability?	<b>Population</b> A. Studies which examine generalizability of current models	
	<b>Intervention/Comparator</b> A. Models of integrated payment	
	<b>Outcomes</b> A. Studies examining sustainability	<b><u>Outcomes: A</u></b> NCT00676962
4. To what extent did successful integration programs make use of health information technology?	<b>Intervention/Outcomes</b> A. Use of information technology (IT) in integrated care	<b><u>Intervention/Outcomes: A</u></b> NCT00830700 NCT00719979 NCT00755235 NCT00821678 NCT00854542 R01MH071825-01A2 NCT00996775 5R24MH080827-02 MHI08-098 R01MH081997-01A1 R01MH079831-01A2
5. What financial and/or reimbursement structure was employed in successful integration programs? Is any specific financial/reimbursement strategy superior to another?	<b>Intervention/comparator</b> A. Studies examining the business case for integration B. Cost-effectiveness of integrated models	<b><u>Intervention/Comparator: A</u></b> NCT00781703 2R01MH070437-06A1 NCT00669526 5R37DA010572-14 ROIMH073918-01A1 U01MH070022-01A2

<b>Key Question</b>	<b>Research gaps</b>	<b>Ongoing Studies that may address gaps (N=41)</b>
6. What are the key elements of programs that have been successfully implemented and sustained in large health systems?	<b>Intervention</b> A. Studies investigating the vital elements of successful integration	<b>Intervention: A</b> NCT00676962

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# Appendix E. Prioritization Tools

## Online prioritization tool

**Integration of mental health/substance abuse and primary care: Second Round Voting for Future Research Needs**

**Instructions :** For the following exercise we would like you to vote on the revised gaps. We have provided you with **twelve** total votes. You may use up to four votes on any one gap. Your votes will count toward an overall ranking of the gaps. Gaps are listed in alphabetical order. To add votes to a selection, position your mouse over the dots in the right-hand column.

If you have any questions, please contact Karen Croffty at 919-966-7627 or [kcroffty@schr.unc.edu](mailto:kcroffty@schr.unc.edu)

No votes remain. Since a limited number of votes are allocated, to continue voting you must first reduce the vote for something you already voted on. To complete the survey, please click "Save and Continue" at the bottom of the screen

Cost effectiveness of integrated models from the societal perspective.	★ ★ ★ ★ ★
Effective methods of integrating primary care into specialty mental health practice settings. Studies could include effects on outcomes of both medical conditions (for example obesity, diabetes) as well as mental illness	★ ★ ★ ★ ★
Effective models/strategies of integration for alcohol abuse	★ ★ ★ ★ ★
Effectiveness of cross-cutting models/strategies for integration of mental health into primary care. "Cross-cutting" here indicates care across multiple mental health diagnostic categories, as opposed to a separate strategy for each diagnostic category, such as depression or anxiety disorder.	★ ☆ ☆ ☆ ☆
Effectiveness of current treatments and treatment combinations in relation to integrated care. For example, how does integrated care compare with, or function as an adjunct to, brief psychotherapeutic interventions delivered in a primary care office.	★ ☆ ☆ ☆ ☆
Effectiveness of integrated care for children and adolescents	★ ☆ ☆ ☆ ☆
Effectiveness of integrated care for mental health on general medical health, such as improvement in HgbA1c among diabetics who are treated for depression in an integrated care system.	★ ☆ ☆ ☆ ☆
Effectiveness of integrated care for patients with dual Medicaid and Medicare eligibility	★ ☆ ☆ ☆ ☆
Effectiveness of integrated care in the presence of both physical health comorbidities such as diabetes or chronic pain, as well as mental health comorbidities, such as the co-occurrence of depression and anxiety disorder.	★ ☆ ☆ ☆ ☆

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## Appendix F. AHRQ’s EHC Program Selection Criteria for New Research

<b>1. Appropriateness</b>	<b>1a.</b> Represents a health care drug, intervention, device, technology, or health care system/setting available (or soon to be available) in the United States
	<b>1b.</b> Relevant to 1013 enrollees (Medicare, Medicaid, S-CHIP, other federal health care programs)
	<b>1c.</b> Represents one of the priority conditions designated by the Department of Health and Human Services (DHHS)
<b>2. Importance</b>	<b>2a.</b> Represents a significant disease burden; large proportion or priority population
	<b>2b.</b> Is of high public interest; affects health care decisionmaking, outcomes, or costs for a large proportion of the US population or for a priority population in particular
	<b>2c.</b> Was nominated/strongly supported by one or more stakeholder groups
	<b>2d.</b> Represents important uncertainty for decisionmakers
	<b>2e.</b> Incorporates issues around both clinical benefits and potential clinical harms
	<b>2f.</b> Represents important variation in clinical care, or controversy in what constitutes appropriate clinical care
	<b>2g.</b> Represents high costs due to common use, to high unit costs, or to high associated costs to consumers, to patients, to health care systems, or to payers
<b>3. Desirability of New Research/ Duplication</b>	<b>3.</b> Would not be redundant (i.e., the proposed new research is not sufficiently researched by AHRQ or others, considering both completed and in-process research)
<b>4. Potential Impact</b>	<b>4a.</b> Potential for significant health impact: <ul style="list-style-type: none"> <li>- To improve health outcomes</li> <li>- To reduce significant variation in clinical practices known to be related to quality of care</li> <li>- To reduce unnecessary burden on those with health care problems</li> </ul>
	<b>4b.</b> Potential for significant economic impact: <ul style="list-style-type: none"> <li>- To reduce unnecessary or excessive costs</li> </ul>
	<b>4c.</b> Potential for change: <ul style="list-style-type: none"> <li>- The proposed topic exists within a clinical, consumer, or policymaking context that is amenable to evidence-based change</li> <li>- A product from the EHC program could be an appropriate vehicle</li> </ul>
	<b>4d.</b> Potential risk from inaction: <ul style="list-style-type: none"> <li>- Unintended harms from lack of prioritization of a nominated topic</li> </ul>
	<b>4e.</b> Addresses inequities, vulnerable populations (including issues for patient subgroups)
	<b>4f.</b> Addresses a topic that has clear implications for resolving important dilemmas in health and health care decisions made by one or more stakeholder groups
<b>5. Capacity</b>	<b>5a.</b> Efficiency (i.e., considering the timing of the need for new evidence, it is likely that a result could be produced in a timely manner)
	<b>5b.</b> Utilizes existing AHRQ resources or builds desired additional research capacity or decisional support for the EHC Program
	<b>5c.</b> Costs associated with the likely study design are reasonable considering limited program resources

## Appendix G. Levels of Integration Matrix (Developed from the Integration Matrix Outlined in figure 3 of the 2008 AHRQ Review<sup>2</sup>)

Level of integrated process of care		Low level	Intermediate level	High level
Low level		Example: Referral, no collaboration or reported communication between providers, separate locations, PCP directed	Example: Computer-generated reports or presentation of report by nurse/pharmacist to PCP, separate location, PCP directed	Example: Communication through electronic medical record recommendations and progress notes, face-to-face meetings with care manager, separate locations linked by telemedicine, PCP directed but team recommendations
Intermediate level II		Example: Referral, communication through weekly consultation between PCP and MH provider, separate locations, PCP directed	Example: Referral, PCP and MH provider review cases weekly, medication changes communicated between providers, separate locations, decisionmaking coordinated between providers	Example: Cases identified through screening, both providers review cases weekly, formal communication between providers, co-located, PCP directed
Intermediate level I		Example: Referral, communication through weekly consultation between PCP and MH provider, separate locations, MH provider directed	Example: Recruitment through screening, PCP receives consultation letter after each MH visit, psychiatrist directed	Example: Cases identified through referral and screening, care manager reviews cases weekly, formal and informal contact between providers, co-located, coordinated decisionmaking
High level		Example: No case identification, regular case conferences between PCP and MH providers, co-located, consensus on decisionmaking	Example: Case identification through screening, treatment plan developed jointly between providers, co-located, joint decisionmaking in defined roles	Example: Cases identified through screening and referral, regular team meetings between providers (formal and informal), treatment plan consensus, co-located, joint decisionmaking and consensus

MH=mental health; PCP=primary care physician.

Level of Integrated Providers

## Appendix H. Interim Results from the First and Second Rounds of Prioritization with Stakeholders

**Results of the initial prioritization exercise.** Figure H-1 and Table H-1 present findings from the two priority-setting exercises. Figure H-1 presents results from the Likert scale exercise where stakeholders were asked to rank each of the 40 research gaps on a scale of 1-5 (1 being low priority for future research, 5 being high priority). Mean Likert scores for each gap along with the standard deviation are provided. Results suggest that all the identified gaps represent research needs since all were ranked as moderately or very important. All but one gap received a mean priority score greater than 3, with 58% scoring 4 or above. Effectiveness of integrated care for minor depression versus major depression (gap #19) received a mean Likert score of  $2.9 \pm 0.9$ , placing it at the bottom of the priority list. Studies examining effective models/strategies of integrated payment for integrated care (gap #31) topped the list as the highest research need, with a mean Likert score of  $4.8 \pm 0.44$ .

Figure H-1. Likert scale priority

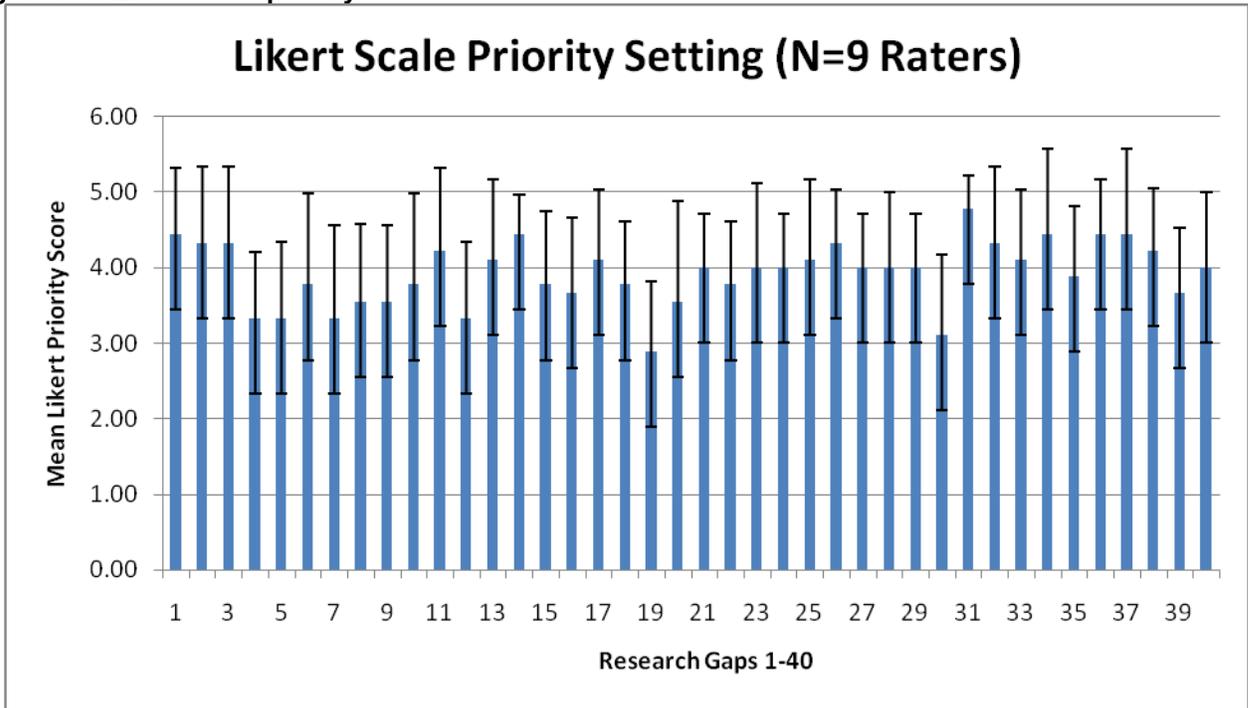


Table H-1 presents results for the second exercise, which employed a “forced prioritization” method by providing each stakeholder with 20 “chits” to assign among 40 gaps, allowing a maximum of 5 chits to be allotted to any one gap. This method proved most effective, clearly showing a rank order of priority gaps for future research needs. The effectiveness of cross-cutting models/strategies across multiple mental health diagnostic categories, as opposed to a separate strategy for each diagnostic category, emerged as the top priority for future research among our stakeholders obtaining 16 of a possible 45 chits.

A resource for researchers and policymakers to identify existing programs that already show return on investment related to different levels of integration was identified as an important

need by stakeholders. This gap is worthy of mention while recognizing that it is not an actual research topic and was not included in the second round of voting. Also of note is the fact that some of the initial 40 gaps could be combined under similar headings, changing the rank order of results. The second stakeholder call included a discussion of combining similar gaps as well as deleting those that ranked poorly as low-priority research needs; from this a refined, more focused list was developed for subsequent prioritization.

**Table H-1. Total for each of 40 research gaps**

<b>Research Gap</b>	<b>Total (out of a possible 45)</b>
Effectiveness of cross-cutting models/strategies for integration of mental health into primary care	16
A resource where researchers and policymakers can go to identify existing programs that already show return on investment related to different levels of integration.	14
Cost-effectiveness of integrated models	11
Studies examining effective models/strategies of integrated payment for integrated care	10
Studies examining the use of information technology (IT) including telemedicine, text messaging, and use of the Internet	10
Effectiveness and use of electronic medical records	9
Effectiveness of the medical home as a model/strategy for integrated care	8
Studies examining sustainability of integrated care independent of grant funding	8
Studies examining the business case for integration	8
Studies examining the translation/adaption/implementation of successful models/strategies in community settings	8
Effective models/strategies of integration for severe mental illness	7
Effective methods of integrating primary care into specialty mental health practice settings	6
Effectiveness of current treatments and treatment combinations in relation to integrated care	5
Effectiveness of integrated care for children and adolescents	5
Effectiveness of integrated care on health disparities	5
Effectiveness of measurement-based care for case identification, monitoring, and disease management	5
Effectiveness of very brief psychotherapies that may be more readily delivered in primary care settings as part of an integrated treatment approach	5
Studies identifying the various components of integrated care and determine the value added by each component individually and synergistically	5
Effectiveness of integrated care for patients with dual Medicaid and Medicare eligibility	4
Effectiveness of integrated care in rural settings	3
Effectiveness of integrated care in the presence of comorbidities	3
Studies examining integrated care for severe mental illness as a population of focus	3
Effectiveness of integrated care and consistency with cultural values of various minority groups	2
Effectiveness of integrated care for mental health on general medical	2
Effectiveness of integration in community settings, particularly when addressing multiple mental health problems rather than single conditions (such as depression)	2
Effective models/strategies of integration for alcohol abuse	1
Effective models/strategies of integration for posttraumatic stress disorder	1
Effectiveness of web-based psychotherapies in combination with primary care pharmacotherapy	1
Studies assessing the populations most likely to benefit from integrated care	1
Studies comparing integrated care to systematic practice (i.e., some variation of usual care)	1
Studies examining the fidelity of integration principles (evidence-based intervention, communication among clinicians, followup) to what is delivered in integrated care	1
Studies testing the comparative efficacy and effectiveness of explicit variations of integration	1

<b>Research Gap</b>	<b>Total (out of a possible 45)</b>
Studies examining the generalizability of current integration models	1
Effective models/strategies for bipolar disorder	0
Effective models/strategies for postpartum depression	0
Effective models/strategies of integration for anxiety disorder	0
Effective models/strategies of integration for attention deficit hyperactivity disorder	0
Effective models/strategies of integration for mood disorders	0
Effective models/strategies of integration for somatization	0
Effectiveness of integrated care for minor depression versus major depression	0

**Results of the second prioritization exercise.** The second prioritization exercise presented stakeholders with a nonranked list of 20 gaps and 12 chits, 4 of which could be assigned to any one gap. Stakeholders were asked to consider the 20 gaps and to prioritize what they considered to be the most important research needs for future study. The results are presented in Table H-2. Each gap could in theory have been awarded a maximum of 28 chits.

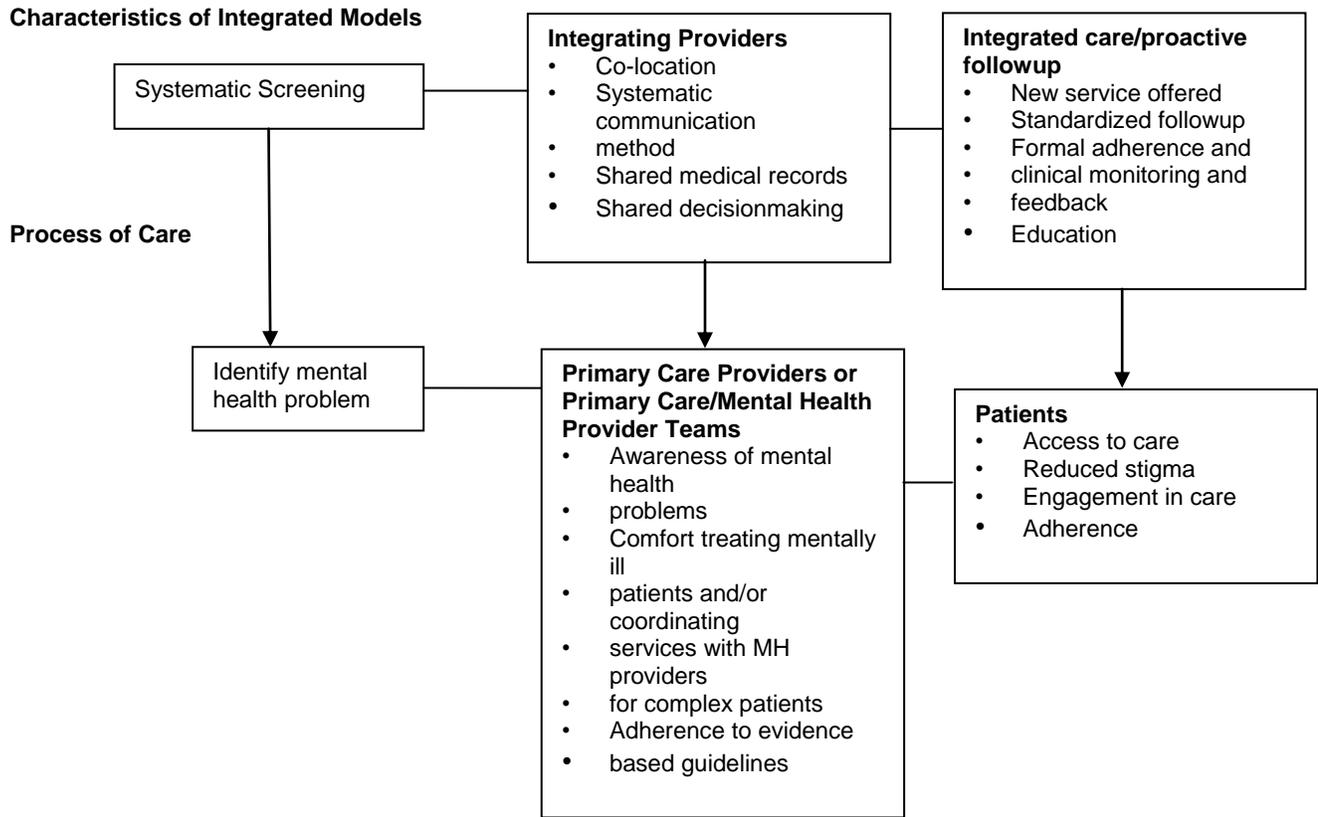
**Table H-2. Results from the Second Prioritization Exercise**

<b>Research Need</b>	<b>Number of chits out of 28 (7 raters)</b>
Effective methods of integrating primary care into specialty mental health practice settings. Studies could include effects on outcomes of both medical conditions (for example obesity, diabetes) as well as mental illness.	10
Effectiveness of cross-cutting models/strategies for integration of mental health into primary care. "Cross-cutting" here indicates care across multiple mental health diagnostic categories, as opposed to a separate strategy for each diagnostic category, such as depression or anxiety disorder.	10
Studies examining the use of information technology (IT) including text messaging, use of the Internet, and effective use of electronic medical records for integrated mental and general medical health care. These would focus on true interoperability and sharing of information between the primary care and the mental health professionals.	10
Studies examining sustainability of integrated care without external support such as grant funding. Integrated care can be delivered with special grant funding but are there ways of supporting it following or in lieu of grant funding?	9
Studies examining the translation/adaption/implementation of successful models/strategies in community settings. How can efficacious interventions be incorporated into everyday practice in the face of weak incentives and competing medical priorities?	7
Studies examining effective models/strategies of integrated or "bundled" payment for integrated care. Are there effective ways of combining primary care reimbursement mechanisms with reimbursements for mental health care services?	6
Studies identifying the effectiveness of various components of integrated care, determining the value added by each component individually and synergistically. What are the efficacious elements in integrated care?	6
Cost effectiveness of integrated models from the societal perspective.	5
Studies examining the business case for integration. When a practice or system invests in integrated care staffing and services, what are the revenues generated, and what are the effects on downstream costs such as hospitalization? Studies could take the perspective of the practice, the health care system, or the payer.	5
Effectiveness of measurement-based integrated care for case identification, treatment, and monitoring, focusing on mental health conditions other than depression.	4
Effectiveness of integrated care for patients with dual Medicaid and Medicare eligibility.	3
Effectiveness of integrated care in the presence of both physical health comorbidities such as diabetes or chronic pain, as well as mental health comorbidities, such as the co-occurrence of depression and anxiety disorder.	2
Effectiveness of the medical home as a model/strategy for integrated care. The "medical home" could be a primary care office for many patients, but could also be a specialty mental health practice with elements of primary care integrated to form the "home."	2

<b>Research Need</b>	<b>Number of chits out of 28 (7 raters)</b>
Effective models/strategies of integration for alcohol abuse.	1
Effectiveness of current treatments and treatment combinations in relation to integrated care. For example, how does integrated care compare with, or function as an adjunct to, brief psychotherapeutic interventions delivered in a primary care office?	1
Effectiveness of integrated care for children and adolescents.	1
Effectiveness of integrated care on health disparities, including racial and ethnic disparities in care patterns and outcomes in mental health and medical outcomes	1
Effectiveness of telemedicine as a model of integrated care for mental and general medical health care.	1
Effectiveness of integrated care for mental health on general medical health, such as improvement in hemoglobin A1c among diabetics who are treated for depression in an integrated care system.	0
Effectiveness of web-based psychotherapies in combination with primary care pharmacotherapy, when there is involvement of a mental health professional in the care.	0

# Appendix I. Analytic Framework (figure 1 from the 2008 AHRQ review<sup>2</sup>)

Characteristics of integration linked to process of care



508 compliance text for Appendix I:

*This figure outlines an analytic framework for integrated care. The framework describes both the characteristics of care and the process of care. Characteristics of care include, systematic screening which is linked to the integration of providers through co-location, systematic communication methods, shared medical records and shared decision making. This in turn is linked to integrated care and proactive follow-up through the delivery of new services, standardizing followup, ensuring formal adherence and clinical monitoring with feedback and also through education. These characteristics of care are shown to be linked to the process of care as follows. Systematic screening identifies mental health problems, which is directly linked to the ability of primary care providers or primary care/mental health provider teams to be more aware of mental health problems, more comfortable treating mentally ill patients and more likely to adhere to evidence based guidelines. This in turn affects patients by providing improved access to care, reduces stigma, encourages patient engagement and adherence to care. Integrating providers is also shown to have a direct influence on providers and integrated care coupled with proactive followup is shown to directly affect patients.*