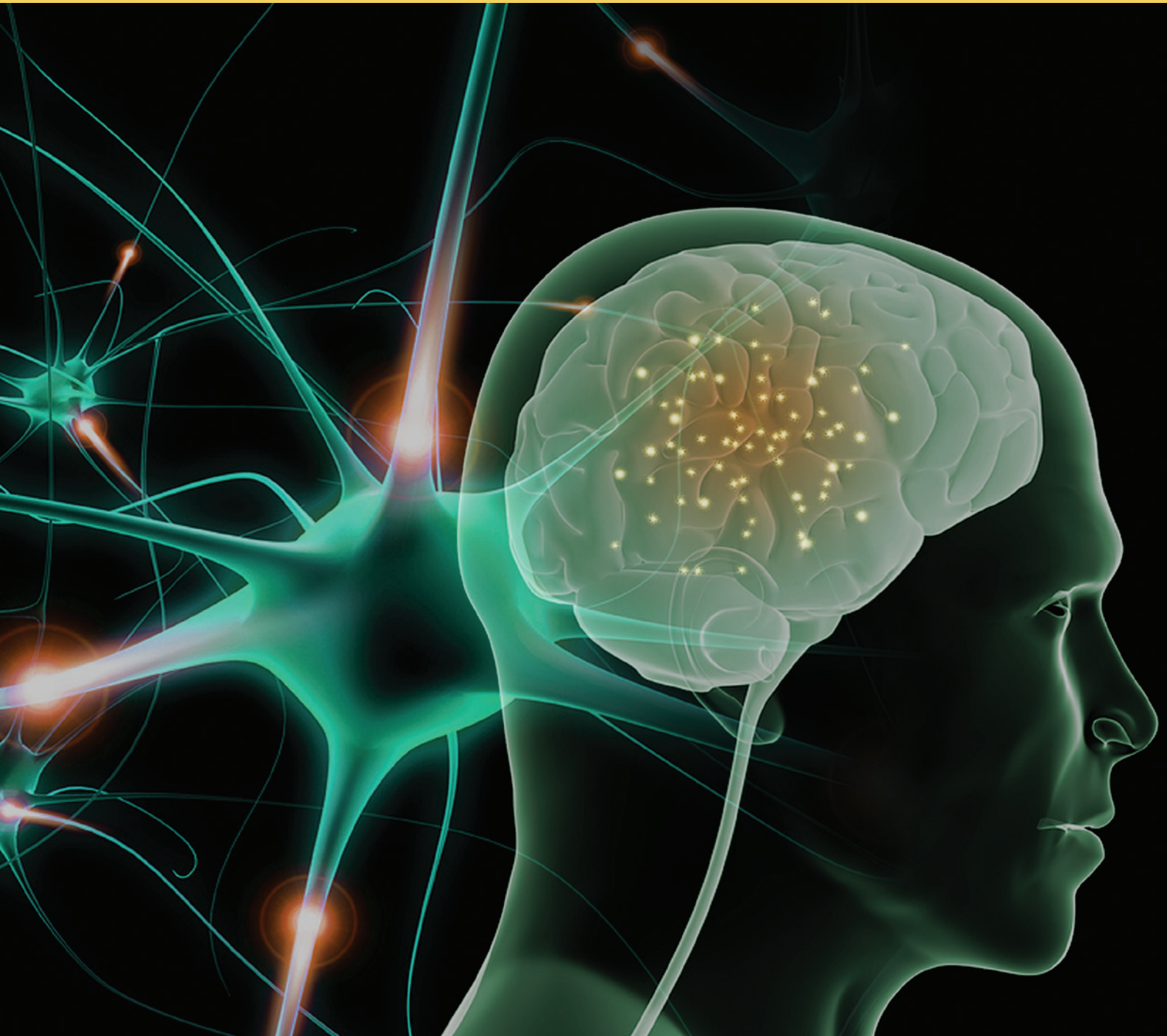


ADULT MAJOR DEPRESSIVE DISORDER (MDD)

T R E A T M E N T T O O L B O X



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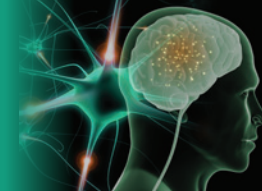
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ADULT MDD TREATMENT TOOL BOX



Release date: October 13, 2011

Expiration date: April 30, 2013

Estimated time to complete activity: 1.0 hours

Intended Audience

This activity has been designed to meet the educational needs of:

- Psychiatrists, primary care physicians, and other clinicians involved with the care of adult patients with major depressive disorder
- Medical Directors and Pharmacy Directors from health plans, HMOs, integrated health systems, employers, quality organizations, public payer groups, and other managed care organizations and health insurers
- Managed care affiliated care team members involved with patient evaluation, education, and follow-up for adult patients with MDD including: physicians, pharmacists, registered nurses, and care managers

Statement of Educational Need

Adult MDD is a serious medical illness affecting 15 million American adults, or approximately 5-8% of the adult population in a given year. Unlike normal emotional experiences of sadness, loss, or passing mood states, MDD is persistent and can significantly interfere with an individual's thoughts, behavior, mood, activity, and physical health. Over 50% of patients with adult MDD develop role impairment. There is no single cause of MDD—psychological, biological, and environmental factors may all contribute to its development.

Adult MDD has also been associated with significant medical comorbidity. In addition, adult MDD affects patients' marital, parental, social, and vocational functioning. The disorder is unremitting in about 15% of patients and recurrent in another 35%. Compounding the problem is that treatment is often delayed. These factors highlight the need for changes in the delivery of mental health services to enhance timeliness and quality of care in adult MDD.

The economic toll associated with the treatment of depression is enormous—in 2000, the U.S. economic burden of depressive disorders was estimated to be \$83.1 billion. More than 30% of these costs are attributable to direct medical expenses.

Educational Objectives

After completing this activity, the participant should be better able to:

- Implement evidence-based sequenced management strategies based on the 2010 APA Practice Guideline to enhance clinical decision-making for adult patients with MDD
- Assess the clinical and economic value of atypical antipsychotics for the treatment of adult patients with MDD who do not achieve full remission
- Explain how the 2010 APA Practice Guideline can integrate with a managed care algorithm for optimal value of therapeutic options
- Apply the use of decision support tools, such as comparative effectiveness research (CER) and pharmacoeconomic (PE) models, that enable evidence-based treatment decisions for adult patients with MDD

- Implement a system-wide approach to collaborative care, stepped care, and medication therapy management
- Implement patient screening and monitoring that leverages health information technology advances to improve outcomes for adult patients with MDD
- Provide appropriate care and counsel for patients and their families
- Provide accurate and appropriate counsel as part of the treatment team

Physician Continuing Medical Education

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 through the joint sponsorship of Postgraduate Institute for Medicine and Impact Education, LLC. Postgraduate Institute for Medicine is accredited by the ACCME to provide continuing medical education for physicians.

Credit Designation Statement

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Pharmacist Continuing Education

Accreditation Statement

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Credit Designation

Postgraduate Institute for Medicine designates this continuing education activity for 1.0 contact hours (0.10 CEUs) of the Accreditation Council for Pharmacy Education. (Universal Activity Number - 0809-9999-11-132-H01-P)

Type of Activity

Knowledge-based

Nursing Continuing Education

Credit Designation Statement

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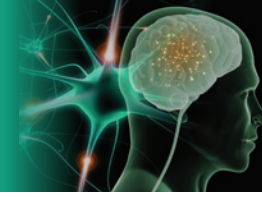
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A statement of credit will be issued only upon receipt of a completed activity evaluation form.

CME/CE information continued on page 4



The purpose of the *Adult Major Depressive Disorder (MDD) Treatment Tool Box* is to provide examples of resources that have been used successfully by clinicians, educators, peer review organizations, managed care organizations and others to improve care of patients with MDD. This Tool Box does not specifically endorse any of the enclosed tools.

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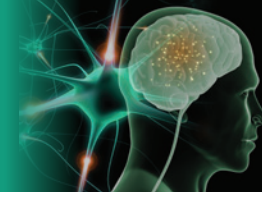
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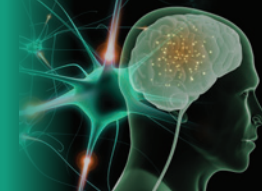
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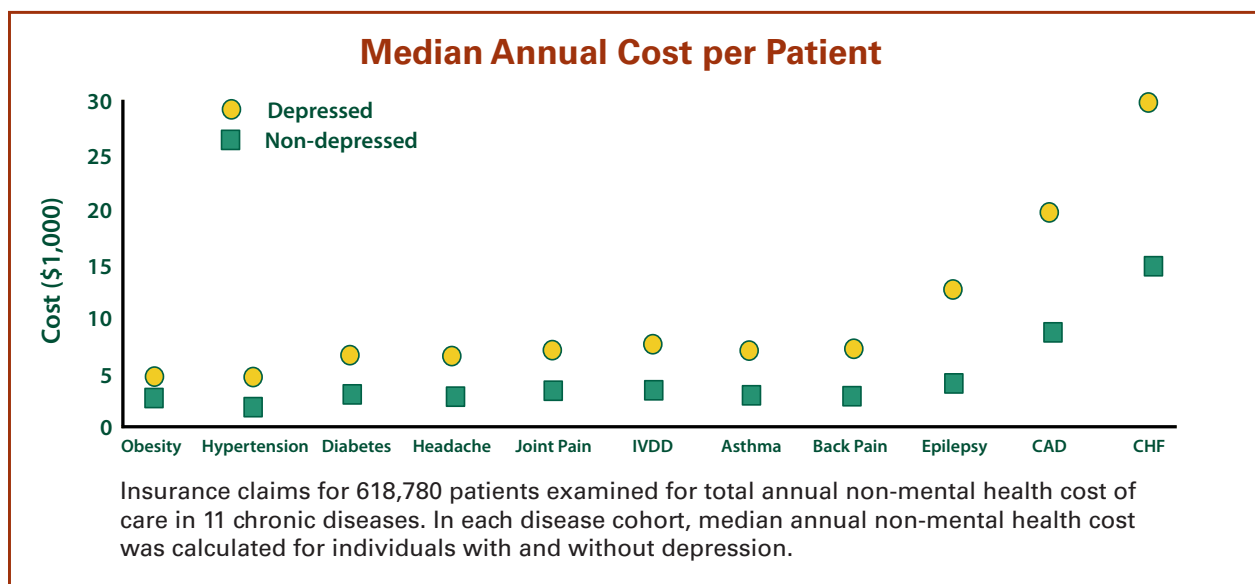
Introduction

Burden of Major Depressive Disorder (MDD) in Adults

- MDD affects >18 million Americans^{1,2}
- The lifetime prevalence of MDD is 16.2%^{1,2}
- The disease prevalence, treatment rate, and degree of impairment contribute to the clinical and economic burden of the disease³
- MDD patients achieving National Committee for Quality Assurance (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS) treatment goals cost >\$3400 less in annual direct (medical and drug) costs than those not meeting these standards⁴

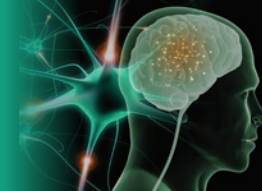
1. Greenberg PE, et al. *J Clin Psychiatry*. 2003;64:1465-1475; 2. Kessler RC, et al. *JAMA*. 2003;289:3095-3105; 3. Luppia M, et al. *J Affect Disord*. 2007;98: Epub 2006 Sep 6; 4. Greenberg HG, et al. *J Med Econ*. 2009;12:36-45.

Annual Per-patient Healthcare Costs for Patients With MDD

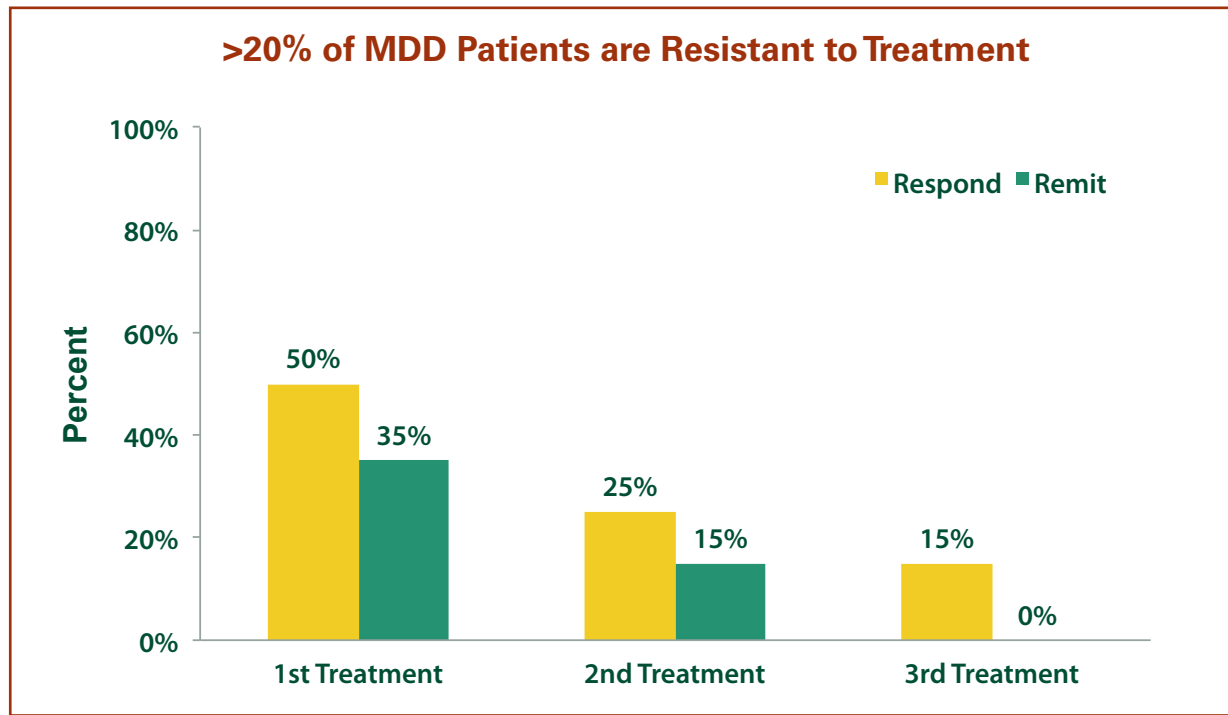


CAD=coronary artery disease; CHF=congestive heart failure; IVDD=intervertebral disc disease.

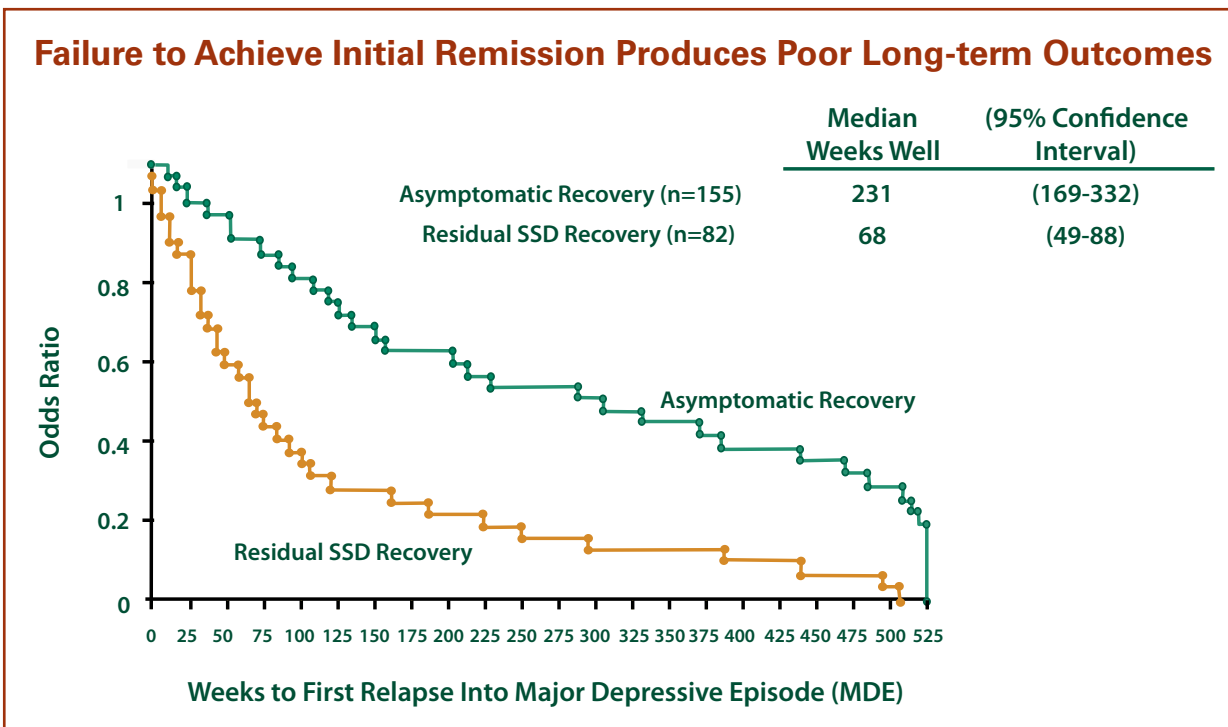
Welch CA, et al. *Psychosomatics*. 2009;50:392-401.



Unmet Needs and MDD Treatment Challenges

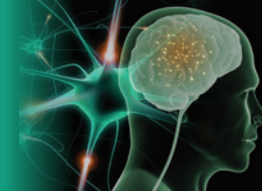


Robinson WD, et al. *J Am Board Fam Pract.* 2005;18:79-86.
 Fava M, et al. *Psychiatr Clin North Am.* 2003;26:457-494.



SSD=sub-syndromal depression; subthreshold depressive symptoms.

Judd LL, et al. *J Affect Disord.* 1998;50:97-108.



MDD Treatment Challenges

- Poorly defined condition which is often misdiagnosed
- Inadequate treatment, under-treatment, delayed treatment
 - Failure to achieve remission with prior therapy
 - “Pseudo-resistance” observed in patients who have not received guideline-defined treatment
- Failure to address comorbid disorders
 - Substance abuse
 - Concurrent Axis I or II disorders
 - Other medical conditions
- Non-adherence to prescribed treatment regimen
 - Premature discontinuation of treatment associated with higher rates of relapse

Gaynes B. *J Clin Psychiatry*. 2009;70(suppl 6):10-15; Fava M. *Biol Psychiatry*. 2003;53:649-659.



Management of Major Depressive Disorder (MDD) in Adults

General Approach to Treatment

According to the APA Guidelines, the Goal of Treatment is Remission

Response

- ≥50% improvement in symptoms
- Allows for significant residual symptoms

Vs

Remission

- At least 3 weeks of the absence of both sad mood and reduced interest
- No more than 3 remaining symptoms

American Psychiatric Association (APA). *Am J Psychiatry*. 2010;167:1-152.

Timing of Intervention

- Goal of Acute Phase of therapy is remission¹
- Measurement-based care is key¹
- Delay in achieving remission of symptoms is characteristic^{2,3}
 - Discontinuing a treatment prematurely (ie, <4 weeks) due to lack of efficacy alone may deprive some patients of a potentially effective therapy
 - Waiting too long in the face of complete non-response (ie, >8 weeks) may unnecessarily increase patient's exposure to an ineffective therapy and, ultimately, delay improvement

1. American Psychiatric Association. *Am J Psychiatry*. 2010;167:1-152; 2. Trivedi MH, et al. *Am J Psychiatry*. 2006;163:28-40; 3. Quitkin FM, et al. *Am J Psychiatry*. 2003;160:734-740.

Assessment of Therapeutic Failure

- Adequacy of treatment
 - Dose, duration, quality of therapy
- Appropriateness of diagnosis
 - Bipolar disorder, psychotic features
- Adequacy of diagnosis
 - Psychiatric/medical co-morbidity
- Compliance and tolerability
- Pharmacokinetic factors

American Psychiatric Association. *Am J Psychiatry*. 2010;167:1-152.

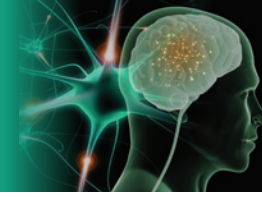


American Psychiatric Association (APA): Recommended Treatment Approaches

- Increase dosage
- Switching
- Augmentation
 - Addition of a non-antidepressant agent to enhance the effect of the antidepressant
- Combination
 - Addition of a second antidepressant agent to enhance the effect of the original antidepressant

Augmentation, Combination, and Switching

- Augmentation and combination
 - Avoid loss of any therapeutic benefits from first-line agent
 - No risk of withdrawal symptoms
 - May target side effects of first-line treatment
- Switching
 - Better compliance
 - Lower risk of drug interactions
 - Resolution of side effects
 - Cost implications must be determined
- Partial response (vs non-response)
 - Favors retention of initial agent
 - Augmentation
 - Combination
 - Dose-increase
- Poor tolerability (vs good tolerability)
 - Favors discontinuation of initial agent
 - Switching
- Knowledge of relative efficacy and tolerability of 2nd+ line strategies key to guiding treatment selection



Antidepressant Therapy Augmentation Strategies

Drug	Advantages	Disadvantages (Varies by Agent & Dose)
Antipsychotics <ul style="list-style-type: none"> • aripiprazole 5-15 mg • olanzapine 5-15 mg • quetiapine 150-300 mg • risperidone 0.5-2 mg 	<ul style="list-style-type: none"> • Best studied strategy 	<ul style="list-style-type: none"> • Tolerability <ul style="list-style-type: none"> - Neuroendocrine - Metabolic - Extrapyramidal symptoms • Efficacy as second-line treatment not well-described
Lithium <ul style="list-style-type: none"> • 600-1200 mg/d 	<ul style="list-style-type: none"> • Pooled odds ratio of response during lithium augmentation vs placebo: 3.31 (95% CI, 1.46-7.53) 	<ul style="list-style-type: none"> • Margin of efficacy vs dose increase, other strategies • All “positive” placebo-controlled studies of short duration • Paucity of studies on newer agents • Risk of toxicity and need for blood monitoring
Mirtazapine/Mianserin <ul style="list-style-type: none"> • 600-1200 mg qs 	<ul style="list-style-type: none"> • Strong efficacy data • May help with insomnia 	<ul style="list-style-type: none"> • Weight gain • Sedation • Agranulocytosis (very rare)
Pindolol <ul style="list-style-type: none"> • 2.5-7.5 mg tid 	<ul style="list-style-type: none"> • May accelerate response to selective serotonin reuptake inhibitors (SSRIs) 	<ul style="list-style-type: none"> • No difference from placebo in 2 largest studies • Increased irritability
Testosterone	<ul style="list-style-type: none"> • Positive results seen in one small study 	<ul style="list-style-type: none"> • No difference from placebo observed in at least 3 larger studies
Omega-3 Fatty Acids	<ul style="list-style-type: none"> • Tolerability • Acceptability • May possess other health-promoting benefits 	<ul style="list-style-type: none"> • Optimal dose unknown • Cost
Triiodothyronine (T3) <ul style="list-style-type: none"> • 600-1200 mg qd 	<ul style="list-style-type: none"> • May accelerate clinical response 	<ul style="list-style-type: none"> • All placebo-controlled studies involved tricyclic antidepressants (TCAs) • Among the 4 randomized controlled trials (RCTs), pooled effect were not significant ($p>0.05$)
Modafinil <ul style="list-style-type: none"> • 600-1200 mg qd 	<ul style="list-style-type: none"> • Efficacy demonstrated in pooled results of 2 trials • May resolve symptoms in patients who also present with residual somnolence and fatigue • Useful for residual somnolence 	<ul style="list-style-type: none"> • Unclear efficacy in patients without fatigue and sleepiness • Unclear effect in patients with insomnia
Buspirone <ul style="list-style-type: none"> • 10-30 mg 	<p>_____</p>	<ul style="list-style-type: none"> • Equivalent to placebo in 2 controlled studies
Osmotic-release Oral System (OROS) Methylphenidate <ul style="list-style-type: none"> • 18-54 mg/d 	<ul style="list-style-type: none"> • May help with fatigue, apathy, and somnolence • May help with comorbid attention-deficit/hyperactivity disorder (ADHD) 	<ul style="list-style-type: none"> • 2 negative studies • Potential for abuse
L-methylfolate <ul style="list-style-type: none"> • 7.5-15 mg/d 	<ul style="list-style-type: none"> • Significantly better than monotherapy at higher dose 	<ul style="list-style-type: none"> • No difference than monotherapy at lower dose
S-adenosyl Methionine (SAME)	<ul style="list-style-type: none"> • Pilot data indicate SAME is an effective, well-tolerated, and safe adjunctive treatment strategy for SRI nonresponders 	<ul style="list-style-type: none"> • Study was underpowered and of short duration

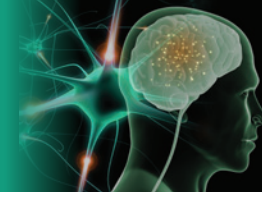


Therapeutic Options in Patients With Refractory Depression

- Electroconvulsive therapy
- Vagus nerve stimulation
- Deep brain stimulation
- Variable data for efficacy
- Timing for introduction depending upon
 - Refractoriness of illness
 - Use in past episodes
 - Patient preference
 - Availability

Benefits of the Placebo Effect

- Psychotherapy, antidepressants, and somatic therapies are all part of the reason why patients improve
- Strategies for placebo enhancement
 - Assuage fears, worry, and embarrassment about illness
 - Work on problem-solving skills
 - Plan resumption of pleasurable activities
 - Provide hope
 - Involve patients in treatment decisions – incorporate patient preference into the treatment regimen
- Supportive components of MDD care
 - Team approach
 - Use of a case manager
 - Assess to a psychiatrist
 - Adherence monitoring and support
 - Provide education to patient and family



Integrating Current Major Depressive Disorder (MDD) Practice Guidelines Into a Managed Care Treatment Algorithm

- Identify optimal, cost-effective treatment strategies¹
 - Inadequate dose or duration of antidepressant therapy can prevent remission^{2,3}
- Goal of treatment is remission³
 - 4-8 weeks of treatment are needed before concluding that a patient is partially responsive or unresponsive to a specific intervention
 - If at least a moderate improvement in symptoms is not observed within 4-8 weeks of treatment initiation, the treatment plan should be adjusted

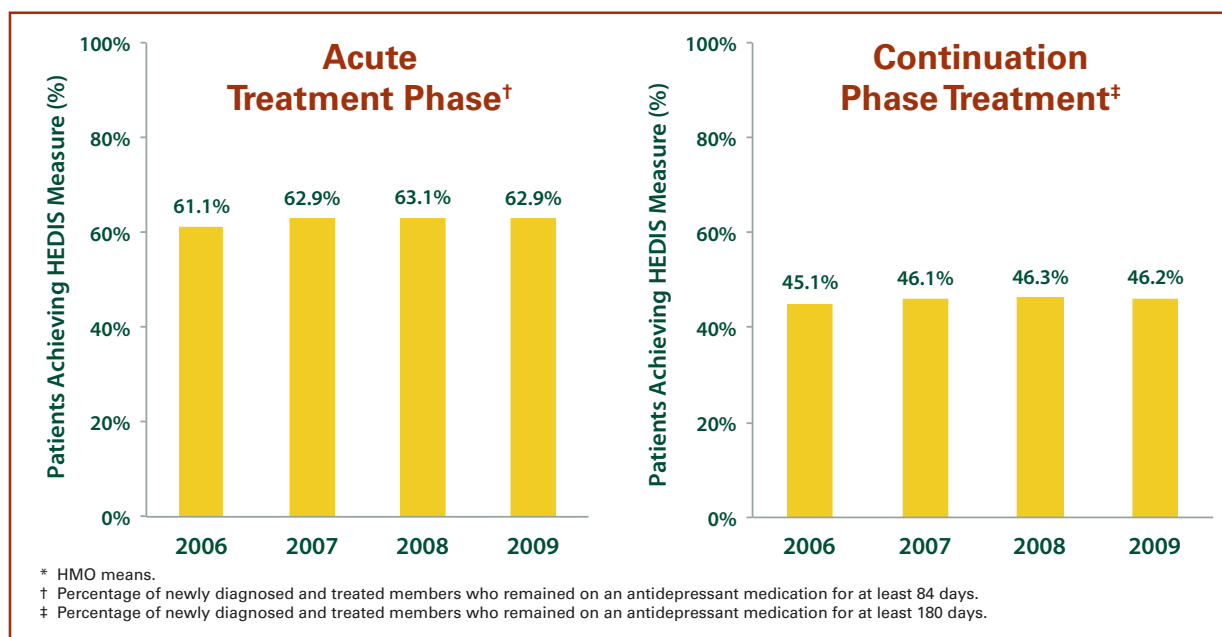
1. Hoffman L, et al. *Am J Manag Care*. 2002;9:70-80; 2. Tierney JG. *J Manag Care Pharm*. 2007;13(suppl S-a):S2-S7; 3. American Psychiatric Association. *Am J Psychiatry*. 2010;167:1-152.

Guideline-recommended Strategies for Treatment of Refractory Depression

- Optimize the medication dose
- Switch to a different antidepressant
 - Within class or different class
- Augment the treatment regimen with a non-depressant agent
- Combine the initial antidepressant with a second anti-depressant agent or depression-focused psychotherapy

American Psychiatric Association. *Am J Psychiatry*. 2010;167:1-152.

Implementation of MDD Sequenced Treatment Strategies May Improve Healthcare Effectiveness Data and Information Set (HEDIS) Scores*



National Committee for Quality Assurance. *The State of Healthcare Quality*. 2010.



Decision Support Tools for Adult Major Depressive Disorder (MDD)

Decision support tools are designed to integrate a medical knowledge base and patient data to guide clinical decision-making. Components include:

1. Decision support
 - Supporting clinical diagnosis and treatment plan processes; promoting use of best practices, condition-specific guidelines, and population-based management
2. Managing clinical complexity and details
 - Adhering to treatment protocols; tracking orders, referrals follow-up, and preventive care
3. Cost control
 - Monitoring medication orders; avoiding duplicate or unnecessary tests
4. Administrative
 - Supporting clinical coding and documentation, authorization of procedures, and referrals

Examples include:

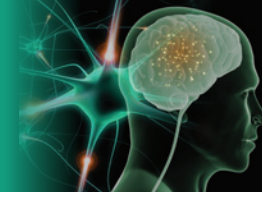
- Comparative Effectiveness research (CER)
- Pharmacoeconomic analysis

Perreault L, Metzger J. *J Healthcare Info Manag.* 1999;13:5-21.

Comparative Effectiveness Research

- Definition
 - Generation and synthesis of evidence that compares benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care
- Goal
 - To assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve healthcare at both the individual and population levels
- Drivers
 - Desire to improve the quality of care through evidence-based medicine
 - Imperative to be more cost-effective
 - Need to reflect patients' and clinicians' real-world experiences

Agency for Healthcare Research and Quality. Available at: <http://www.effectivehealthcare.ahrq.gov/index.cfm/what-is-comparative-effectiveness-research1/>. Accessed September 13, 2011.



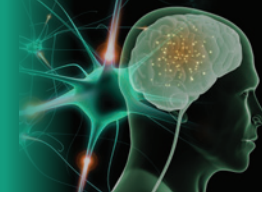
Conducting Comparative Effectiveness Research (CER): Key Steps

1. Identify new and emerging clinical interventions
2. Review and synthesize current medical research
3. Identify gaps between existing medical research and the needs of clinical practice
4. Promote and generate new scientific evidence and analytic tools
5. Train and develop clinical researchers
6. Translate and disseminate research findings to diverse stakeholders
7. Reach out to stakeholders via a citizens forum

Agency for Healthcare Research and Quality. Available at: <http://www.effectivehealthcare.ahrq.gov/index.cfm/what-is-comparative-effectiveness-research1/>. Accessed September 13, 2011.

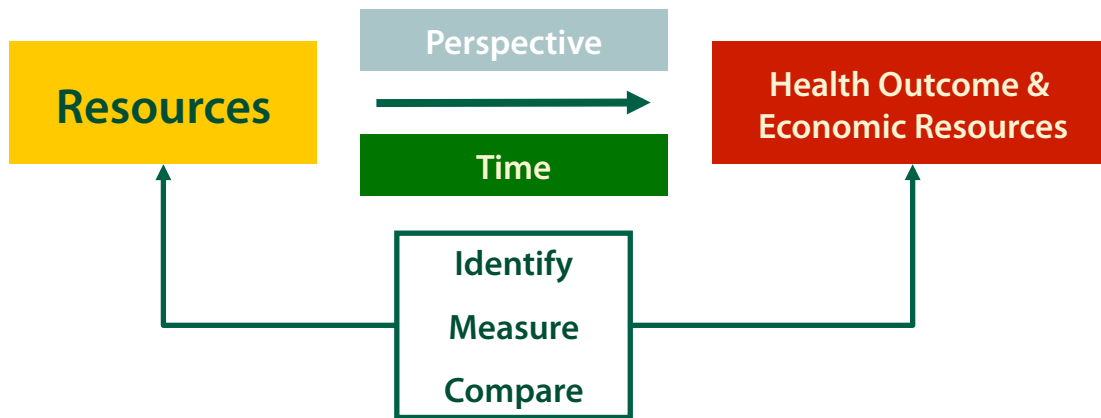
Comparative Effectiveness Research in MDD: Summary

- Depression treatment is ranked by the Institute of Medicine (IOM) as the 6th highest priority for CER
- More than half of medical treatments provided lack clear evidence of effectiveness
- CER involves a rigorous evaluation of 2 or more treatment options for a given medical condition
- Uses current, unbiased evidence in making head-to-head comparisons to determine which interventions:
 - Add value
 - Offer minimal benefit above current choices
 - Fail to reach their potential
 - Work for some patients, but not others



Pharmacoeconomic Analysis

Pharmacoeconomics Used to *Identify, Measure, and Compare* Costs and Outcomes of the Use of Pharmaceutical Products and Services



Perspective Influences the Costs Included in the Pharmacoeconomic Model

Payers' Perspective

- Hospital costs
- Physician costs
- Lab costs
- Rx costs (if covered)

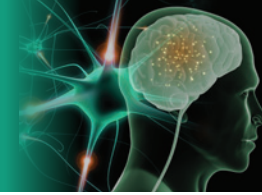
Employers' Perspective

- Hospital costs
- Physician costs
- Lab costs
- Rx costs (if covered)
- Indirect (productivity) costs

Patients' Perspective

- Deductible costs
- Co-insurance costs
- Co-pay costs
- Out-of-pocket costs
- Transportation costs





Types of Pharmacoeconomic Analysis

Analysis	Cost Measurement Unit	Outcome Unit
Cost-minimization	Monetary units*	Natural units [†]
Cost-effectiveness	Monetary units*	Natural units [†]
Cost-utility	Monetary units*	Quality-adjusted life years (QALYs)
Cost-benefit	Monetary units*	Monetary units*
Cost-consequence	Monetary units*	All the above* [†]

* \$, €, £, etc.; † Life years, mg/dL, etc.

Costs Included in a Pharmacoeconomic Analysis

Costs			
Mental Health	Collaborative Care	Outpatient	Inpatient
<ul style="list-style-type: none"> • Antidepressant Rx • Specialty care • Collaborative care-specific 	<ul style="list-style-type: none"> • Care manager compensation • Specialty consultation/supervision in excess of routine care • Educational materials 	<ul style="list-style-type: none"> • Sum of costs for outpatient mental healthcare and other medical, diagnostic, and testing costs 	<ul style="list-style-type: none"> • Sum of costs for all inpatient medical/surgical admissions

Katon WJ, et al. *Arch Gen Psychiatry*. 2005;62:1313-1320.

Pharmacoeconomics: Summary

- Helps decision-makers in “optimizing” healthcare resource use
- Analysis requires direct and indirect costs and outcomes
- Results only applicable when interpreted within the relevant perspective of the analysis
- Types of pharmacoeconomic analyses
 - Cost-minimization
 - Cost-effectiveness
 - Cost-utility
 - Cost-benefit
 - Cost-consequence



Coverage Decision-making

When considering the use of coverage decision-making tools, managed care organizations must be aware that regulatory agencies and governments may require coverage of many or all oncology agents including use for non-FDA-approved indications that would be considered investigational or experimental and outside of clinical trials. Therefore, nationally accepted guidelines and evidence-based compendia may not be applicable to coverage restrictions, prior authorization, or treatment algorithms based on local, state, or national coverage mandates.

Treatment Algorithms

Treatment algorithms and prior authorization guidelines can be based on national guidelines such as those from the American Psychiatric Association. These algorithms can be accessed at the following website:

- http://www.psych.org/psych_pract/treatg/pg/prac_guide.cfm

However, due to ongoing advances in the identification and development of novel therapies, treatment guidelines may not include findings from the latest clinical trials. If a proposed treatment falls outside of accepted treatment guidelines, the managed care organization (MCO) can direct providers to clinical trial sites such as www.clinicaltrials.gov.

Decision Factors

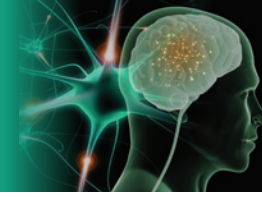
When comparing guidelines to clinical practices, it should be stressed that the choice of treatment is based on multiple factors including:

- Presence and type of risk factors
- Patient comorbidities
- Previous or current adverse drug reactions
- Previous therapies
- Route and frequency of administration
- Patient preference (convenience; fear of potential toxicities)
- Out-of-pocket expense (co-pay for outpatient drugs versus in-office drugs)
- Medical benefit (maximum out-of-pocket per year) versus pharmacy benefit

It must also be stressed that treatment algorithms, guidelines, and prior authorization processes must be created in cooperation with and be endorsed by clinicians associated with the plan. They must also be updated frequently as new data is continually emerging.

Organizations can also use Centers for Medicare and Medicaid Services (CMS)-approved and -mandated compendia; American Hospital Formulary Service (AHFS) Drug Information (www.ahfsdruginformation.com), Gold Standard Clinical Pharmacology (www.clinicalpharmacology.com), and DrugDex (www.micromedex.com/products/drugdex), for coverage decisions.

If coverage is unavailable through the plan, members may find a host of alternative coverage sources for their drugs. MCOs should maintain a file of these potential sources to provide the appropriate level of service to members. One example of a clearing house of patient assistance programs is IndiCare (www.indicare.com).



Benefit Design and Major Depressive Disorder (MDD)

The benefit design can play a significant role in choice of therapy. For members with commercial insurance, the common design required only a modest co-pay for drugs provided in a physician office, clinic. As outpatient prescription co-pays have escalated, members are choosing in-office therapies. In addition, if members are required to meet a deductible or have a maximum out-of-pocket, choice can be influenced based on the allocation of medical (in-office infusion) drug costs and/or pharmacy (outpatient oral) drug costs to the deductible or maximum. Medicare members less often face a differential co-pay based on place of service; however, they must consider that in-office co-pays do not accumulate against their Part D benefit and therefore never reach the catastrophic Part D limit.

Basic Tenets of Benefit Design

- Manage costs by restricting utilization of resources
 - Medical and Pharmacy designs usually independent
- Cost-sharing used to influence utilization patterns
 - Patient cost-share related to acquisition cost of service or product
 - Assumes inelastic demand or willingness to pay

Willey VJ, et al. *Am J Manag Care*. 2008;14:S252-S263.

Cost and Utilization Management in Benefit Design

Cost Management	Utilization Management
Drug discounts	Medical necessity review
Channel management	Clinical management via: <ul style="list-style-type: none"> • Treatment algorithms • Patient eligibility • Duration of therapy
Rebates	Prior authorization
Benefit design options	Formulary management <ul style="list-style-type: none"> • Tiers • Utilization caps

Stern D, et al. *J Manag Care Pharm*. 2008;14(suppl S):S12-S16.



Value-based Benefit Design Principles

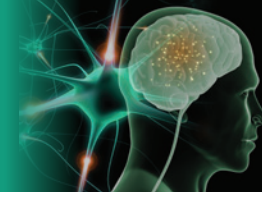
- Focus on long-term outcome of improved health
- Assess total cost picture including medical spending and productivity
- The more beneficial the therapy, the lower the patient's cost-share
- Adjust out-of-pocket costs for specific services based on patient characteristics

- Value-based benefit designs are being implemented by some employer plan sponsors in an effort to restrain escalating costs
 - Full integration of medical and pharmacy benefits
 - Uniform plan design
 - Lowered cost-sharing if patient uses the most effective resource
 - High cost-sharing for utilizing non-network resources
- Typically involves co-insurance with an out-of-pocket limit
- Data used to invest in incentives that change behaviors to improve health, productivity, quality, and financial trends



Application of Value-based Benefit Design to MDD Therapy Management

- Primary focus is on overall health outcomes
- Out-of-pocket costs may be waived or reduced to achieve specific goals
- Prevention
 - Increase use of evidence-based preventive care, services, and/or products
- Condition
 - Establish integrated care management
 - Promote medication adherence (patients) and compliance with evidence-based treatment guidelines (providers)
- Service Provider(s)
 - Incent utilization of a specific provider or service (ie, condition management)
 - Incorporate outcomes-based contracting
- Research
 - Use of comparative effective research (CER) to guide therapeutic selection



Improving Major Depressive Disorder (MDD) Outcomes by Coordinating Care and Leveraging Technology

Goals

- Implement a system-wide approach to collaborative care, stepped care, and medication therapy management
- Implement patient screening and monitoring that leverages health information technology advances to improve outcomes for adult patients with MDD

Depression Screening in a Busy Practice

- Ease of administration and interpretation are key
 - Depression screening should be considered as a “vital sign” (ie, an easy-to-assess and reliable marker of depression)
- It is not enough to know that formal depression criteria are met; functioning must be assessed
 - Functioning should be “clinically” assessed, even when a patient meets criteria for depression
 - Many patients may expect some form of intervention with a positive test, even though impairment may be relatively mild
 - Certain other patients may resist any treatment at all, in spite of clear functional impairment and likely benefit of treatment

DeJesus RS, et al. *Mayo Clin Proc.* 2007;82:1395-1402.

Screening Instruments

- Screening instruments
 - Diagnostic assessment
 - Functional assessment
- Symptom count instruments (diagnostic) help establish whether a clinical picture “meets the criteria” for a depression diagnosis, but may not fully take into account its functional impact
- Assessment instruments (functional) provide a sense of severity of symptoms and their functional impact
- The Personal Health Questionnaire (PHQ-9) incorporates the best elements of both approaches

Zuithoff NP, et al. *BMC Family Practice.* 2010;11:98.

ADULT MDD TREATMENT TOOL BOX



Patient Health Questionnaire-9 (PHQ-9): Self-rating Depression Screening Tool

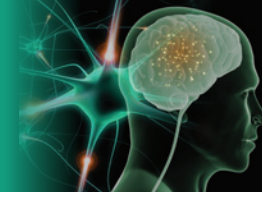
Over the last 2 weeks, how often have you been bothered by any of the following problems?

(use "✓" to indicate your answer)

1. Little interest or pleasure in doing things
2. Feeling down, depressed, or hopeless
3. Trouble falling or staying asleep, or sleeping too much
4. Feeling tired or having little energy
5. Poor appetite or overeating
6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down
7. Trouble concentrating on things, such as reading the newspaper or watching television
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual
9. Thoughts that you would be better off dead, or of hurting yourself in some way

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself in some way	0	1	2	3
add columns:			+	+
TOTAL:				
10. If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	Not difficult at all	_____	Somewhat difficult	_____
	Very difficult	_____	Extremely difficult	_____

PHQ-9 is adapted from PRIME MDTODAY, developed by Robert L. Spitzer, Janet B.W. Williams, K. Kroenke, and colleagues, with an educational grant from Pfizer Inc. For research information, contact Dr. Spitzer at rls@columbia.edu. Use of the PHQ-9 may only be made in accordance with the Terms of Use available at www.pfizer.com. Copyright ©1999 Pfizer Inc. All rights reserved. PRIME MDTODAY is a trademark of Pfizer Inc.



Collaborative Care Models

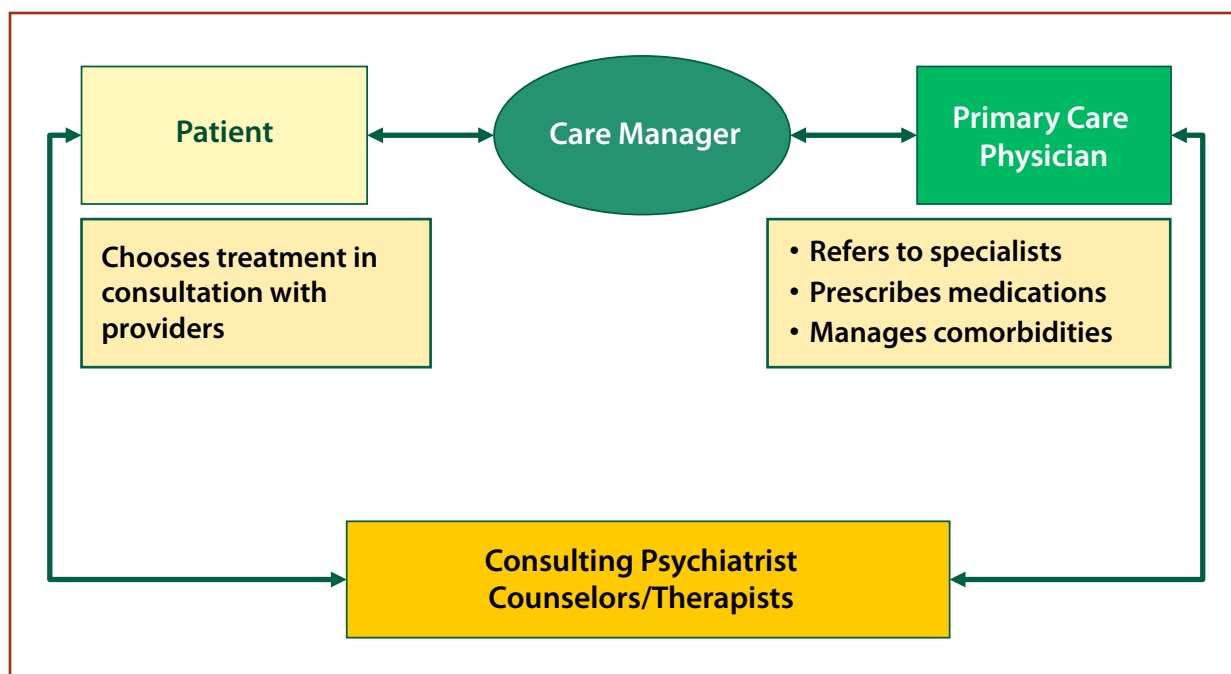
- Coordinated model: behavioral services available at a separate clinic/location
 - Access and convenience is low; patients may not show up for referral/follow-up care, less-than-effective communication
- Co-located model: behavioral services available at the same medical center/clinic
 - More convenient for patients and providers
- Integrated: behavioral services are part of the medical treatment within the clinic or practice
 - Creates a “medical home” for the patient with behavioral health services incorporated into a single primary care practice
 - Facilitates more integrated communication, patient tracking, and follow up

Components Common to Successful Collaborative Models

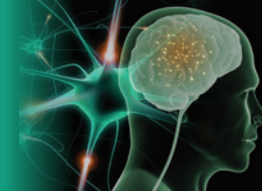
- Components found in the most successful collaborative models include
 - Validated screening tools and evidence-based treatment guidelines
 - Care management geared toward increasing patient awareness and self-management
 - Co-location or integrated service delivery
 - Integrated information technology support including appointment tracking, charting, registry, risk stratification, evidence-based medicine support, and electronic medical records
 - Robust administrative and financial support from the healthcare system

Robinson PJ, Strosahl KD. *J Clin Psychol Med Settings*. 2009;16:58-71.

Interaction Between Members of the Collaborative Care Team



Unutzer J, et al. *Med Care*. 2001;39:785-799.

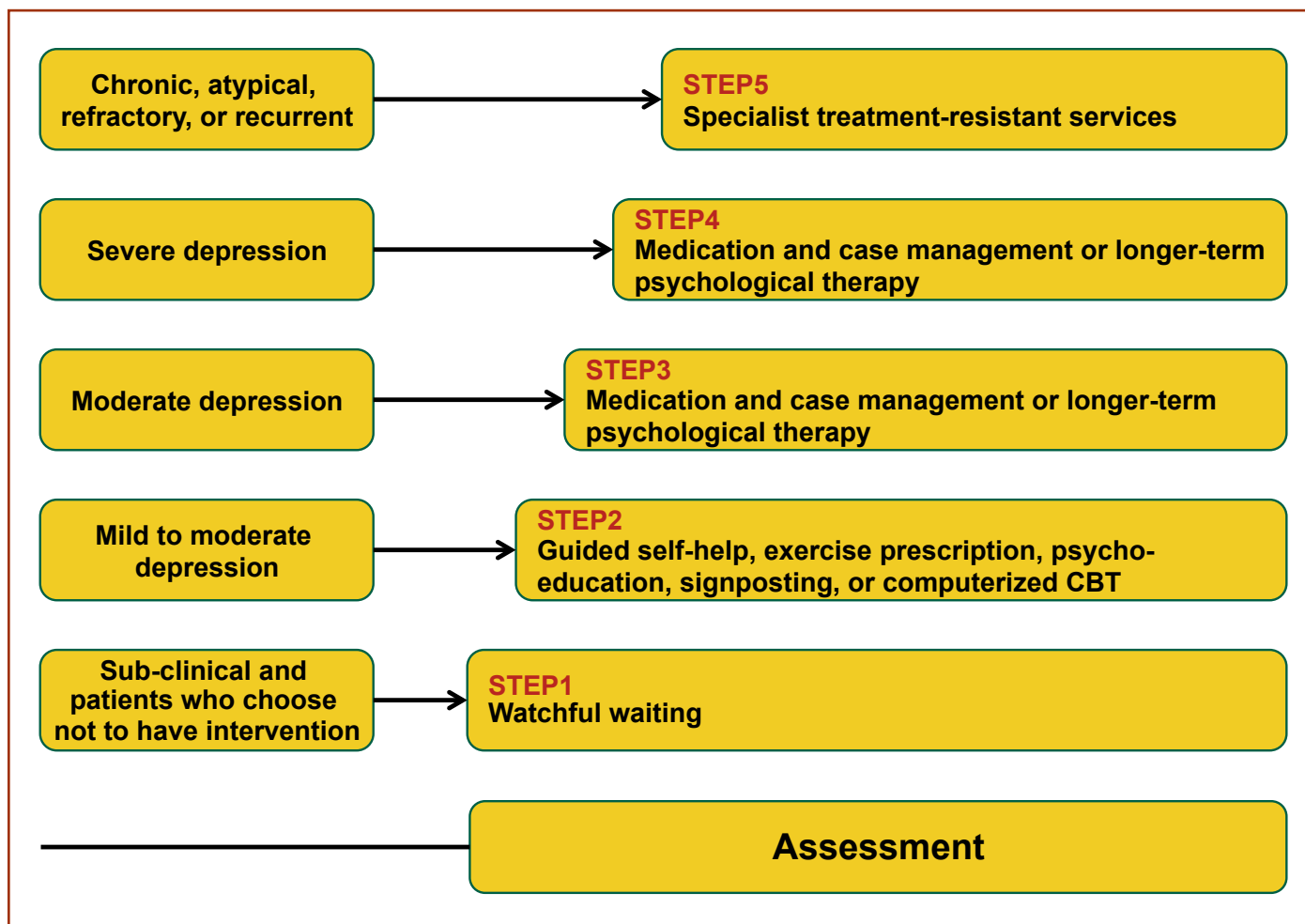


Stepped Care

- In a stepped care model, all eligible patients start with low intensity intervention
 - Progress is monitored and patients who do not respond adequately can ‘step up’ to a subsequent treatment of higher intensity
- All steps are aligned with recognized evidence-based guidelines
- Care manager (eg, nurse or social worker) monitors patients, provides the first treatments, and refers the patient to the appropriate mental healthcare specialist if necessary

Bowers P, Gilbody S. *Br J Psychiatry*. 2005;186:11-17; Seekles W, et al. *Trials*. 2011;12:171.

Stepped Care: An Example



CBT=cognitive-behavioral therapy

Bowers P, Gilbody S. *Br J Psychiatry*. 2005;186:11-17



Use of Medication Therapy Management (MTM) in MDD

- MTM is a group of services designed to
 - Ensure optimum therapeutic outcomes through improved medication use
 - Reduce the risk of adverse events
 - Reduce drug-drug interactions
- Core elements of MTM
 - Medication therapy review
 - Personal medication record
 - Medication action plan
 - Education and coaching
 - Intervention and/or referral
 - Documentation and follow up

Patient-Centered Primary Care Collaborative. Integrating Comprehensive Medication Management to Optimize Patient Outcomes. Available at: <http://www.pcpcc.net/medication-management>. Accessed September 14, 2011.

Characteristics of Patients Who May Benefit From MTM

- Patients who
 - Have not reached or are not maintaining the intended therapeutic goal
 - Are experiencing adverse effects from medications
 - Have difficulty understanding and following the medication regimen
 - Are in need of preventive therapy
- Are frequently admitted to the hospital

Patient-Centered Primary Care Collaborative. Integrating Comprehensive Medication Management to Optimize Patient Outcomes. Available at: <http://www.pcpcc.net/medication-management>. Accessed September 14, 2011.

MTM Design Considerations and Factors Associated With Success

- Eligibility
 - Targeted high-risk patients vs all beneficiaries?
- Focus
 - Appropriateness of medication therapy
- Method of delivery/interaction
 - Face-to-face
 - Telephone
 - Email
 - Regular mail
 - Combination
- Factors associated with success include
 - Pharmacists with dedicated time to provide MTM services
 - Patient educators and healthcare providers who can inform patients about the value of MTM services
 - Risk stratification models to determine patients who could benefit most from MTM services
 - Access to patient health information (eg, electronic medical records)
 - Consistent, efficient format for documentation of MTM services
 - Outcomes measures to evaluate the impact of MTM services

Patient-Centered Primary Care Collaborative. Integrating Comprehensive Medication Management to Optimize Patient Outcomes. Available at: <http://www.pcpcc.net/medication-management>. Accessed September 14, 2011.



Leveraging Technology: Electronic Health Records (EHR)

- Definition
 - Longitudinal collection of health information with real-time access to person- and population-level data
 - Provides knowledge and decision-support systems which enhance the quality, safety, and efficiency of patient care
 - Improves the accuracy and efficiency of healthcare delivery
- An EHR is NOT a paper record converted to an electronic format

Core EHR Functions

- Health information and data
- Order management
- Results management
- Decision support
- Electronic communication and connectivity
- Patient support
- Administrative processes
- Reporting and population health management

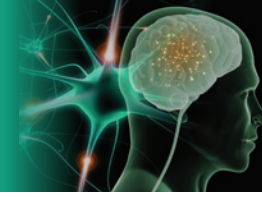
Why Implement an EHR?

- Timely access to accurate and complete patient information
- Improved patient care and safety
- Enhanced outcomes
- Minimize/avoid adverse drug events
- Improved quality measures
- Increased operational efficiencies and staff productivity

Features of the EHR That Promote Quality Care

- Patient chart templates with built-in guideline prompts
 - Flow sheets, checklists, tables, summaries, etc., as decision aids
- Internal messaging and flags for coordination, collaboration, referral, and reminders
- Personalized results for patient discussion/education
- Lab interface for results reporting
- Scheduling tool for follow up
- Queries to identify patients needing specific care

IOM. Key Capabilities of an Electronic Health Record System. Available at: http://www.providersedge.com/ehdocs/ehr_articles/Key_Capabilities_of_an_EHR_System.pdf. Accessed September 21, 2011.



Coordination of Care to Improve Major Depressive Disorder (MDD) Treatment Outcomes: Summary

- >50% of patients with depression are treated in primary care
- Early recognition and treatment in primary care can minimize depression severity
- Collaboration between primary care, specialists, counselors/therapists, pharmacists, patients, and caregivers can improve depression care
- In stepped care, all interventions are aligned with recognized evidence-based guidelines
- Medication therapy management ensures optimum outcomes through improved medication use
 - The electronic health record (EHR) provides health information with real-time access to person- and population-level data



Instructions for Online Posttest Completion and Certificate Retrieval

Postgraduate Institute for Medicine supports Green CME by offering your Request for Credit online. If you wish to receive acknowledgment for completing this activity, please complete the posttest and evaluation on www.cmeuniversity.com. On the navigation menu, click on "Find Post-test/Evaluation by Course" and search by course ID 8262. Upon registering and successfully completing the posttest with a score of 70% or better and the activity evaluation, your certificate will be made available immediately. Processing credit requests online will reduce the amount of paper used by nearly 100,000 sheets per year.

Post-test

- 1. What percentage of patients with Major Depressive Disorder (MDD) is estimated to be resistant to treatment?**
 - A. 35%
 - B. <10%
 - C. >20%
 - D. 63%
- 2. Failure to achieve initial remission has minimal effect on achieving beneficial long-term outcomes in patients with MDD.**
 - A. True
 - B. False
- 3. Sustained remission of MDD in adults is defined by the 2010 APA Guideline as:**
 - A. $\geq 50\%$ improvement in symptoms
 - B. At least 3 weeks of the absence of sad mood and reduced interest
 - C. <5 remaining symptoms
 - D. Both B and C
- 4. The addition of a second antidepressant medication to enhance the effect of a first-line agent is best defined as:**
 - A. Augmentation
 - B. Stepped therapy
 - C. Medication management
 - D. Combination
- 5. All of the following are advantages of switching MDD therapies EXCEPT:**
 - A. Avoids risk of withdrawal symptoms
 - B. Lower risk of drug interactions
 - C. May improve compliance
 - D. May minimize adverse events
- 6. Which of the following statements about atypical antipsychotic agents is FALSE?**
 - A. Many possess antidepressant properties
 - B. They can be used to augment treatment with standard antidepressants
 - C. They are effective adjunctive treatment for depression that has failed to respond to standard therapy
 - D. They are classified as antidepressant drugs
- 7. The goal of comparative effectiveness research is to assist patients, physicians, payers, and policy makers in making informed decisions about the utilization of healthcare.**
 - A. True
 - B. False
- 8. The type of analysis used to identify, measure, and compare costs and outcomes associated with the use of a pharmaceutical product is called a ____ analysis.**
 - A. Health economic
 - B. Cost-effectiveness
 - C. Cost-benefit
 - D. Pharmacoeconomic
- 9. Which of the following screening tools provides an indication of the severity of depression symptoms and their functional impact?**
 - A. Depression assessment scales
 - B. Depression symptom count instruments
 - C. Depression symptom survey
 - D. MDD evaluation scale
- 10. Which of the following is NOT a feature of collaborative care?**
 - A. Delivers evidence-based treatment aligned with recognized guidelines
 - B. Limits access to specialists
 - C. Includes a relapse-prevention plan
 - D. Provides integrated service delivery