

Major Depressive Disorder Workgroup

Morning Session



Introduction: Chair



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Disclaimer

Dr. Wang is participating in this workgroup meeting in a non-official capacity. His remarks represent his professional expertise, experience, and opinions as a psychiatrist and health services researcher. They do not reflect the opinions or policies of the Department of Health and Human Services or any of its components.



Housekeeping

Today's meeting is broadcast to the public and is being recorded

- Please indicate that you would like to speak by placing your name placard on end and raising your hand
- Where possible, we encourage you to avoid technical language in your discussion
- Please speak loudly and clearly into the microphone
- Please be mindful of noise when exiting rooms, as there are other meetings taking place



Introductions

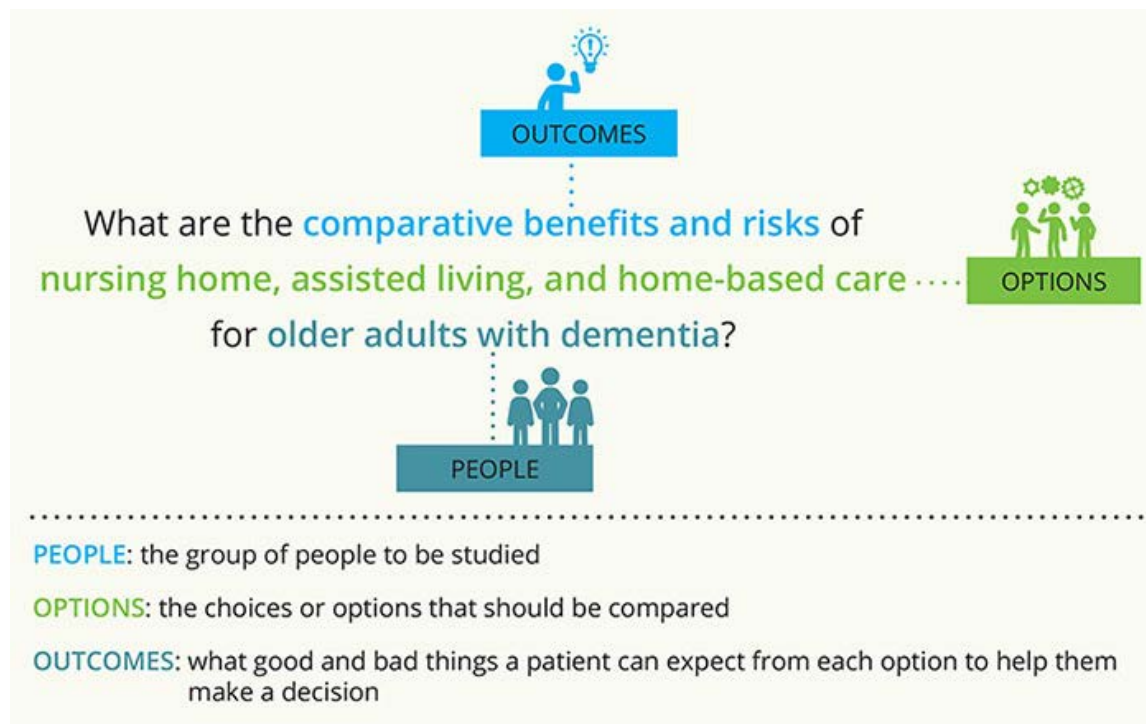
Please state:

- Your name
- Affiliation



Purpose of the Workshop

- Identify, refine, and prioritize up to 3 clinical comparative effectiveness research questions on the treatment of **severe depression** whose findings could improve patient-centered outcomes.



Question refinement process

- **Step 1: Discuss the top 5 ranked questions submitted by the group**
 - » PCORI Criteria
- **Step 2: Rank the questions in order of priority**
- **Step 3: Refine the top 3 research questions**
 - » Identification and discussion of populations, interventions, comparators, outcomes, time frame and settings
 - » Consideration of study design, challenges to conducting research on specific question, and ongoing work in the field



Major Depression Disorder

Severe Depression for the purposes of this meeting

Severe depression causes considerable distress or agitation, loss of self-esteem or feelings of uselessness and guilt. Symptoms are multiple, disabling, and interfere with functioning in work, school, social, and domestic settings such that they are obvious to others. Suicide can be a risk, and some patients may suffer from delusions or hallucinations.

Treatment-resistant depression is one type of severe depression and represents those patients who have not responded to two adequate antidepressant trials.



Selection of Questions

Submitted questions (56)

Duplicates, non-CER, non-severe depression questions removed by PCORI staff

Distinct and within scope questions (30)

Refinement and distillation by PCORI staff

Questions shared via SurveyGizmo (8)

Ranking & gap filling by Workshop attendees

Review ranking and discuss the top ranked questions (5)



Results of Initial Prioritization

Overall Rank		Score*
1	What is the comparative effectiveness of competing interventions to engage and enable patients in following effective treatments for their severe depression, such as adherence to medications or regular attendance of individual/group therapy sessions? What is their comparative effectiveness in promoting stability of symptoms and functioning?	110
2	What is the comparative effectiveness of cognitive behavioral therapy for severe depression when delivered by alternatives to individual face to face therapy? Examples include remote delivery (e.g. phone, online delivery, or patient use of self-guided online programs), use of health care professionals with varying levels of postgraduate training, and individual versus group settings.	108
3	For patients at high risk of under-treatment for severe depression due to socio-demographics (e.g. racial minorities, cultural differences in expressing/seeking help for depression, living in areas with few service providers), what is the comparative effectiveness of interventions designed to overcome these limitations?	104
4	What is the comparative effectiveness of competing "add-on" therapies in improving symptoms and functioning in severe depression when first line pharmacotherapy is incompletely effective? For example, transcranial magnetic stimulation (TMS) vs. second-generation antipsychotics (SGAs) vs. cognitive behavioral therapy (CBT) vs. electroconvulsive therapy (ECT) vs. algorithm-guided care. Does this vary with age (e.g. in adolescents or the elderly) and medical comorbidities (e.g. patients with cancer or myocardial infarction) or special circumstances (e.g. post-partum)?	93
5	What is the comparative effectiveness of manualized therapies as "add-on" treatment to severely depressed patients who are incompletely treated with pharmacotherapies? Examples include Wellness Recovery Action Plan (WRAP), Whole Health Action Management (WHAM), and others.	86
6	What is the comparative effectiveness of competing interventions for severely depressed patients experiencing a mental health crisis (e.g. psychosis, suicidal ideation or attempt)? What is their comparative effectiveness in acute and long-term stabilization of these patients?	70
7	What is the comparative effectiveness of peer-support interventions in managing crises or relapses of severe depression?	67
8	What are the comparative benefits and harms of using benzodiazepines vs. evidence-based "add-on" therapies for patients whose severe depression is complicated by anxiety? Are there subpopulations (e.g. adolescents, the elderly, patients with comorbidities) that are high priorities to study? (Note: benzodiazepines are commonly used but not recommended).	46



Step 1: Discuss the Top Ranked Questions

PCORI Criteria

1. **Patient-Centeredness:** is the comparison relevant to patients, their caregivers, clinicians or other key stakeholders and are the outcomes relevant to patients?
2. **Impact of the Condition on the Health of Individuals and Populations:** Is the condition or disease associated with a significant burden in the US population, in terms of disease prevalence, costs to society, loss of productivity or individual suffering?
3. **Assessment of Current Options:** Does the topic reflect an important evidence gap related to current options that is not being addressed by ongoing research.
4. **Likelihood of Implementation in Practice:** Would new information generated by research be likely to have an impact in practice? (E.g. do one or more major stakeholder groups endorse the question?)
5. **Durability of Information:** Would new information on this topic remain current for several years, or would it be rendered obsolete quickly by new technologies or subsequent studies?



Rank #1 What is the comparative effectiveness of competing interventions to engage and enable patients in following effective treatments for their severe depression, such as adherence to medications or regular attendance of individual/group therapy sessions? What is their comparative effectiveness in promoting stability of symptoms and functioning?



Rank #2 What is the comparative effectiveness of cognitive behavioral therapy for severe depression when delivered by alternatives to individual face to face therapy? Examples include remote delivery (e.g. phone, online delivery, or patient use of self-guided online programs), use of health care professionals with varying levels of postgraduate training, and individual versus group settings.



Rank #3 For patients at high risk of under-treatment for severe depression due to socio-demographics (e.g. racial minorities, cultural differences in expressing/seeking help for depression, living in areas with few service providers), what is the comparative effectiveness of interventions designed to overcome these limitations?



Rank #4 What is the comparative effectiveness of competing "add-on" therapies in improving symptoms and functioning in severe depression when first line pharmacotherapy is incompletely effective? For example, transcranial magnetic stimulation (TMS) vs. second-generation antipsychotics (SGAs) vs. cognitive behavioral therapy (CBT) vs. electroconvulsive therapy (ECT) vs. algorithm-guided care. Does this vary with age (e.g. in adolescents or the elderly) and medical comorbidities (e.g. patients with cancer or myocardial infarction) or special circumstances (e.g. post-partum)?



Rank #5 What is the comparative effectiveness of manualized therapies as “add-on” treatment to severely depressed patients who are incompletely treated with pharmacotherapies? Examples include Wellness Recovery Action Plan (WRAP), Whole Health Action Management (WHAM), and others.



Step 2: Rank the 5 Questions in Order of Priority

- Please check your email. You will receive a link to a prioritization survey.
- You will see the newly revised questions discussed this morning. Please rank the questions in order of priority, with 1 being highest.
- Once you have completed the prioritization survey, you may get your lunch to bring back to the meeting room.
- Please return to the meeting room before 1pm, so that we may resume our meeting promptly at 1pm.



Major Depressive Disorder Workgroup

Afternoon session



Results from Morning Prioritization Session

Overall Rank	Question
1	D. What is the comparative effectiveness of switching and/or augmenting therapies in improving symptoms and functioning in treatment-resistant depression? For example, transcranial magnetic stimulation (TMS) vs. second-generation antipsychotics (SGAs) vs. psychosocial therapy vs. electroconvulsive therapy (ECT). Does this vary with age (e.g. in adolescents or the elderly) and medical comorbidities (e.g. patients with cancer or myocardial infarction) or special circumstances (e.g. post-partum)?
2	A. What is the comparative effectiveness of different available interventions to engage and enable patients in following effective treatments for their severe depression, such as interventions that promote adherence to medications or regular attendance of individual/group therapy sessions? What is their comparative effectiveness in promoting adherence to treatment and therapy, improvement of wellness, symptoms, and functioning?
3	C. For patients who are likely to lack access to comprehensive assessment or at high risk of under or inappropriate treatment for severe depression due to socio-demographics (e.g. racial minorities, cultural, and linguistic differences in expressing/seeking help for depression, living in areas with few service providers), what is the comparative effectiveness of interventions designed to increase access to appropriate treatment.
4	B. What is the comparative effectiveness of evidence-based psychosocial treatment traditionally delivered face-to-face for severe depression when delivered by alternatives to individual face to face therapy? Examples include remote delivery (e.g. phone, online delivery, or patient use of self-guided online programs), expertise in CBT delivery, and individual versus group settings.
5	E. What is the comparative effectiveness of manualized therapies as “add-on” treatment to severely depressed patients who are incompletely treated with first-line or any other therapies? Examples include Wellness Recovery Action Plan (WRAP), Whole Health Action Management (WHAM), and others.

Step 3: Refine the Top Research Questions

- Identify PICOTS related to each question:
 - **P**atient population
 - **I**ntervention
 - **C**omparators
 - Patient-centered **O**utcomes of interest
 - **T**ime frame
 - **S**etting
- Discuss study design, challenges to conducting research, feasibility of study and ongoing work in the field
- Refine question wording to best reflect research and clinical priorities



Rank #1: What is the comparative effectiveness of switching and/or augmenting therapies in improving symptoms and functioning in treatment-resistant depression? For example, transcranial magnetic stimulation (TMS) vs. second-generation antipsychotics (SGAs) vs. psychosocial therapy vs. electroconvulsive therapy (ECT). Does this vary with age (e.g. in adolescents or the elderly) and medical comorbidities (e.g. patients with cancer or myocardial infarction) or special circumstances (e.g. post-partum)?

- Patient Population:
- Intervention:
- Comparators:
- Patient-Centered Outcomes:
- Time Frame:
- Setting:
- Other Comments:



Rank #2: What is the comparative effectiveness of different available interventions to engage and enable patients in following effective treatments for their severe depression, such as interventions that promote adherence to medications or regular attendance of individual/group therapy sessions? What is their comparative effectiveness in promoting adherence to treatment and therapy, improvement of wellness, symptoms, and functioning?

- Patient Population:
- Intervention:
- Comparators:
- Patient-Centered Outcomes:
- Time Frame:
- Setting:
- Other Comments:



Rank #3: What is the comparative effectiveness of different available interventions to engage and enable patients in following effective treatments for their severe depression, such as interventions that promote adherence to medications or regular attendance of individual/group therapy sessions? What is their comparative effectiveness in promoting adherence to treatment and therapy, improvement of wellness, symptoms, and functioning?

- Patient Population:
- Intervention:
- Comparators:
- Patient-Centered Outcomes:
- Time Frame:
- Setting:
- Other Comments:



Closing remarks

- Meeting summary will be distributed in a few weeks
- Prioritized questions and deliberations from workshop will be shared with PCORI leadership
- PCORI will pursue development of research funding opportunities

