

CME PSYCHCAST™

EFFICACY, SAFETY, AND TOLERABILITY CONSIDERATIONS IN THE NOVEL TREATMENT OF MAJOR DEPRESSIVE DISORDER

FACULTY

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CME]

ABSTRACT

Although studies have shown that current medications do offer benefit over placebo for major depressive disorder (MDD) treatment, there exist various barriers to the implementation of a treatment plan for both clinicians and patients. Once a treatment course is determined, patients may hold a negative perception of pharmacologic treatment of MDD, have limited access to additional care, or cease taking medication due to a poor relationship with their clinician. In addition, clinicians must ensure that the correct diagnosis of MDD is made at presentation, despite a potentially differing profile among patients, and that if patients do not respond to treatment, augmentation with other medications is evaluated. Lastly, researchers are investigating novel treatments for MDD, which may allow for more precise treatment of the disorder.

In this Expert Panel PsychCast™, Andrew Nierenberg, MD, reviews MDD treatment barriers including the heterogeneity of MDD, societal factors, the clinician-patient relationship, and treatment adherence; Sidney Kennedy, MD, FRCPC, discusses the efficacy, safety, and tolerability of current MDD treatments in the context of societal, patient, and methodological variables; R. Bruce Lydiard, PhD, MD, describes novel treatments for MDD, including augmentation strategies; and Mark Hyman Rapaport, MD, reviews the development of MDD treatment beyond the traditional monoamine models of the disorder.



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The activity content has been peer-reviewed by **Sanjay J. Mathew, MD**.

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Mark Hyman Rapaport, MD, is chairman and professor of psychiatry and behavioral neurosciences, and the Poiler Endowed Chair in Schizophrenia and Related Disorders at Cedars-Sinai Medical Center and vice chairman and professor in residence in the Department of Psychiatry and Biobehavioral Sciences at the David Geffen School of Medicine at UCLA.

Faculty Disclosure Policy Statement

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Faculty Disclosures

Dr. Nierenberg is a consultant to or serves on the advisory boards of Abbott, Appliance Computing, Inc. (MindSite), AstraZeneca, Basilea, Brain Cells, Bristol-Myers Squibb, Eli Lilly, Genassance, GlaxoSmithKline, Innapharma, Jazz, Merck, the National Institute of Mental Health (NIMH), Novartis, Ortho-McNeil/Janssen, Pfizer, PGx Health, Schering-Plough,

Sepracor, Shire, Somerset, Takeda, and Targacept; is on the speaker's bureaus of Bristol-Myers Squibb, Cyberonics, Forest, Eli Lilly, GlaxoSmithKline, Massachusetts General Hospital Psychiatry Academy, and Wyeth; receives research support from Bristol-Myers Squibb, Cederroth, Cyberonics, Forest, Eli Lilly, GlaxoSmithKline, Lichtwer Pharma, NARSAD, NIMH, Ortho-McNeil/Janssen, PamLab, Pfizer, the Stanley Foundation, and Wyeth; receives honoraria from Massachusetts General Hospital Psychiatry Academy; and owns stock in Appliance Computing, Inc. (MindSite).

Dr. Kennedy is a consultant to and on the advisory boards of Advanced Neuromodulation Systems (ANS), AstraZeneca, Biovail, Eli Lilly, Lundbeck, Pfizer, Servier, and Wyeth; is on the speaker's bureau of ANS, AstraZeneca, Biovail, Boehringer-Ingelheim, Eli Lilly, Lundbeck, Servier, and Wyeth; and receives research support from ANS, AstraZeneca, the Canadian Institutes of Health Research, Eli Lilly, GlaxoSmithKline, Lundbeck, NARSAD, the Ontario Mental Health Foundation, the Ontario Problem Gambling Research Society, and the Stanley Foundation.

Dr. Lydiard is a consultant to Eli Lilly and Takeda; and has received research support from AstraZeneca, Bristol-Myers Squibb, Eli Lilly, Forest, Pfizer, sanofi-aventis, UCB Pharma, and Wyeth. He discusses unapproved/investigational uses of quetiapine.

Dr. Rapaport is consultant to Astellas, Brain Cells, Cyberonics, Dainippon-Sumitomo, the National Institute of Mental Health, and Wyeth; and receives research support from AstraZeneca, the National Center for Complementary and Alternative Medicine, the National Institute of Mental Health, Pfizer and Solvay. He discusses unapproved/investigational uses of celecoxib, MK-801.

CME Course Director **James C.-Y. Chou, MD**, is associate professor of psychiatry at Mount Sinai School of Medicine. Dr. Chou has received honoraria from AstraZeneca, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Janssen, and Pfizer.

Dr. Mathew is associate professor of psychiatry at Mount Sinai School of Medicine. Dr. Mathew has served as an advisor/consultant to AstraZeneca and Jazz.

Learning Objectives

At the completion of this activity, participants should be better able to:

- Estimate barriers to treatment response for patients with major depressive disorder (MDD) to limit a chronic course of illness
- Evaluate the role of novel treatments for patients with MDD who do not achieve full remission
- Explain the efficacy, safety, and tolerability of novel treatment options available for MDD

Statement of Need and Purpose

Major depressive disorder (MDD) is a chronic condition, especially in cases that do not respond easily to treatment. Despite the availability of different classes of drugs for the treatment of MDD, there are a number of

clinically significant unmet needs, such as a high prevalence of drug resistance, partial response, subsyndromal symptomatology, recurrence, and relapse. Treatment resistant depression (TRD) is frequently defined as depressive illness that does not fully remit after a single initial treatment failure. Up to 50% of patients in primary care settings do not show a full response to their first antidepressant treatment. The likelihood of successful treatment of MDD decreases with an increasing number of unsuccessful treatment attempts. There is a higher frequency of suicide in patients with TRD as opposed to those with treatment responsive MDD.

The strengths and limitations of selective serotonin reuptake inhibitors and selective norepinephrine reuptake inhibitors have been realized, as many patients do not respond well to initial antidepressant treatment or achieve remission. This has led to a re-emergence of interest in treatment augmentation research. It is apparent that mood regulation involves multiple neurotransmitter systems, and this widens the potential for chemical manipulation and, thus, treatment options. The advent of atypical antipsychotics has had a major impact in schizophrenia and may offer clinical advantages in mood regulation beyond bipolar disorder. Clinicians need to be made aware of recent medical advances related to depression in order to improve their treatment capabilities. Patients who only achieve partial response or continue to experience residual symptoms are likely to show reduced functioning and an increased risk of relapse.

Target Audience

This activity is designed to meet the educational needs of psychiatrists.

Accreditation Statement

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of the Mount Sinai School of Medicine and MBL Communications, Inc. The Mount Sinai School of Medicine is accredited by the ACCME to provide continuing medical education for physicians.



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The Mount Sinai School of Medicine designates this educational activity for a maximum of 1 *AMA PRA Category 1 Credit™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

To Receive Credit for this Activity

Read this Expert Panel Supplement, reflect on the information presented, and complete the CME posttest and evaluation. To obtain credit, you should score 70% or better. Early submission of this posttest is encouraged. Please submit this posttest by June 1, 2011 to be eligible for credit.



MAJOR DEPRESSIVE DISORDER: BARRIERS TO TREATMENT

By Andrew Nierenberg, MD

SLIDE LIBRARY

SLIDE 1

MDD: Common Psychological Symptoms¹

Depressed mood	Indecisiveness
Irritability	Pessimism/hopelessness
Anxiety/nervousness	Feelings of helplessness
Reduced concentration	Cognitive distortions
Lack of interest/motivation	Feeling stressed
Inability to enjoy things	Low self-esteem/feelings of worthlessness
Lack of pleasure	Excessive guilt
Hypersensitivity to rejection/criticism	Thoughts of death or suicide
Perfectionism/obsessiveness	Thoughts of hurting other people

MDD=major depressive disorder.

SLIDE 3

Major Depressive Disorder: Common Somatic/Physical Symptoms¹

Fatigue	Reduced libido/arousal difficulties
Leadens feelings in arms or legs	Erectile dysfunction
Sleeping too little/insomnia	Delayed orgasm/inability to achieve orgasm
Sleeping too much/hypersomnia	Headaches
Decreased appetite	Muscle tension
Weight loss	Gastrointestinal upset
Increased appetite	Heart palpitations
Weight gain	Burning or tingling sensations

SLIDE 2

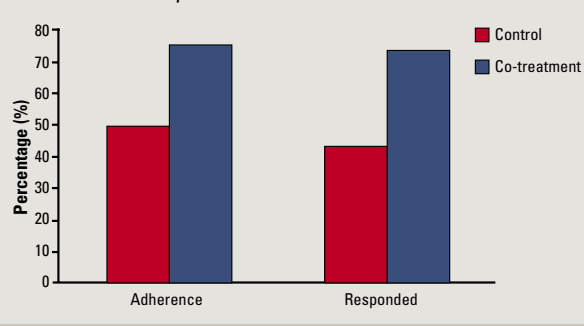
MDD: Common Behavioral Symptoms¹

Crying spells	Reduced leisure activities
Interpersonal friction/confrontation	Development of rituals or compulsions
Anger attacks/outbursts	“Workaholic” behaviors
Avoidance of anxiety-provoking situations	Substance use/abuse
Reduced productivity	Self-sacrifice/victimization
Social withdrawal	Self-injury/mutilation
Avoidance of emotional and sexual intimacy	Suicide attempts/gestures
Violent behavior/assault	

MDD=major depressive disorder.

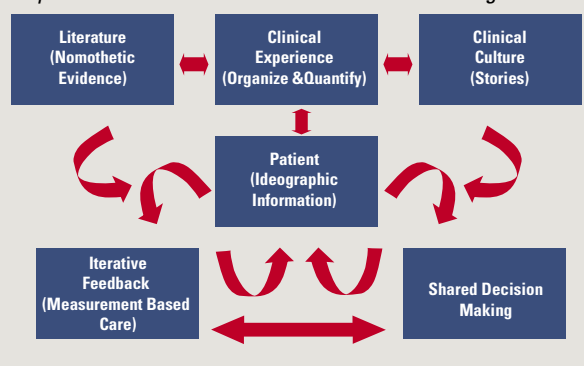
SLIDE 4

Co-Treatment Helps²



SLIDE 5

Implementation of Evidence Based Decision Making



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PERCEPTIONS OF EFFICACY, SAFETY, AND TOLERABILITY: *IMPACT ON EVALUATING NEW TREATMENTS*

By Sidney Kennedy, MD, FRCPC

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SLIDE 1

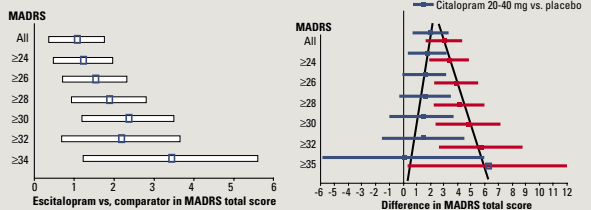
Conflicting Views on Antidepressants¹⁻⁴

Evidence for Efficacy

- Impact of unpublished negative or failed trials³
- The benefit falls below accepted criteria for clinical significance⁴
- Arbitrary selection of effect size based on National Institute for Clinical Excellence Guidelines^{3,5}
- Extension to quality of life, cost effectiveness, and relapse prevention trials⁶

SLIDE 2

Escitalopram vs. Comparators: End Differences by Baseline Severity^{5,6}



SLIDE 3

Efficacy, Safety, and Tolerability: Methodology Issues in Clinical Trials

- Dose and duration
- Choice of rating scales
- Consensus on endpoint
- Veracity of trial conditions
- Handling side effects
- Selection of statistical analyses
- Use of meta-analyses

SLIDE 4

Antidepressant Tolerability⁷

Sexual Dysfunction: SSRIs, highest risk (>50%), followed by SNRIs, bupropion, low-risk

Drowsiness/Fatigue: Mirtazapine, SSRIs, and SNRIs, high risk (>10%), bupropion and reboxetine, low risk

Weight Gain: TCAs, highest risk (22%), Mirtazapine, SSRIs, varies between antidepressants, SNRIs, nefazodone, and bupropion, low-risk

Insomnia: Reboxetine, SSRIs, bupropion, highest risk (>15%), mirtazapine and nefazodone, lower risk

Nausea: SSRIs and SNRIs, highest risk (>20%), bupropion, reboxetine, and mirtazapine, lower risk

SSRIs=selective serotonin reuptake inhibitors; SNRIs=serotonin-norepinephrine reuptake inhibitors; TCAs=tricyclic antidepressants.

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NOVEL TREATMENTS FOR MAJOR DEPRESSIVE DISORDER

By R. Bruce Lydiard, PhD, MD

SLIDE LIBRARY

SLIDE 1

Antidepressants "Plus"??¹

Established:

- Lithium
- Triiodothyronine (T3)
- Atypical antipsychotic

Combinations:

- Antidepressant and bupropion
- Buspirone
- Mirtazapine
- Cognitive-behavioral therapy

Possibly Effective:

- Stimulants
- Dopaminergic agonists
- Pindolol
- Buspirone
- Modafinil
- Estrogen
- Testosterone
- Lamotrigine
- Folate

The most clearly effective augmentations are rarely used by psychiatrists.

SLIDE 2

Dopamine Agonists for TRD²⁻⁶

Bupropion: Few RCTs, but most popular augmentation; numerous favorable open studies; in STAR*D step 2 bupropion, sertraline or venlafaxine showed similar effect

Other Stimulants

Modafinil 200 mg vs. placebo partial responders

Methylphenidate extended release: one small RCT in TRD (n=60; 4-week treatment) favored drug but not statistically significant possibly due to small sample

Pramipexole, ropinorole, pergolide, bromocriptine show limited support; newer agents need RCT

TRD=treatment-resistant depression; RCTs=randomized controlled trials; STAR*D=Sequenced Treatment Alternatives to Relieve Depression.

SLIDE 3

Atypical Antipsychotics for TRD^{7,8}

Olanzapine, Fluoxetine, Both, or Placebo

- One of three large trials n>500 robustly positive, one of two smaller positive; methodology differed

Risperidone relapse prevention study

- Failed 1–3 trials with citalopram 20–60 mg
- Non-responders given open-label risperidone
- 274 non-remitters randomized to continue or to placebo

Quetiapine augmentation

- Three small studies, all positive; two large RCTs positive for unipolar MDD (non-TRD)

Ziprasidone

- Open-label studies, one RCT, unpublished

Aripiprazole

- Two large positive RCTs
- FDA approved for TRD

TRD=treatment-resistant depression; RCTs=randomized controlled trials; MDD=major depressive disorder; FDA=Food and Drug Administration.

SLIDE 4

Other Augmentation Strategies⁹⁻¹³

Clonazepam (two RCTs), more rapid antidepressant effect; eszopiclone (one RCT), more rapid onset and larger antidepressant effect

- Both placebo controlled
- No significant discontinuation problems

Lamotrigine (one placebo-controlled RCT), no end-study difference, potential shortened response time

Estrogen (two RCTs), showed superiority to placebo in perimenopausal women; health concerns limit enthusiasm

Buspirone (several RCTs with equivocal findings); STAR*D recipients had response similar to venlafaxine augmentation

Folate (suggestive literature); RCT with tetramethyl-folate nearing conclusion

RCTs=randomized controlled trials; STAR*D=Sequenced Treatment Alternatives to Relieve Depression.

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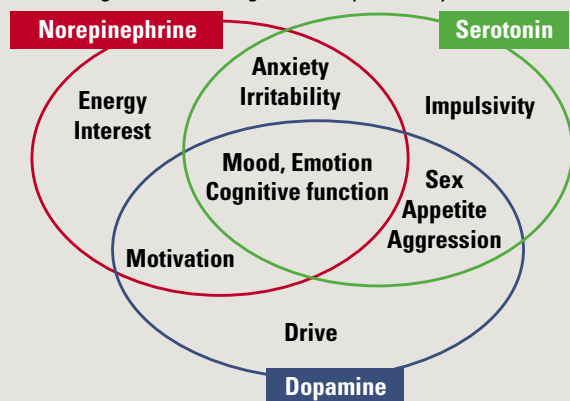
FUTURE DRUGS FOR THE TREATMENT OF DEPRESSION: *THE NEED TO LOOK BEYOND MONOAMINE SYSTEMS*

By Mark Hyman Rapaport, MD

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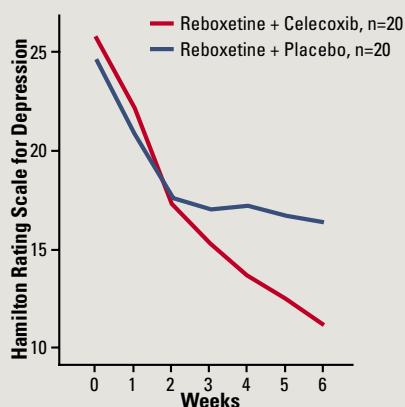
SLIDE 1

Serotonergic, Noradrenergic, and Dopamine Systems



SLIDE 3

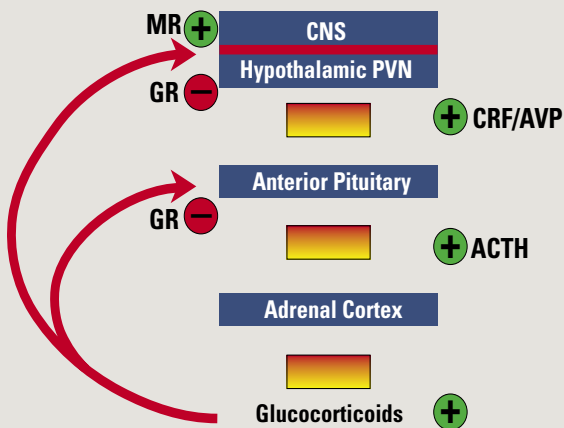
Celecoxib and Reboxetine in Major Depressive Disorder¹



Last observation carried forward (LOCF); $P < .015$.

SLIDE 2

Hypothalamic Pituitary Adrenal Axis



MR=mineralocorticoid receptor; CNS=central nervous system; GR=glucocorticoid receptor; PVN=paraventricular nucleus; CRF=corticotrophin releasing factor; AVP=arginine vasopressin; ACTH=adrenocorticotropic hormone.

SLIDE 4

Other Potential Therapeutic Approaches²

Omega-3 fatty acids (inhibition of interleukin-1 and tumor necrosis factor- α production) show a significant antidepressant effect in 10 studies (n=329); effect size .61 ($P < .03$)

Anti-phosphodiesterase 4

Kynurenine 3-mono-oxygenase inhibitors

Mitogen-activated protein kinase systems, protein kinase C, ERK1-2 and other components related to cAMP response element binding protein

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EFFICACY, SAFETY, AND TOLERABILITY CONSIDERATIONS IN THE NOVEL TREATMENT OF MAJOR DEPRESSIVE DISORDER

CME POSTTEST

- 1. Which of the following augmenting agents has been established to be effective in treatment-resistant major depressive disorder (MDD) under double-blind, placebo-controlled study conditions?**
 - A. Folate
 - B. Mirtazapine
 - C. Lithium
 - D. Bupropion
- 2. Seventy-five percent of people with MDD have a 4–5 year delay from the onset of symptoms to seeking treatment.**
 - A. True
 - B. False
- 3. Which of the following long-term side effects are most likely to result in discontinuation of treatment with a selective serotonin reuptake inhibitor?**
 - A. Weight loss and central nervous system stimulation
 - B. Dizziness and constipation
 - C. Weight gain and sexual dysfunction
 - D. Persisting nausea and diarrhea
- 4. Current antidepressant therapy relies on the modulation of which of the following:**
 - A. Substance P
 - B. Corticotropin-releasing hormone
 - C. Norepinephrine
 - D. Glucocorticoid receptors
- 5. Meta-analyses are most useful when:**
 - A. All studies use the same entrance criteria and outcome measures
 - B. Different methodologies are included across trials
 - C. Widely different sample sizes are represented across studies
 - D. None of the above
- 6. Factors associated with increased efficacy for antidepressants compared to placebo in research include which one of the following?**
 - A. Mild level of severity at baseline
 - B. Longer duration of clinical trial
 - C. Comorbid anxiety disorder diagnosis
 - D. Presence of heterogeneity of serotonin transporter
- 7. Technologies that may help extend knowledge about antidepressant development include all of the following except:**
 - A. Imaging
 - B. Animal models
 - C. Molecular genetics
 - D. Clinical trials
- 8. Symptoms of MDD omitted from the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*, include:**
 - A. Anxiety
 - B. Hypersomnia
 - C. Social withdrawal
 - D. A and C
 - E. All of the above

REGISTRATION

JUNE 2009 CME POSTTEST

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ANSWER FORM

Expert Panel PsychCast™ – Efficacy, Safety, and Tolerability Considerations in the Novel Treatment of Major Depressive Disorder

TERMINATION DATE: June 5, 2011

To receive credit, you should score 70% or better (participants will receive certification for their records in approximately 4–6 weeks). Early submission of this posttest is encouraged. Please submit this test by June 1, 2011, to be eligible for credit. If you have any questions about this, or any of our other CME materials, please e-mail CME@mblcommunications.com

Please circle your answers

1. A B C D 2. A B 3. A B C D 4. A B C D 5. A B C D 6. A B C D 7. A B C D 8. A B C D E

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