*Research White Paper*

# Identifying Priorities for Patient-Centered Outcomes Research for Serious Mental Illness

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# Identifying Priorities for Patient-Centered Outcomes Research for Serious Mental Illness

**Prepared for:**
Agency for Healthcare Research and Quality
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None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

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# Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To improve the scientific rigor of these evidence reports, AHRQ supports empiric research by the EPCs to help understand or improve complex methodologic issues in systematic reviews. These methods research projects are intended to contribute to the research base and be used to improve the science of systematic reviews. They are not intended to be guidance to the EPC program, although may be considered by EPCs along with other scientific research when determining EPC program methods guidance.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers; as well as the health care system as a whole by providing important information to help improve health care quality. The reports undergo peer review prior to their release as a final report.

We welcome comments on this Methods Research Project. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by e-mail to epc@ahrq.hhs.gov.

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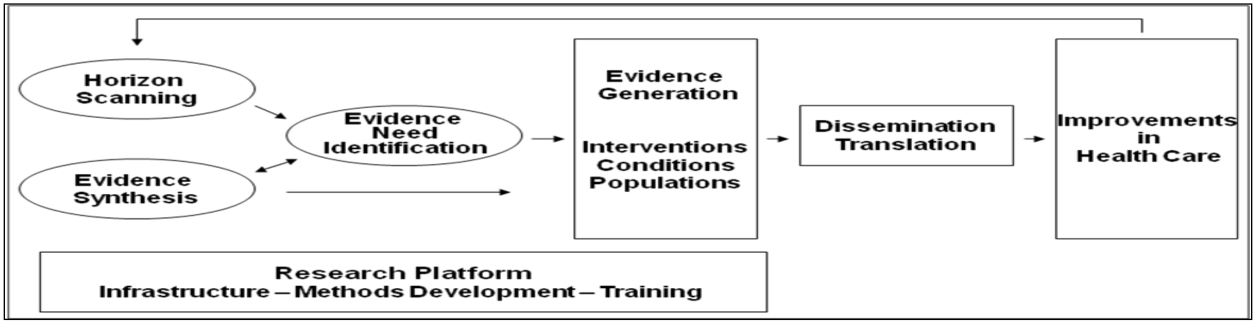
# Introduction

Comparative effectiveness or patient-centered outcomes research (CER/PCOR) has been defined by the Federal Coordinating Council for CER as “the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in ‘real world’ settings.”[1] The purpose of CER/PCOR is “to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decisionmakers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.”[1] The interventions compared may include medications, procedures, medical and assistive devices and technologies, diagnostic tests, behavioral changes, and delivery system strategies.[1] CER/PCOR designs may include clinical trials, observational studies, secondary analyses of databases, systematic reviews with or without meta-analyses, and cost-effectiveness analyses. CER/PCOR is conducted within a framework that encompasses a variety of activities as illustrated in Figure 1. All of these activities are ultimately aimed at improving health care.

**Figure 1. Framework for comparative effectiveness research**



The Agency for Healthcare Research and Quality (AHRQ) is the lead Federal agency charged with improving the quality, safety, efficiency, and effectiveness of health care for all Americans. As 1 of 12 agencies within the Department of Health and Human Services, AHRQ supports health services research to improve the quality of health care and promote evidence-based decisionmaking; AHRQ supports a variety of CER/PCOR activities through its Effective Health Care (EHC) Program.[2] The EHC Program funds individual researchers, research centers, and academic organizations that work with AHRQ to produce effectiveness and comparative effectiveness research for clinicians, consumers, and policymakers. To contribute to its agenda for CER/PCOR activities related to mental health, AHRQ contracted the RTI International-University of North Carolina (RTI-UNC) Evidence-based Practice Center (EPC) and the Scientific Resource Center Stakeholder Engagement Team to engage a broad and representative group of stakeholders to discuss issues related to serious mental illness (SMI) in a series of three meetings (*Issues Exploration Forum* [IEF]), as detailed in the methods section.

The results of three large comparative effectiveness trials have been sobering, and arguably have highlighted the limitations of our current ability to help many patients afflicted with schizophrenia, bipolar disorder, and depression. The Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) study reported that an older typical antipsychotic medication was as effective as the newer, more publicized atypical antipsychotics when used as a first-line treatment. In addition, nonadherence to medication was the norm, not the exception, with almost

75 percent of patients not using their medication after 18 months of treatment.[3] The Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD) trial reported that about 40 percent of bipolar patients do not recover from a manic episode.[4] In addition, for those who do recover, the relapse rates for either a subsequent depressive or manic episode were about 50 percent over the following 2 years. In the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) trial, after 13 weeks of treatment with a selective serotonin reuptake inhibitor only a third of patients met remission criteria.[5] Furthermore, after another 39 weeks of treatment only another third of the initial cohort remitted, leaving a full third of patients symptomatic.[6] Reports from the Schizophrenia Patient Outcomes Research Team (PORT) underscore the point that effective treatments are available, but implementation and uptake are suboptimal.[7]

More than 30 percent of the U.S. population suffers from a mental illness each year.[8] Of this group, 22 percent are classified as serious, 37 percent as moderate, and 40 percent as mild.[9] In sum, about 17.8 million people (5.8 percent of the U.S. population) live with SMI in any given year, resulting in significant economic and societal consequences. Several working definitions of SMI, severe mental illness, or severe and persistent mental illness have been used.[10-18] For this IEF's purposes, we used the following criteria to define adults with SMI:[18] people who (1) are ages 18 or older; (2) currently have, or at any time during the past year had, a diagnosable mental, behavioral, or emotional disorder of sufficient duration to meet diagnostic criteria specified within the *Diagnostic and Statistical Manual of Mental Disorders*, 4th Edition (DSM-IV) or the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) equivalent (and subsequent revisions); and (3) have functional impairment that substantially interferes with or limits one or more major life activities. Major life activities (in part 3 of the definition) include basic daily living skills (e.g., eating, maintaining personal hygiene); instrumental living skills (e.g., managing money, negotiating transportation, taking medication as prescribed); and functioning in social, family, and vocational or educational contexts.[19]

American adults living with SMI die about 25 years earlier than other Americans, largely owing to treatable medical conditions.[20] In fact, many people with SMI do not seek any health care.[21] On average, those with SMI report being totally unable to carry out their normal daily activities for 88 days per year compared with 4.7 and 1.9 days, respectively, for those classified as having a moderate or mild mental illness.[9] SMI is the second-leading cause of disability in the United States for ages 15 to 44[22] and accounts for between 5,000 and 10,000 disability-adjusted life years lost worldwide per year per 1 million population.

In 2002, SMI was estimated to cost more than $100 billion in health care expenditures alone.[23] Loss of earnings as a result of SMI was estimated to be about $193 billion, and disability benefits cost an additional $24.3 billion, resulting in a total of more than $317 billion spent on SMI in 2002.[23] SMI represents the largest diagnostic category for people receiving Supplemental Security Income (SSI) and Social Security Disability Insurance (SSDI) payments from the Federal Government. Table 1 provides data on the burden of disease associated with SMI and mood and psychotic disorders.

**Table 1. The burden of serious mental illness: Mood and psychotic disorders****

| Mental Health Disorder | Prevalence* (12-month) % | Mental Health Services Utilization (12-month)† % | % of Total DALYs in High-Income Countries % | Cost (direct and indirect; adjusted to 2010 dollars) $ (Billions) |
|---|---|---|---|---|
| Any mental health disorder | 32.4[8] | 41.1[21] | 20.9[24] | — |
| Serious mental illness | 5.8[21] | — | — | $383.5[23] |
| Mood Disorders | | | | |
| Any mood disorder | 9.7[8] | 56.4[21] | — | — |
| Major depressive disorder | 6.8[8] | 56.8[21] | 5.6[24] | $105[25] |
| Dysthymia | 1.5[8] | 67.5[21] | — | — |
| Any bipolar disorder | 2.8[8] | 55.5[21] | 0.71[24] | $72.2[26] |
| Bipolar I | 0.6[27] | — | — | — |
| Bipolar II | 0.8[27] | — | — | — |
| Subthreshold bipolar disorder | 1.4[27] | — | — | — |
| Psychotic Disorders | | | | |
| Any nonaffective** psychosis | 1.5[28] | — | — | — |
| Schizophrenia | 1.1[29] | — | 0.75[24] | $76[30] |

DALY= disability-adjusted life year.

*"12-month prevalence" refers to the proportion of study participants who identified symptoms occurring in the 12 months preceding the study interview that could be categorized as a mental health disorder.

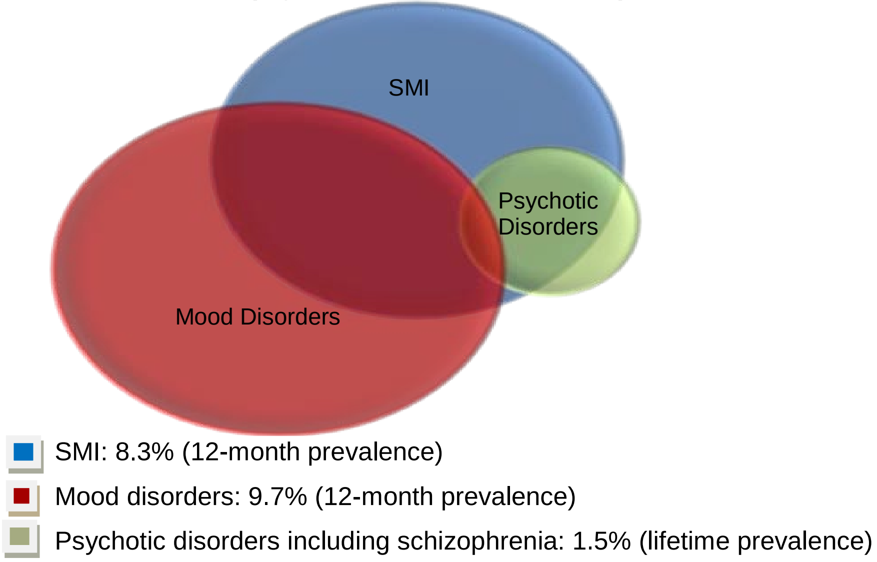
**"Lifetime prevalence" was estimated based on the proportion of respondents who had ever had the mental health disorder at the time of the interview. Mood disorders are broadly recognized as either depressive disorders, including major depressive disorder (MDD) or bipolar disorder (BD). MDD affects approximately 14.8 million American adults, or 6.8% of the U.S. population ages 18 and older in a given year.[31] Of the 9.7% of the population diagnosed with mood disorders in a 12-month period, 45% are classified as serious.[9] About 30% of MDDs, 50% of dysthymias, and 83% of BDs are serious.[9]

†Receiving any treatment in the 12 months before interview, by a psychiatrist, general practitioner, family physician, any other physician, social worker, counselor, any other mental health professional, religious or spiritual advisor, or any other healer.

We limited the scope of the IEF to adults with SMI who have psychotic or mood disorders because these disorders account for the majority of SMI and because our time and resources were limited. We did not include alcohol- and substance-related disorders, developmental disorders, anxiety disorders, or personality disorders, unless they co-occurred with a psychotic or mood disorder. Figure 2 illustrates the focus of the IEF and the relationship among SMI, mood disorders, and psychotic disorders.

The overarching purpose of this Issues Exploration Forum was to contribute to the establishment of priorities to guide CER/PCOR activities in mental health by engaging a diverse group of stakeholders. We aimed to focus on an area of mental health with significant unmet need despite available interventions and an area in which conducting CER/PCOR is likely to have an impact on reducing variation and uncertainty in clinical practice and outcomes, reducing methodological and conceptual uncertainty, and reducing disease burden. Additional objectives were to identify knowledge gaps in the area of SMI and to generate and prioritize topics for future CER/PCOR, including topics for evidence synthesis (i.e., systematic reviews, comparative effectiveness reviews).

**Figure 1. The relationship between SMI, mood disorders, and psychotic disorders (this IEF focused on adults with SMI who have psychotic or mood disorders)**



**Sources:** National Comorbidity Survey.[8] Epstein J, et al.[32]

# Methods

## Stakeholder Engagement

We sought a broad array of stakeholder opinions to balance perspective, minimize bias, and ensure that diverse perspectives were reflected. We made sure to include stakeholders who represented important subpopulations, such as those with ethnic, cultural, socioeconomic, or racial disparities associated with SMI.

Stakeholders were identified by input from the RTI-UNC EPC, AHRQ, and the Scientific Resource Center, and they represented a cross-section of patients, family members, consumers, advocates, practicing clinicians, professional societies, policymakers, public and private payers, Federal agencies, researchers, and methodologists. We used standard recruitment practices to secure participation. Stakeholders were contacted via telephone followed by a written e-mail invitation that included a brief overview of the IEF. Those stakeholders who declined to participate were asked to provide a substitute from their organization or who represented their perspective if there was no organizational affiliation, to ensure a broad and balanced representation. If a substitute was unavailable, we used a substitution list to find a comparable replacement.

**Preparation.** Confirmed participants were offered an orientation on AHRQ and the EHC Program. Orientation sessions reviewed the history, goals, and objectives of the EHC Program, discussed AHRQ research processes most relevant to the forum (topic generation, nomination, and selection), discussed the goals and objectives of the forum, and reviewed expected roles of participants in the forum. A brief outline of all EHC Program public involvement opportunities was also included. Several dates and times were offered over the course of 3 weeks before the forum began. The sessions were conducted using a Web-hosted PowerPoint presentation. Participants received a PDF version of the presentation, the Federal Coordinating Council’s definition of CER, a brief definition of a PICOTS (Patients, Interventions, Comparators, Outcomes, Treatments, Settings) framework for research synthesis questions, and a draft version of the EHC Program selection criteria for new research.

Prior to the IEF phone and in-person meetings, participants received materials by e-mail. Materials included documents describing the background and objectives of the forum, the definition of CER and related terminology, the definition of SMI and the scope of the forum, the organizing framework, a process summary for determining the focus area of the forum, draft selection criteria for new research, examples of mental health CER/PCOR topics, a summary of the burden of SMI, past CER tables, a summary of the populated organizing framework, a populated framework, and an environmental scan bibliography.

**Topic generation.** To generate topics, three meetings were held; the first and third meetings were held via conference call, using Web-hosted presentations, whereas the second was an all-day, in-person meeting at the AHRQ offices in Rockville, Maryland. A professional facilitator was used to aid the discussion during all meetings.

The objectives of the first meeting were to introduce the goals and format, and to gather initial feedback related to stakeholder areas of interest. At the meeting, participants received a brief summary of the meeting materials described above, and then discussed them by providing feedback in the areas of greatest interest related to research on SMI.

We invited participants to continue the discussion and submit research ideas and broader ideas using an online forum hosted by AHRQ. They received login information and instructions for posting to the online forum. Potential research topics were accepted for 5 days following the meeting. We also accepted topics by e-mail and phone and posted them on behalf of participants to the online forum. The suggestions made by participants readily grouped into three main themes: (1) patient-centered care—improving outcomes that matter to patients, (2) conceptual frameworks for research, and (3) reduction of disparities for subpopulations.

The objectives of the in-person meeting (second meeting) were to discuss broad issues in the area, identify gaps, and generate and prioritize research topics that can address these issues and gaps. Participants received meeting materials via e-mail in advance and binders with hard copies of related materials at the meeting.

Participants were pre-assigned to one of three workgroups corresponding to the themes emerging from the potential research topics that participants suggested during and following the first meeting. Group assignments were made to balance perspectives in each of the workgroups. Each workgroup reviewed the list of previously submitted topics in its theme and generated additional topic ideas through facilitated group discussion. The workgroups presented brief overviews of their discussions and reviewed the additional topic ideas generated. All topic ideas were recorded and displayed in the meeting room. Following a facilitated discussion of the full group, participants offered amendments using a rolling feedback process. Suggested changes were written on self-adhesive notes and placed next to the appropriate topic idea.

**Topic prioritization.** After final review and discussion, a nominal group process was used to identify initial priorities. Stakeholders used stickers to indicate which topics should be given highest priority for research. Participants were allotted 20 stickers, and allowed to place between 1 and 5 stickers on any one topic idea. We tallied the stickers and reported the results of the initial prioritization to the group. All topic ideas were captured in meeting notes for further analysis.

**Organization of prioritized topics into common themes.** Following the in-person meeting, we sorted and organized the topics by theme across the meeting workgroups. Topics were qualitatively assessed by teams of investigators and compared both within and across initial groupings. Special attention was given to topics that were closely related. Topics were then exchanged with other teams and reanalyzed. We organized the topics from the second meeting into 21 common topic themes. Two documents were created to organize results and display the topics according to priority, based on the number of stickers received at the in-person meeting.

The objectives of the final meeting were to review the prioritized topic themes, gather feedback on the process used to organize the prioritized topics, and get a preliminary sense of which topics are appropriate for evidence synthesis, evidence generation, and other research activities and products. Before the meeting, participants received the list of prioritized topics and were given a chance to give feedback and to comment on the list.

# Results

Appendix A provides a list of IEF stakeholder attendees. Nineteen stakeholders attended the first, Web-based IEF meeting. The initial topics given to the stakeholders for consideration at the start of the IEF and resulting discussion among stakeholders via the AHRQ Extranet Web site yielded 59 topics and 23 ideas. These 82 combined topics and ideas formed the basis for the three small group discussions during the breakout session of the in-person meeting on July 30, 2010.

The second IEF meeting included 33 stakeholders. The 82 topics and ideas generated prior to the in-person meeting were fairly equally divided among the three small groups with slightly more topics and ideas falling within the realm of patient-centered care. The small group sessions generated approximately 80 additional topics and ideas; the majority again fell into the patient-centered care group (~42 percent), followed by the reducing disparities for subpopulations (~33 percent) and conceptual framework for research (~25 percent) groups. After initial prioritization, nearly half had received at least 1 sticker from stakeholders, with 15 topics/ideas receiving 12 or more stickers. Following the in-person meeting, the RTI-UNC EPC staff combined similar topics into unique groups. After eliminating duplicate topics/ideas, the result was roughly 140 topics subsumed within 21 main themes (Table 2) prioritized by total number of stickers received during the second meeting.

During the final IEF meeting, the 13 stakeholders in attendance identified 11 of the 21 prioritized themes as being appropriate for evidence synthesis. Stakeholders were also provided an opportunity to help develop the themes deemed appropriate for systematic and comparative effectiveness reviews into research nominations to the AHRQ EHC Program. Eleven stakeholders expressed interest in assisting with the forthcoming topic nomination process. Appendix B provides a brief description of the main themes and the topics/ideas constituting them, as well as those deemed appropriate for evidence synthesis during the final IEF meeting.

**Table 2. Prioritized list of themes**[†]

| List of Themes |
|---|
| **1. Measurement and outcomes need consensus definitions.*** Develop measurements and outcome assessment tools for mental health research that are based on a chronic care model and are appropriate metrics for mental health, rather than the inadequate metrics that exist today that are based on an acute-care model. This process includes identifying priority outcomes for consumers, defining more appropriate outcomes criteria, and improving the standardization and consistency of documentation. **(49) [R]** |
| **2. Development of infrastructure for research: longitudinal studies, new investigators, and datasets.*** Infrastructure is needed that supports longitudinal studies including developing new investigators/investigator teams, providing additional training, and facilitating development of comparable datasets (detailed registries). **(47) [R, PC]** |
| **3. Service delivery, treatment settings, and structuring the delivery of care.** This thread includes topics related to making treatment settings and service delivery systems into experiments for studies such as (a) comparing the effectiveness of different systems for structuring the delivery of care, such as psychiatric medical homes vs. usual care; (b) comparing how variation across settings, systems, and States impacts disparities for specific groups (e.g., rural residents or racial and ethnic minorities); (c) State-to-State or smaller area comparisons; (d) public systems vs. various models of private insurance; (e) systems that deliver care in teams versus those settings that deliver care in solo-health-practitioner or split-care arrangements; (f) delivery tools, such as prior authorization, and their impact; and (g) ethnic-specific provider supports. **(44) [R]** |

**Table 2. Prioritized list of themes[†] (continued)**

| List of Themes |
|---|
| **4. Development of CER/PCOR methodology**. This thread includes topics related to the need to develop methodology for comparative effectiveness research (CER/PCOR) for mental health, including the need for (a) methods to adjust for confounding during followup; (b) more work using performance-based measures for increased validity and reliability; (c) exploring and expanding the use of new and different study designs and data analysis strategies (e.g., illness trajectories, propensity scores, time series); (d) longer-term studies and research conduct and design strategies aiming to optimize long-term followup, while avoiding attrition bias and avoiding confounding; (e) consumer and patient involvement; (f) a taxonomy to define and describe psychosocial and psychotherapeutic interventions; and (g) integration of biological and psychosocial research. **(40) [R]** |
| **5. Identify disparities and reasons for disparities and reevaluate the framework for researching disparities.*** This thread includes topics related to the need to clearly document disparities (in both public and private settings) and identify the reasons for disparities. Considerations for further research include (but are not limited to) barriers and access issues, clinical reasons, systems issues, institutional racism, and lack of services to people with limited English-language skills. In addition, this thread includes topics related to the need to reevaluate the framework for researching disparities. For example, needs were identified for more research focused on specific racial and ethnic communities, outcomes of greatest interest to specific populations or communities, and addressing the overall lack of inclusion as participants in research. **(40) [PC]** |
| **6. Role of the therapeutic relationship.*** This thread includes topics related to the relationship between client and provider as central to effectiveness research. The therapeutic alliance accounts for a large degree of variance in psychotherapy treatment outcome(s). Measurement of this factor should be part of the evaluation of treatment outcomes. This could include comparing the effectiveness of treatment strategies, including a continuous therapeutic relationship (e.g., with a coach, therapist, or other clinician), to usual care on long-term functional outcomes in patients with SMI. In addition, this thread includes research assessing the features of health professionals who support the development of a continuous healing relationship and factors associated with better patient outcomes (related to the person or the organization providing care). **(40) [PC]** |
| **7. Strategies to personalize/individualize treatment.** This thread includes comparisons of strategies to personalize/individualize psychotropic medication treatment for people with SMI. This includes identifying variations in patient response and predictors of response/tolerance that could inform the selection of treatments for specific groups of patients (e.g., by age, race, ethnicity, culture, and common comorbidities). This may include using biomarkers/pharmacogenomics, studying the relationship of race and ethnicity with intervention and outcome, using large databases to assess individualized treatments, targeting specific interventions to individuals’ goals and wishes, or integrating decision analysis into a comparative effectiveness trial to develop approaches to improving outcomes through individualizing care. **(39) [PC]** |
| **8. Treatment approaches to avoid early mortality and morbidity.*** This thread includes topics related to comparisons of different interventions and treatment approaches in avoiding early mortality, including suicide, and comorbidity for people with SMI, including racial, ethnic, and cultural minority groups, and pregnant women, with SMI. For example, this could include integrating mental health care and primary care, improving consumer self-care, or combining integration and self-care. This could also include comparing various types of integrated care, such as co-locating mental health providers in primary care versus co-locating primary care providers in mental health treatment settings, various approaches to improving communication between primary care and mental health providers, the use of medications alone versus medications plus psychosocial treatments, various versions of assertive community treatment, older (and less expensive) versus newer psychotropic medications, combinations of psychotropic medications, bundled programs of antipsychotic medications with various bundled psychosocial interventions, and pharmaceutical company interventions to educate patients and their families about potential harms of medications. **(34) [PC]** |
| **9. Role of the psychiatric hospital, lengths of stay, and transition support services after discharge**.* This thread includes topics focused on comparing the effectiveness of different lengths of inpatient hospital stay (e.g., ultrashort stays of 1 to 4 days vs. longer stays of 7 to 10 days), different approaches to support transitions after hospital discharge, or alternatives to inpatient hospitalization (e.g., comparing inpatient psychiatric hospitalization, crisis residential services, extended observation, partial hospitalization, and intensive outpatient care). **(29) [PC]** |

**Table 2. Prioritized list of themes† (continued)**

| List of Themes |
|---|
| **10. Retooling universities and education**. This thread includes topics focused on addressing the discrepancy between university-based education and approaches/methods purported to work better. This includes the potential need for innovative incentives to address the discrepancy. **(27) [R]** |
| **11. Strategies to increase adherence to evidence-based guidelines and treatment regimens**.***** This thread includes topics related to comparing alternative redesign strategies—such as using electronic medical records (EMRs), multidisciplinary treatment, decision support capabilities, and personal health records—for increasing health professionals' compliance with evidence-based guidelines, increasing patients' adherence to guideline-based regimens, and improving continuity of care and communication**.** This includes comparisons of technological interventions with standard care as well as exploring the role and future role of EMRs and how the relationship among structure, process, and outcomes in EMRs might contribute to new mental health research. This thread also includes comparing the effectiveness of strategies for enhancing adherence to medication regimens for people with SMI or comparing preference-sensitive care to other approaches. **(27) [PC]** |
| **12. Correctional programs and interventions for people involved with the criminal justice system**.***** This thread includes comparisons of the effectiveness of the following: (a) various correctional programs and evidence-based correctional practices with psychiatric treatment alone on outcomes such as community reentry among criminal offenders with SMI; (b) supported employment and traditional job counseling on job placement, job retention, and criminal recidivism; (c) various approaches to training the law enforcement workforce to identify and appropriately disposition people with SMI; (d) suspending Medicaid benefits at the time of admission with terminating Medicaid benefits followed by expedited restoration prior to release on time; and (e) organized interventions (e.g., crisis intervention teams, mental health courts, and mental health probation or parole; forensically adapted intensive case management with forensically adapted assertive community treatment [FACT]; or FACT with FACT plus cognitive behavioral therapy for criminogenic thinking) that can prevent re-arrest or re-incarceration, and/or the effects on community adjustment, reductions in criminal recidivism, and costs. **(26) [D]** |
| **13. Interventions for people with comorbid medical illness or substance abuse**. This includes topics related to comparing the effectiveness of pharmacologic and nonpharmacologic interventions for mental and physical health outcomes for people with SMI and comorbid medical illnesses (e.g., diabetes, HIV, cardiovascular disease, sleep apnea) or people with SMI and comorbid substance abuse. **(26) [D]** |
| **14. Prevention, early identification, trajectories, and developmental perspective**.***** This includes topics related to the need for frameworks that address prevention strategies or strategies to delay the onset of SMI, mental health research that also includes a developmental perspective/trajectory (e.g., catch at first episode), and the effectiveness of strategies to identify and treat SMI early in the course of illness. This could include studying psychosocial stressors that precipitate mood disorders. **(25) [R]** |
| **15. Dissemination and implementation**.***** This thread covers the need for more work on implementation science and comparing the effectiveness of strategies to disseminate and implement research findings and new discoveries into community practice to foster evidence-based treatment. This includes exploring how we approach communities and whether this affects outcomes. This also includes comparing strategies to advance evidence-based practices using dissemination and demonstration projects. **(23) [R]** |
| **16. Reducing barriers and improving access.** This thread includes topics related to comparing sustainable interventions to reduce barriers to access for mental health services, general medical services, or regular dental care for people with SMI, including transportation, financial, and insurance coverage barriers. For example, this could include interventions providing streamlined access to Medicaid benefits or using health technology (e.g., telehealth). **(13) [D]** |
| **17. Mental health policy.** This thread includes comparisons of the impact of various policy practices in mental health on outcomes including (but not limited to) cost-effectiveness and reach. This thread also includes policies to establish legal panels or agencies to ensure dissemination of information and legislation or policies related to the availability of medical information for family members of people with SMI. **(11) [D]** |
| **18. Modifiable factors: tobacco, exercise, and nutrition**. This includes comparisons of the effectiveness of interventions targeting modifiable factors such as tobacco abuse, physical exercise, mental exercise, and nutrition on health outcomes for people with SMI. This includes comparing various tobacco cessation strategies for individuals with SMI and tobacco addiction. **(10) [PC, D]** |

**Table 2. Prioritized list of themes† (continued)**

| List of Themes |
|---|
| **20. Providing housing or social support**. This thread is focused on comparisons of the effectiveness of different strategies, such as providing stable housing or social support, for people with SMI on mental health outcomes, readmission rates, or normative success (e.g., success in education, relationships, employment). **(9) [PC]** |
| **21. Strategies to reduce stigma, prejudice, and discrimination.*** This includes comparisons of strategies to reduce stigma, prejudice, and discrimination against people with SMI and to encourage their social inclusion. **(3) [PC]** |

†A detailed list of all topics related to the 21 themes is provided in Appendix B.
Number in bold in parentheses after each item indicates the number of times a stakeholder expressed a preference for that topic.
* This topic was determined by the stakeholder to be appropriate for evidence synthesis.
R – Topics for this theme came from the conceptual framework for research workgroup.
PC – Topics for this theme came from the patient-centered care workgroup.
D – Topics for this theme came from the reducing disparities workgroup.

# Discussion

## Need To Fundamentally Change Our Approach to Clinical Research for Serious Mental Illness

The topics prioritized by stakeholders deviated somewhat from our expectations. We had anticipated that stakeholders would focus mostly on head-to-head comparisons of evidence-based treatments or interventions, or on studies to fill gaps in the literature. Instead, three of the top four priorities focused on *how* research was conducted, namely (1) developing consensus measurement and outcomes definitions; (2) improving infrastructure for research, longitudinal studies, new data sets, and new investigators; and (3) developing CER/PCOR methodology. These findings highlight a feeling expressed by many stakeholders: failure to fundamentally change the way research on SMI is conducted will significantly prevent the field from moving forward.

Briefly examining landmark studies conducted over the last decade may explain how and why this occurred. First, the CATIE, STEP-BD, and STAR*D trials reported very sobering results, clearly demonstrating that our treatments are not as effective as we might have hoped.[33-35] Most patients with a psychotic disorder and many patients with a mood disorder suffer significant morbidity. Although those studies were originally designed in the late 1990s, arguably no new pharmacological or psychosocial treatments have become available since then that could be considered “game changers.” Despite the pessimism, PORT[7] reports highlight a number of both types of treatments that are clearly superior to placebo, though almost all available treatment algorithms typically characterize these independently (i.e., separate algorithms for each). Further, the rates at which patients’ treatment conformed to PORT recommendations were modest at best (generally below 50 percent), and rates were higher for pharmacological than for psychosocial treatments, and in rural areas than in urban areas.[7]

As the results of large comparative effectiveness trials like CATIE, STEP-BD, and STAR*D have become available, there is a growing recognition that although most SMI is a chronic lifetime disorder, most current research evaluates outcomes after an intervention over a much shorter time frame.[33-35] Long-term studies reporting the most important outcomes (e.g., disability, functional ability, and quality of life) are lacking for people with SMI despite the chronic and disabling nature of these conditions. How does one rationally place treatments with 6-week to, at most, 1- to 2-year outcomes, typical in previous pharmacologic and psychosocial intervention trials, in the framework of an illness that will last 30, 40, or 50 years? How would one actually assess outcomes in a lifelong illness? Many individuals with SMI are initially diagnosed in their 20s. Thus, they live the majority of their lives with considerable disabilities in comparison with people who do not have the illness. Given this, our current model for treatment may need to shift to one that is more consistent with a chronic illness model of care. This shift has occurred with certain medical illnesses with some benefits reported.[36] Interestingly, stakeholders emphasized the value of the therapeutic relationship in the treatment of chronic mental illness and the need for further CER/PCOR to clearly consider or further evaluate the role of the therapeutic relationship. A good therapeutic relationship is critical for many aspects of successful treatment, including engagement in treatment, and is very consistent with a chronic illness model of care.

Perhaps the most significant change in the conceptualization of severe mental illness over the past 20 years has been the emergence of the Recovery Model.[37] The main impetus for this change came from consumers themselves, who felt that the classic medical model of disease led to unnecessary stigmatization and the perception of hopelessness. Although there is strong evidence of continuing morbidity for most patients with SMI, there is also strong evidence that the vast majority of patients do not progressively deteriorate over time, and that as many as 50 percent to 70 percent of people with schizophrenia can go on to work and have "productive" lives. There are 10 core components of the Recovery Model with an emphasis on choice, empowerment, and hope. The model focuses on people's strengths, not their symptoms. Recovery from a major mental illness is seen similarly to recovery from a severe myocardial infarction. Individuals may have a damaged myocardium, but they are people with other aspects to their lives and are not wholly characterized with labels as cardiac patients. Currently, there is very limited research on this model.

On the surface there seems to be a possible disconnect between talking about "recovery" on one hand and suggesting on the other hand that this is a chronic lifetime illness that needs to be studied long term. However, it may well be that the stakeholders (who included two consumers) were also getting at the different phases of chronic mental illness. Although most of the research has been on the more acute phase of the illness, most individuals spend the vast majority of their illness in the nonacute phase. A recent published report suggested that schizophrenia could be conceptualized as a neurodevelopmental disorder with a later onset psychotic portion.[38] More research on what factors promote recovery over the long term would seem to be consistent with both models.

## Comparisons of Evidence-Based Interventions and Addressing Knowledge Gaps

Although the top priorities centered on the need to revamp the research framework, stakeholders also identified a number of priority interventions for comparative effectiveness research. Service delivery, treatment settings, and structuring the delivery of care were identified as priority interventions for CER/PCOR (priority 3), which is not surprising and seems to follow a trend. Close to half of all mental health topics in the Institute of Medicine report *Initial National Priorities for Comparative Effectiveness Research* are related to systems and delivery of care.[39] The Federal Coordinating Council for CER also noted that CER to date "has been disproportionately focused on pharmacologic treatments rather than the full spectrum of intervention types" and further concluded that "the emphasis on pharmacologic treatments has meant fewer resources for other interventions, including behavioral, procedures, prevention, and delivery system interventions that can have major impacts on health outcomes."[1] Comparisons of treatment approaches to avoid early morbidity and mortality were highlighted as a priority (priority 8). A point of emphasis at the in-person meeting was that people with SMI die 25 years earlier[20] on average and that something must be done to improve this early mortality. Comparisons of strategies to personalize and individualize treatment and to increase adherence to evidence-based guidelines and treatment regimens, including the role of EMRs and decision support, were identified as other priority interventions for CER/PCOR.

## Priority Populations

Stakeholders identified two priority populations as targets for CER/PCOR: people with SMI and comorbid medical illness or substance abuse and people with SMI involved in the criminal justice system (priorities 8, 12, and 13). A need for research focused on specific ethnic and racial communities and a need to identify disparities and the reasons for disparities related to access, systems issues, institutional racism, and lack of services to people with limited English-language skills (priority 5) highlight additional possible targets for CER/PCOR.

## Using Stakeholder Engagement to Identify Priorities for Research

The process used to establish research priorities during the IEF was considered successful. Engagement of a broad and representative group of stakeholders in a transparent process driven by the participants and aided by a neutral facilitator resulted in the identification of knowledge gaps, broad conceptual and methodological issues related to research, and priority areas for CER/PCOR. Stakeholders with a variety of decisional needs identified their priorities and preferences, clearly indicating a need to change the way research on SMI is conducted, including a need for improved methodologies to result in better evidence, practice, and patient outcomes. Using a process similar to this IEF can provide a novel way to generate state-of-the-field thinking, allowing the overarching issues in a field to emerge. Even more robust results could likely be obtained by addressing identified process limitations. Resource constraints limited the number and scope of participants. Similarly, although the most productive part of the process was the in-person meeting (meeting 2), resources limited face-to-face interaction to a single meeting. We experienced attrition in participation at meeting 3 following the in-person meeting and a request for more face-to-face interaction from some stakeholders.

Many of the organizations that participated in the IEF were not initially familiar with the EHC Program and CER. To participate fully, they required the context provided at the optional orientation sessions and a basic understanding of how CER/PCOR might be beneficial to them. This was a critical step, especially for nonclinician/researcher participants. At the end of the process, the majority of participants indicated a basic understanding of CER/PCOR and the EHC Program as well as a willingness to continue to participate in similar processes. To that end, investigators and individual stakeholders are currently working together to advance priority topics for consideration in the EHC Program.

It was necessary to identify, define, and communicate to the stakeholders the variables that might have affected the outcome of the process and the stakeholder experience. These variables included the goal of the IEF, expected outputs, how stakeholders were involved and represented, how the process was facilitated, and what was driving the process.

Having a dedicated and neutral focus enhanced the likelihood of a successful process and outcome. It was important to have a topic-neutral “bridge” between stakeholders with different perspectives in the research process and to facilitate communication between stakeholders and researchers or program staff. Having a facilitator to act in a neutral capacity focused on process allowed us to establish common ground among myriad perspectives, communicate stakeholder interests in ways understandable by a research-savvy audience, and translate basic evidence-synthesis needs so that stakeholders could communicate their ideas in ways that could be acted upon by the EHC Program.

As stakeholder and public involvement in the research enterprise becomes increasingly expected, it will be important to invest in the processes and tools that enable successful engagement.

# References

1. Federal Coordinating Council for Comparative Effectiveness Research, United States Department of Health and Human Services. Report to the President and the Congress. Available at: http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf. Accessed May 29, 2011,
2. Agency for Healthcare Research and Quality. What is the effective health care program. Available at: http://www.effectivehealthcare.ahrq.gov/index.cfm/what-is-the-effective-health-care-program1/. Accessed November 24, 2010.
3. Lieberman JA, Stroup TS, McEvoy JP, et al. Effectiveness of antipsychotic drugs in patients with chronic schizophrenia. N Engl J Med 2005;353(12):1209-23.
4. Perlis RH, Ostacher MJ, Patel JK, et al. Predictors of recurrence in bipolar disorder: primary outcomes from the Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD). Am J Psychiatry 2006;163(2):217-24.
5. Ziffra MS, Gilmer WS. STAR*D: Lessons learned for primary care. MBL Communications 2007;14(1):8.
6. Rush AJ. Limitations in efficacy of antidepressant monotherapy. J Clin Psychiatry 2007;68 Suppl 108-10.
7. Lehman AF, Steinwachs DM, The Survey Co-Investigators of the PORT Project. Patterns of usual care for schizophrenia: initial results from the schizophrenia Patient Outcomes Research Team (PORT) Client Survey. Schizophr Bull 1998;24(1):11-20.
8. National Comorbidity Survey. 12-month prevalence of DSM-IV/WMH-CIDI disorders by sex and cohort. 2007.
9. Kessler RC, Wang PS. The descriptive epidemiology of commonly occurring mental disorders in the United States. Annu Rev Public Health 2008;29115-29.
10. Kessler RC, Chiu WT, Colpe L, et al. The prevalence and correlates of serious mental illness (SMI) in the National Comorbidity Survey Replication (NCS-R) Website. n.d. Available at: http://mentalhealth.samhsa.gov/publications/allpubs/SMA06-4195/Chapter15.asp. Accessed April 29, 2010.
11. Ruggeri M, Leese M, Thornicroft G, et al. Definition and prevalence of severe and persistent mental illness. Br J Psychiatry 2000;177149-55.
12. Peck MC, Scheffler RM. An analysis of the definitions of mental illness used in state parity laws. Psychiatr Serv 2002;53(9):1089-95.
13. Kessler RC, Galea S, Jones RT, et al. Mental illness and suicidality after Hurricane Katrina. Bull World Health Org 2006.
14. David A, Adams CE, Eisenbruch M, et al. Depot fluphenazine decanoate and enanthate for schizophrenia. Cochrane Database Syst Rev 2004(2).
15. National Advisory Mental Health Council. Health care reform for Americans with severe mental illnesses: report of the National Advisory Mental Health Council. Am J Psychiatry 1993;150(10):1447-65.
16. Bartels SJ, Levine KJ, Shea D. Community-based long-term care for older persons with severe and persistent mental illness in an era of managed care. Psychiatr Serv 1999;50(9):1189-97.
17. Schinnar AP, Rothbard AB, Kanter R, et al. An empirical literature review of definitions of severe and persistent mental illness. Am J Psychiatry 1990;147(12):1602-8.
18. Substance Abuse and Mental Health Services Administration. Mental health dictionary National Mental Health Information Center Webpage. Available at: http://www.samhsa.gov/healthreform/healthhomes/Definitions_SIM_SUD_508.pdf. Accessed June 4, 2010.

19. Center for Substance Abuse Treatment. Definitions and Terms Relating to Co-Occurring Disorders. DHHS Publication No. (SMA) 06-4163, COCE Overview Paper 1. Rockville, MD: Substance Abuse and Mental Health Services Administration, Department of Health and Human Services; 2006.

20. Manderscheid RW, Druss B, Freeman E. Data to manage the mortality crisis: Recommendations to the Substance Abuse and Mental Health Services Administration. Washington, D.C.: Substance Abuse and Mental Health Services Administration; 2007.

21. Wang PS, Lane M, Olfson M, et al. Twelve-month use of mental health services in the United States: results from the national comorbidity survey replication. Arch Gen Psychiatry 2005;62(6):629-40.

22. National Institute of Mental Health. The numbers count: mental disorders in America. Available at: http://www.nimh.nih.gov/health/publications/the-numbers-count-mental-disorders-in-america/index.shtml. Accessed April 29, 2010.

23. Insel TR. Assessing the economic costs of serious mental illness. Am J Psychiatry 2008;165(6):663-5.

24. World Health Organization. Disease control priorities related to mental, neurological, developmental and substance abuse disorders. Geneva, Switzerland: World Health Organization; 2006.

25. Greenberg PE, Kessler RC, Birnbaum HG, et al. The economic burden of depression in the United States: how did it change between 1990 and 2000? J Clin Psychiatry 2003;64(12):1465-75.

26. National Alliance on Mental Illness. The impact and cost of mental illness: the case of bipolar disorder Website. Available at: http://www.nami.org/Content/NavigationMenu/Inform_Yourself/About_Public_Policy/Policy_Research_Institute/Policymakers_Toolkit/Impact_and_Cost_of_Mental_Illness_Bipolar.htm. Accessed April 28, 2010.

27. Merikangas KR, Akiskal HS, Angst J, et al. Lifetime and 12-month prevalence of bipolar spectrum disorder in the National Comorbidity Survey replication. Arch Gen Psychiatry 2007;64(5):543-52.

28. Kessler RC, Birnbaum H, Demler O, et al. The prevalence and correlates of nonaffective psychosis in the National Comorbidity Survey Replication (NCS-R). Biol Psychiatry 2005;58(8):668-76.

29. Regier DA, Narrow WE, Rae DS, et al. The de facto US mental and addictive disorders service system. Epidemiologic catchment area prospective 1-year prevalence rates of disorders and services. Arch Gen Psychiatry 1993;50(2):85-94.

30. Wu EQ, Birnbaum HG, Shi L, et al. The economic burden of schizophrenia in the United States in 2002. J Clin Psychiatry 2005;66(9):1122-9.

31. Kessler RC, Chiu WT, Demler O, et al. Prevalence, severity, and comorbidity of 12-month DSM-IV disorders in the National Comorbidity Survey Replication. Arch Gen Psychiatry 2005;62(6):617-27.

32. Epstein J, Barker P, Vorburger M, et al. Serious mental illness and its co-occurrence with substance use disorders, 2002. DHHS Publication No. SMA 04-3905, Analytic Series A-24. Rockville, MD: Sustance Abuse and Mental Health Services Administration, Office of Applied Studies; 2004.

33. Stroup TS, McEvoy JP, Swartz MS, et al. The National Institute of Mental Health Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) project: schizophrenia trial design and protocol development. Schizophr Bull 2003;29(1):15-31.

34. Sachs GS, Thase ME, Otto MW, et al. Rationale, design, and methods of the systematic treatment enhancement program for bipolar disorder (STEP-BD). Biol Psychiatry 2003;53(11):1028-42.

35. Rush AJ, Fava M, Wisniewski SR, et al. Sequenced treatment alternatives to relieve depression (STAR*D): rationale and design. Control Clin Trials 2004;25(1):119-42.

36. Wagner EH, Austin BT, Davis C, et al. Improving chronic illness care: translating evidence into action. Health Aff (Millwood) 2001;20(6):64-78.

37. Bellack AS. Scientific and consumer models of recovery in schizophrenia: concordance, contrasts, and implications. Schizophr Bull 2006;32(3):432-42.

38. Insel TR. Rethinking schizophrenia. Nature 2010;468(7321):187-93.

39. Institute of Medicine. Initial national priorities for comparative effectiveness research. Washington, DC: National Academy of Sciences; 2009.

# Appendix A. Issues Exploration Forum Stakeholder Participants

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# Appendix B. Detailed Prioritized List of Topics

## Individual Topics Listed Under Corresponding Thread

(Number in bold in parentheses after each item indicates the number of times a stakeholder expressed a preference for that topic)

1. **Measurement and outcomes need consensus definitions. (49)***
   - R NT2. Develop appropriate measurements for mental health research that are based in a chronic care model and are appropriate metrics for mental health, rather than the inadequate metrics that exist today that are based on an acute-care model. Must include defining more appropriate outcomes criteria, larger sample sizes, and longer-term studies that include followup over time. **(22)**
   - PC 31. Measurement and outcomes need consensus definitions. **(14)**
   - PC 39. Identify priority outcomes for consumers—facilitate consensus to develop. **(8)**
   - R NT10. Explore shared decisionmaking with patients in order to capture more information and to lead to more valid measures of coded medical data. **(3)**
   - PC 2. Compare the effectiveness of common treatments for people with SMI with regard to patient-centered and patient-relevant outcomes (e.g., disability, functional capacity, quality of life, employment, and housing). **(2)**
   - R NT19. Develop standardized assessments/tools for mental health, as they are currently lacking. **(0)**
   - R NT21. Identify standard, accepted mental health outcomes, like blood pressure is accepted (e.g., Patient Health Questionnaire [PHQ9] as part of records). **(0)**
   - R NT6. Need to encourage more standard and consistent documentation (in patient records) vs. reality vs. consumer/provider perspective. **(0)**
     i. **SH Note:** The way that documentation requirements (which are driven by a multiplicity of payers and regulatory agents) drive assessment, treatment, and the nature of the relationship between the clinician and the individual receiving care has not been well studied, either in terms of benefits in influencing quality or in terms of the "unintended consequences" of specific requirements that decreased quality. Attention to documentation and specific research to develop effective and efficient approaches is particularly important to enhancing interoperability to developing electronic health records that adequately meet the needs of professionals and patients.
2. **Development of infrastructure for research: longitudinal studies, new investigators, and datasets. (47)***
   - R NT1. Infrastructure is needed that supports longitudinal studies including developing new investigators/investigator teams and providing additional training. **(31)**
   - PC 43. Facilitate infrastructure for comparable datasets (detailed registries)—consumers, care providers, interventions. **(16)**
3. **Service delivery, treatment settings, and structuring the delivery of care. (44)**
   - R NT8. Make treatment settings into experiments for studies. Explore which factors built into the structure of current health care contribute (or not) to patient adherence, especially for SMI—also consider differences in sectors (public or private), and develop needed criteria of evaluation success. **(25)**

    i. **SH Note**: Building an infrastructure for long-term research is critical, but it is expensive. Consider partnering with other agencies (e.g., National Institutes of Health, Department of Housing and Urban Development, Department of Justice, Department of Defense, and Department of Energy) to, for example, create a "superfund" to support long-term outcomes research.

- D 33. Small area variations in overall well-being. **(4)**
    i. Gallup research.
    ii. Pharma only—no psychosocial support.
    iii. Scalability of small area intervention.
- R NT11. Majority of people with SMI not getting care at all (never even touching the mental health care system), or not over time. This is not trivial. Must detect and care for mental health patients in general medical settings. **(4)**
    i. **SH Note**: Education/Medicaid database—but what if those functions/treatments/episodes of care are not applicable to the majority of people with mental illness who are not treated.
- PC 33. Psychiatric medical home vs. usual care—impact on general health outcomes. **(3)**
- PC 18. Compare the effectiveness of interventions for various SMI disorders across settings (community or real-world settings vs. academic settings). **(3)**
    i. **SH Note:** Compare and research the impact of trauma both in the community and the mental health system.
- PC 12. Compare the effectiveness of different systems for structuring the delivery of care on outcomes including quality of life, functioning, individuals lost to followup, time spent in case management activities, and duration of untreated psychosis. For example: (a) state-to-state comparisons of systems with a pure catchment area approach with a single responsible entity vs. systems with a patchwork of hospitals and state, county, and voluntary outpatient programs; (b) public systems vs. various models of private insurance; (c) systems that deliver care in teams vs. those settings that deliver care in solo-health-practitioner or split-care arrangements (one prescriber and one distinct therapist). **(2)**
- PC 7. For people with SMI, compare the effectiveness of medication treatment provided in the context of various health care delivery models or management strategies**. (2)**
    i. **SH Note:** Also include health care delivery tools (e.g., prior authorization) and their effect on medical treatment (e.g., does medical treatment happen? How does it change? Other classes of medications used instead?)
- R I-6. There is a need to provide legal assistance to communities trying to bring about parity. States vary in the availability of treatments and services. **(1)**
- R NT20. Treat service delivery systems as experiments. **(0)**
    i. Availability and linkability of data.
    ii. Consider application of practice-based evidence, rather than evidence-based practice as applied to mental health.
- R NT25. Consider the sectors (public vs. private). **(0)**
- R NT14. Current research models are driving treatment outcomes. **(0)**
    i. **SH Note:** In thinking about research methods and approaches, strong consideration should be give to the potential of qualitative research methods

    and formal medical decisionmaking analysis. The latter requires that data from existing trials be reported in terms of proportions rather than change in symptoms scores (e.g., x  percent of those given treatment y have at least a 50 percent response in symptoms, a percentage of those treated with *y* develop side effect *z*). This information would be more clinically useful than knowing that the treatment leads to a statistically significant (but not clinically significant) effect.

- R NT15. "Organizations of system" mirrors organization of research. **(0)**
    i. **SH Note**: The infrastructure daily registry development should involve the National Institute of Mental Health to have standardization and linkage to emerging research around enhancing the registry elements and for generalizability of research findings to natural solutions.
    ii. **SH Note**: Framework—amend the measure development—we desperately need this for behavioral health.
    iii. R NT16. Careful measurements over time. **(0)**
    iv. R NT17. Observational research to art. **(0)**
    v. R NT18. Center Stone of American framework. **(0)**
    vi. TN—Partnered with Vanderbilt.
    vii. Knowledge network.
    viii. Large infrastructure.
- D 41. After "first break" compare outcomes between private vs. public insurance. **(0)**
- D 58. Ethnic-specific provider supports. **(0)**
- D 26. How does variation across systems and states affect subpopulations? **(0)**
- D 45. Compare the effectiveness of various methods to improve provider communication between primary care providers and mental health providers. (0)

4. **Development of CER/PCOR methodology. (40)**
    - R NT7. Need to develop methodology for CER/PCOR for mental health. Need methods to adjust for confounding post-baseline (i.e., during followup)—using global measures of functioning (e.g., more work is needed to use performance-based measures in mental health research for increased validity and reliability for mental health). **(20)**
    - R NT3. Develop a mental health study design that includes how to control for nonspecific affects, outcomes relevant for real-life settings, as current a particular limitation for mental health is that short-term clinical trials do not translate well into long-term trials. **(7)**
        i. **SH Note:** Research on psychosocial and psychotherapeutic interventions requires a guiding taxonomy/framework to define and describe approaches. For instance, labeling/grouping of treatments varies considerably (depending on investigators and available data) across systematic reviews and randomized controlled trials. For instance, mindfulness-based cognitive therapy, cognitive behavioral therapy (CBT) vs. cognitive vs. problem-solving therapy, etc., for major depressive disorder. Should these be evaluated as distinct treatments or are they better viewed as minor variations (or replications) within a broader CBT model? The importance of such a taxonomy for grouping analysis and comparison of treatments cannot be emphasized enough! What are

  “common”/“necessary” components to distinguish CBT, NS interpersonal psychotherapy vs. psychodynamic psychotherapy?

- D 36. Research/reevaluation of priorities in biological vs. psychosocial research. There needs to be better integration of these—need to consider the whole person. **(7)**
- PC 3. Compare the long-term effectiveness of psychotropic medications or other interventions for people with SMI. **(3)**
  i. **SH Note:** Pharmaceutical track record regarding not raising and/or suppressing negative data; their particular medications makes the involvement of Big Pharma highly suspect.
- R T3. Compare the effectiveness of different levels of consumer and patient involvement in topic generation, topic development and refinement, and input related to research design. **(2)**
- R I-10. The use of qualitative approaches has not been adequately exploited. Some interventions could be subjected to qualitative research methods. **(1)**
- R NT23. Explore and expand the use of new and different analyses (e.g., propensity scores, time series, IVs in CER/PCOR) for mental health-related CER/PCOR. **(0)**
- R T4. Compare the effectiveness of research conduct and design strategies aiming to optimize long-term followup, while avoiding attrition bias and avoiding confounding the relationship between interventions and outcomes. **(0)**
- R I-1. Longer-term studies are needed to follow individuals involved in various treatments. For the most part we only study the impact of treatments over short periods. **(0)**
- R I-2. In order to determine the benefits of early interventions in SMI in terms of avoided disability and distress, it is imperative that investigations be funded and conducted over long periods of followup. **(0)**
- R I-7. Long-term study designs need to consider potential confounding factors that may “wash out” the effect of the intervention (e.g., shifts in public mental health services, managed care penetration, hospital lengths of stay). These factors can be taken into consideration but require that a sizeable sample be present at the start. (**0)**
- R I-9. Due to predictable attrition and various potential confounders, sizeable samples are needed for long-term studies to adequately maintain sufficient power for longitudinal conclusions to be drawn. **(0)**
- R T5. Compare different approaches to analyzing long-term trial or observational data, such as using illness trajectories vs. typical measures (e.g., initial and follow-up measures of symptoms and level of functioning). **(0)**
- R I-3. Research is biased toward using randomized controlled trials as the gold standard, but this may not be the most appropriate model for mental health research focused on patient-centered outcomes. **(0)**
- R 1-4. The framework of how care is delivered and research is conducted is based on a short-term model and may not be applicable to chronic diseases or consistent with the nature of SMI. **(0)**
- R I-8. In long-term studies, do diagnostic shifts over time introduce significant confounding? **(0)**
- R NT4. Need to develop longer-term study(ies) with continuous treatment. Must analyze data like an observational study, and could study Medicaid data and population. **(0)**

- R I-24. Specific and nonspecific strategies. **(0)**
- PC Idea1. Need to consider long-term nature of SMI disorders, with relapsing/episodic course. **(0)**

5. **Identify disparities and reasons for disparities and reevaluate the framework for researching disparities. (40)***
    - D 28. Reasons for disparity. **(14)**
        i. Barriers and access issues.
        ii. Clinical.
        iii. Systems.
        iv. Institutional racism.
    - D 57. How to find research collaborative in community-based organizations? **(9)**
    - D 38. Outcomes of interest? **(8)**
        i. Who/what is successful?
        ii. Improved outcomes.
        iii. Quality of life.
        iv. Patient satisfaction/happiness.
        v. Customer services.
    - R I-16. There is a need for more research focused on specific racial and ethnic communities and any research focus should include outcomes specific to these populations. Must address the overall lack of evidence-based practice inclusion of racial and ethnic communities as participants in research. **(4)**
        i. **SH Note:** Mental health research seems far behind. Needs major overhaul.
        ii. **SH Note:** Data clean-up: Must define Latino population more clearly (Mexican, Puerto Rican, South American). Include data such as: (1) years in the United States, (2) language, (3) acculturation.
    - D 46. Need to document disparity in public and private settings. **(2)**
    - D 52. How to identify community-defined evidence? **(2)**
    - D 24. Reevaluate framework for subpopulation research—identify why current research isn't answering the questions. **(1)**
        i. **SH Note:** To break through the current status quo on resolving disparities, perhaps we need to experiment with a different funding mechanism, asking communities to initiate research studies and having community representatives act as research review panels.
    - D Idea2. There is a need to look at the causes and risk factors for lack of services to people with limited English-language skills. **(0)**
    - D 48. Need to understand how to get data from a patient perspective. **(0)**
    - D 51. How to support community infrastructure? **(0)**
    - D 54. How to develop workforce diversity? **(0)**
    - D 55. How to get grassroots organizations to communicate data needs to the community? **(0)**
    - D 56. How to use grassroots organizations to translate intervention in culturally competent ways? **(0)**
    - D 29. What are the outcomes of interest from the specific disparities? **(0)**
    - D 50. What is working in communities; how to get better outcomes? **(0)**
    - D 53. What are best practices in the community? **(0)**

- D 30. What are the cost implications when accounting for vs. not accounting for race/ethnicity? **(0)**
- D 49. What are the disparities within communities? **(0)**
- PC 40. Importance of disaggregating data for subpopulations to identify disparities. **(0)**

6. **Role of the therapeutic relationship. (40)***
   - PC 38. Focus on relationship between client and provider as central to effectiveness research. Therapeutic alliance accounts for a large degree of variance in psychotherapy treatment outcome(s). Measurement of this factor should be part of evaluation of treatment outcomes. **(20)**
   - R Idea12. What are the features of health professionals that support the development of a "continuous healing relationship"? If factors associated with better patient outcomes could be identified (perhaps using qualitative research methods), we may then be able to develop approaches to training professionals to be more effective in their clinical interactions. **(10)**
      i. **SH Note:** What are the qualities of the person or organization providing the care? Does this have implications regarding outcomes?
      ii. **SH Note:** Need Accreditation Council for Graduate Medical Education-approved update training that is consistent with the current/future community practice.
   - R NT12. Study how individual characteristics are the biggest factors in whether one gets a disease, and how well one does; what individual factors predict onset; and how one does after onset. Also, include studying the therapeutic relationship as predictor of patient. **(7)**
      i. **SH Note**: Education/Medicaid database—but what if those functions/treatments/episodes of care are not applicable to the majority of people with mental illness who are not treated.
   - D 44. Comparing outcomes for English, non-English, and non-standard English speakers. **(2)**
   - PC 6. Compare the effectiveness of a recovery-based model of care to usual care on long-term functional outcomes in patients with SMI. This model could include a continuous therapeutic relationship with a coach, therapist, or other clinician. **(1)**
   - PC Idea2. A continuous healing relationship is a beneficial core feature of care. **(0)**
   - D 32. Impact on outcomes for patients utilizing community leaders as providers (clergy, folk healers, traditional healers). **(0)**
   - PC 44. Relationship of provider—disparities. **(0)**
7. **Strategies to personalize/individualize treatment. (39)**
   - D 3. Compare the effectiveness of psychotropic medications in subgroups of patients (e.g., age, race, and common comorbidities) to identify variation in patient responses and predictors of response that could inform the selection of treatments. **(13)**
      i. **SH Note:** Are providers informed about ethnic differences in responses to medications? (Ethno-psychopharmacology)
      ii. **SH Note:** Much is known about this. The variance by race is less than the variance within racial groups, so personalized care is essential.
   - D 40. Individualized treatment vs. one-size-fits-all. **(12)**
      i. Consideration of specific cultural characteristics.

    ii. Interventions/systems that do consider these vs. those that don't.
    iii. **SH Note:** To what degree do we value indigenous ways of knowing and healing methods?
- PC 41. Study relationship of ethnicity and intervention and outcome. **(8)**
- R I-11. Integrating decision analysis into a comparative effectiveness trial could lead to interesting approaches to improving outcomes through individualizing care. **(4)**
- PC 8. Compare the effectiveness of various strategies to best individualize pharmacologic therapy for people with SMI, including how to most efficiently find a tolerable regimen. **(1)**
- PC 37. Large database for individualized treatments. **(1)**
- D 7. Compare the effectiveness of using biomarkers to guide psychotropic medication therapy with usual care for people with SMI. This could include comparing pharmacogenomic-guided therapy with usual care. **(0)**
- PC 15. Compare the effectiveness of targeting specific recovery-related interventions to individual's (or families') goals and wishes. **(0)**

8. **Treatment approaches to avoid early mortality and morbidity. (34)***
    - PC 1. Compare the effectiveness of different treatment approaches in avoiding early mortality and comorbidity among people with SMI. For example, this could include integrating mental health care and primary care, improving consumer self-care, or a combination of integration and self-care. This could also include comparing various types of integrated care, such as co-locating mental health providers in primary care vs. primary care providers in mental health treatment settings. **(16)**
    - PC Idea4. Consider adding warnings/disclaimers on the medication circular that every patient receives. **(6)**
    - PC Idea3. Pharmaceutical companies could establish "Product Learning Centers" with the purpose of providing specific face-to-face support group meetings for the SMI community, patients, and their families to educate them about potential harms of medications, such as weight gain and the increased risk of diabetes, heart disease, and other health problems that may result from obesity. **(4)**
    - D 37. Medications alone vs. medications plus psychosocial treatments in underserved or specific groups. **(4)**
    - D 11. Compare the effectiveness of different approaches to prevent early mortality for subgroups of people with SMI, including racial, ethnic, and cultural subgroups**. ( 2)**
    - PC 28. Compare the effectiveness of interventions (including pharmacologic and nonpharmacologic) to prevent early mortality, including suicide, for people with SMI. **(1)**
    - D 25. Pregnant women as a subpopulation. **(1)**
    - PC 36. Compare versions of assertive community treatment (ACT). **(0)**
        i. **SH Note:** Look into a client-created alternative to ACT-PACE from the National Empowerment Center (Dan Fisher, MD, PhD, Executive Director).
    - PC 19. Compare the effectiveness of older (and less expensive) vs. newer psychotropic medications used at typical doses on long-term outcomes and costs (direct and indirect) of treatment. A detailed analysis of the inherent study biases in such trials as part of a comparative effectiveness review would be a useful addition to the knowledge base. **(0)**

- PC 13. Compare the effectiveness of combinations of psychotropic pharmacologic interventions for controlling SMI as well as for controlling a specific individual's other symptoms. **(0)**
- D 34. Polypharmacy: effectiveness or lack thereof within specific racial/ethnic groups. **(0)**
- PC 16. Given the side effects of medications and many patients' reluctance to consider medications (possibly related to negative and sometimes devastating side effects such as tardive dyskinesia), compare the effectiveness of bundled programs of antipsychotic medications with various bundled psychosocial interventions (partial treatment, supported work, care programs designed by empowerment-oriented consumer groups, residential care, family intervention) on quality of life, patient satisfaction, symptom course, health outcomes, and psychosocial outcomes. **(0)**
- R I-15. There is concern about the problematic relationship and practices of the pharmaceutical industry in mental health treatment and intervention. **(0)**

9. **Role of the psychiatric hospital, lengths of stay, and transition support services after discharge. (29)***
   - D 9. For individuals with SMI (with similar diagnoses and disease severity) and repeated hospital admissions, compare the effectiveness of different lengths of hospitalization on readmission rates, relapse, and remission. This could include assessing the circumstances that are best suited for long-term hospitalization to be more effective and specific interventions that enhance the effectiveness of long-term hospitalization. **(10)**
   - PC 20. Compare the effectiveness of different lengths of hospital stay (e.g., ultra-short stays of 1–4 days vs. longer stays of 7–10 days) on addressing various outcomes, including readmission rate in patients with SMI with similar diagnoses, demographics, and disease severity. **(8)**
     i. **SH Note:** Include readmissions because mental health diagnosis & mental health impact on physical health.
   - PC 21. Compare the effectiveness of different lengths of hospital stay on addressing various outcomes, including whether the individual and involved family felt that the factors prompting the admission were adequately addressed, whether the individual and involved family felt that the stay was sufficient to address safety and dangerousness concerns, and whether differences in length of stay influence other variables (e.g., satisfaction with care, adherence, insight into illness) in SMI patients with similar diagnoses and disease severity. In this comparison, consider whether factors such as housing stability or social support network confound the relationship between length of stay and readmission rates. **(7)**
     i. **SH Note:** Include readmissions because mental health diagnosis & mental health impact on physical health.
     ii. **SH Note:** As part of examining the role of inpatient hospitalization, examine: (1) the role of step-down transition in community-based settings and (2) the role of alternatives to inpatient care (caring (?) residential, home-based, intensive outpatient).
   - D 23. Compare the effectiveness of different approaches to support transitions after hospital discharge for subgroups of people with SMI, including racial, ethnic, and cultural subgroups. **(4)**

- PC 23. Compare the effectiveness of diverse models of transition support services for people with complex health care needs (e.g., the elderly, homeless, and mentally challenged) after hospital discharge on various outcomes, including readmission rates. **(0)**
- PC 30. Compare the effectiveness of management strategies (e.g., inpatient psychiatric hospitalization, crisis residential services, extended observation, partial hospitalization, intensive outpatient care) for people with SMI and various potential indications for hospital admission, including following a suicide attempt. **(0)**
- PC 26. Compare the effectiveness of various characteristics, quality, and intensity of care, along with duration of care (i.e., length of hospital stay), on outcomes for people with SMI. **(0)**
    i. **SH Note:** The unintended consequences of involuntary treatment. The fear of forced treatment actually keeps people from seeking mental health treatment.
- R I-14. The specifics of treatment are important. Concern with treating length of stay as a black box. SMI outcomes are based on differences within similar treatment modalities and systems (vs. between different modalities). **(0)**

10. **Retooling universities and education. (27)**
    - R NT13. Need innovative incentives to address the discrepancy between university-based education and approach/methods that work. **(27)**
11. **Strategies to increase adherence to evidence-based guidelines and treatment regimens. (27)***
    - PC 10. Compare the effectiveness of alternative redesign strategies—such as using multidisciplinary treatment, electronic health records, decision support capabilities, and personal health records—for increasing health professionals' compliance with evidence-based guidelines, increasing patients' adherence to guideline-based regimens, and improving continuity of care and communication. (**17)**
    - R NT5. Must explore the role of (the future role) of EMRs for everyone and how the relationships among structure, process, and outcomes in EMRs might contribute to doing new mental health research. **(5)**
    - PC 35. Compare technological interventions with standard care. **(3)**
    - PC 24. Compare the effectiveness of strategies for enhancing adherence to medication regimens for people with SMI. **(1)**
    - PC 34. Preference sensitive care vs. usual care on adherence and other outcomes of importance. **(1)**
12. **Correctional programs and interventions for people involved with the criminal justice system. (26)***
    - D 21. Compare the effectiveness of evidence-based correctional practices (such as those targeting risk factors for crime, like antisocial attitudes, with cognitive-behavioral techniques) with psychiatric treatment alone for their ability to promote community reentry. **(9)**
    - D 10. Compare the effectiveness of correctional programs vs. psychiatric treatment alone on outcomes such as community reentry among criminal offenders with mental illness. **(7)**
    - D 22. For adults with SMI who are involved with the criminal justice system, compare the effectiveness of organized interventions that can prevent re-arrest and re-incarceration. **(3)**

- D 13. Compare the effectiveness of various approaches to training the law enforcement workforce to identify and appropriately disposition people with SMI. (**2)**
- D 19. For adults with psychotic disorders who are involved with the criminal justice system, compare the effectiveness of supported employment and traditional job counseling on job placement, job retention, and criminal recidivism. **(2)**
- D 39. Criminal justice population differences within populations and recidivism risk. **(1)**
- D 16. For adults with psychotic disorders who are involved with the criminal justice system, compare the effectiveness of crisis intervention teams, mental health courts, and mental health probation or parole on community adjustment, reductions in criminal recidivism, and costs. **(1)**
- D 20. For prisoners with psychotic disorders, compare the effectiveness of suspending Medicaid benefits at the time of admission with terminating Medicaid benefits followed by expedited restoration prior to release on time to first mental health service use following release, engagement in services, criminal recidivism, and costs. **(1)**
- D 43. Compare psychiatric services with evidence-based interventions (EBI) for recidivism. **(0)**
- D 17. For adults with psychotic disorders who are involved with the criminal justice system, compare the effectiveness of forensically adapted intensive case management with forensically adapted assertive community treatment on community adjustment, reductions in criminal recidivism, and costs. **(0)**
- D 18. For adults with psychotic disorders who are involved with the criminal justice system, compare the effectiveness of forensically adapted assertive community treatment (FACT) with FACT plus cognitive behavioral therapy for criminogenic thinking on community adjustment, reductions in criminal recidivism, and costs. **(0)**
- D Idea1. The interrelationship between the criminal justice system and individuals with SMI is important (e.g., training of criminal justice professionals, care for SMI individuals in the criminal justice system). **(0)**
- R I-5. There is a need to include criminal justice perspectives in discussions of mental health research and policy. **(0)**

13. **Interventions for people with comorbid medical illness or substance abuse. (26)**
    - D 1. Compare the effectiveness of pharmacologic and nonpharmacologic interventions for people with SMI and comorbid medical illnesses (e.g., diabetes, HIV, and cardiovascular disease). **(16)**
    - D 27. Compare the effectiveness of treating mental illness and comorbidities on both mental and physical health. **(8)**
    - D 2. Compare the effectiveness of interventions or programs for people with both substance abuse and SMI (multiple diagnoses/comorbidities) on outcomes for both diagnoses. **(2)**
    - D 5. Compare the effectiveness of treatment interventions for SMI in people with coexisting symptoms, such as anxiety, insomnia, irritability, pain, or somatization. **(0)**
    - D 6. Compare the effectiveness of strategies to screen for and treat sleep apnea in people with SMI. **(0)**

- D 8. Compare the effectiveness of antipsychotic medications with and without concurrent medical marijuana in the treatment of psychotic patients who are already prone to marijuana use. **(0)**

14. **Prevention, early identification, trajectories, and developmental perspective. (25)***
    - R NT9. Need frameworks that address prevention strategies/mental health research that also includes a developmental perspective/trajectory (e.g., catch at first episode). **(18)**
    - D 42. Look at psychosocial stressors that precipitate mood disorders. **(4)**
    - PC 5. Compare the effectiveness of strategies to identify and treat SMI early in the course of illness on long-term outcomes, including quality of life. **(3)**
    - R NT22. Expand understanding that prevention is not just about prevention, but is also about delaying the onset of the condition. **(0)**
15. **Dissemination and implementation. (23)***
    - PC 32. Need for more work on implementation science. **(19)**
        i. **SH Note:** Plus more work on science in mental health—so much remains unknown.
    - R T1. Compare the effectiveness of strategies to disseminate and implement research findings and new discoveries into community practice to foster evidence-based, state-of-the-art treatment. **(4)**
        i. **SH Note:** How do we *approach* communities? Does this affect outcomes?
    - R T2. Compare the effectiveness of strategies to advance evidence-based practices using dissemination and demonstration projects. **(0)**
16. **Reducing barriers and improving access. (13)**
    - PC 11. Compare the effectiveness of sustainable interventions to reduce barriers to access for mental health services, including transportation, financial barriers, and insurance coverage barriers. For example, for those with clearly documented SMI, intervention groups (vs. bureaucracy-as-usual groups) could have streamlined access to Medicaid including access to essential medication while benefits are pending, meeting with a Medicaid worker at their home or their follow-up care site rather than at social services, automatic Medicaid renewal rather than having to reregister, ability to reenter the workforce part-time without losing key benefits, etc. What about changes in benefits packages to enhance health promotion (e.g., giving additional money for food stamps but designating that a certain percentage can only be used for fresh fruits and vegetables)? **(4)**
    - PC 14. Compare the effectiveness of strategies to obtain regular dental care for people with SMI on outcomes such as quality of life and physical well-being. **(3)**
    - D 15. Compare the effectiveness of strategies to reduce the barriers to accessing effective programs and to sustaining recovery for underserved populations, such as homeless people with SMI. **(3)**
    - D 14. Compare the effectiveness of health technology and telehealth to improve access to and coordination of care, especially for Americans in remote areas or in underserved populations. **(2)**
    - D 4. Compare the effectiveness of interventions to reduce barriers and improve access to care for people with SMI living in rural locations. **(1)**

17. **Mental health policy. (11)**
    - R T6. Compare the effectiveness of various policy practices in mental health on outcomes including cost-effectiveness and reach. **(7)**
    - R I-13. There is a need to establish national, regional, and/or state legal panels and/or watchdog agencies to ensure dissemination (and enforcement, if made law) of information and legislation related to persons with SMI. **(2)**
    - D 31. Receipt of information by families—patient outcomes. **(1)**
    - D 60. Medical information that is not made available to family members can grossly affect the quality of life of people with SMI as well as any future medical treatments (including physical health and mental health, emotional health). **(1)**
    - D 47. Need watchdog agency. **(0)**
18. **Modifiable factors: tobacco, exercise, and nutrition. (10)**
    - D 12. Compare the effectiveness of various tobacco cessation strategies for individuals with SMI and tobacco addiction. **(6)**
    - PC 25. Compare the effectiveness of interventions targeting modifiable factors such as daily caloric intake, physical exercise, mental exercise, and nutrition on health outcomes for people with SMI**. (4)**
19. **Alternatives to force or involuntary approaches. (9)**
    - PC 27. Compare the effectiveness of alternatives to interventions using force or involuntary approaches (e.g., seclusion and restraint) in people with SMI. **(9)**
20. **Providing housing or social support. (9)**
    - PC 4. Compare the effectiveness of different strategies to provide stable housing for people with SMI on mental health outcomes. **(6)**
    - PC 22. Compare the effectiveness of various approaches to providing housing or social support on outcomes, such as readmission rates. **(3)**
    - PC 9. Compare the effectiveness of various strategies to assist people with SMI with achieving normative success in education, relationships, employment, and housing on mental health outcomes including quality of life. This could be to assist with meeting normal developmental challenges or early adulthood or during later stages of life. **(0)**
        i. **SH Note:** Include outcomes like school attendance, missed work, etc.
21. **Strategies to reduce stigma, prejudice, and discrimination. (3)***
    - PC 29. Compare the effectiveness of strategies to reduce stigma, prejudice, and discrimination against people with SMI and to encourage their social inclusion. **(3)**

* This topic was determined by the stakeholders to be appropriate for evidence synthesis.
R NT = Conceptual framework for Research Workgroup–*New Topic*
R T = Conceptual framework for Research Workgroup –*Topic*
R I = = Conceptual framework for Research Workgroup–*Idea*
PC = Patient-centered Workgroup
D = Disparities Workgroup
SH Note = Stakeholder Note