

Measurement-Based Care (MBC): Isn't It About Time We Used It?

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Disclosures (Past 12 months)

- Consulting Fees: Brain Resource Inc., Curbstone Consultant LLC, Eli Lilly, Emmes Corp, Mind Linc, Montana State Univ., UT Southwestern Medical Center at Dallas, Sunovion, Texas Tech
- Royalties: Guilford Press, UT Southwestern
- Speaking Fees: Stanford Univ., Global Medical Education Inc., Sing-Health, Univ. Montana, Montana State Univ., John Peter Smith Healthcare
- **Note:** UT Southwestern Medical Center pays royalties to Dr. Rush when it licenses out use of the rating scales to for profit companies (i.e. Inventory of Depressive Symptoms and its several variations)

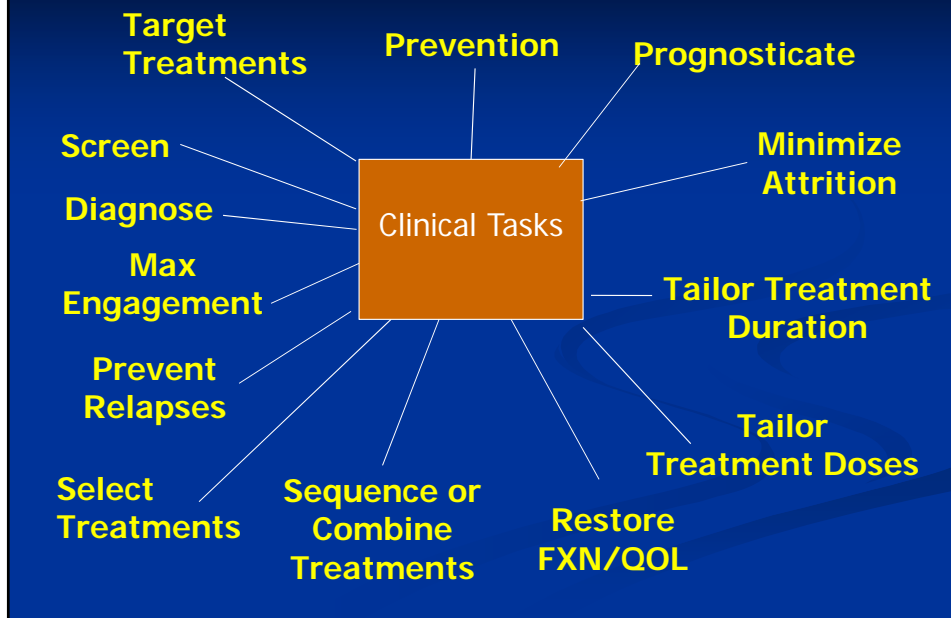
Objectives

- To illustrate HOW:
- MBC can improve the diagnostic accuracy and the clinical outcomes achieved in the management of mood disorders
- To use MBC information to assess performance of clinical care programs
- To incorporate MBC into the education and training psychotherapists and psychopharmacologists

MBC Definition

MBC entails the use of **standard clinical tools** and **systematic clinical processes** to accomplish **essential clinical tasks** (e.g., early detection, diagnosis, treatment selection, treatment implementation, side-effect and longer-term management) to achieve a clinically important level of precision.

MBC Can Address Multiple Clinical Tasks



History of MBC with Mood Disorders

- Depression rating scales – 1957(H), 1967(B), 1978(M), 1986(I), 1999(P)
- Criteria for MDE – 1972 (Wash U), 1975 (RDC), 1980 (DSM)
- Clinical Practice Guidelines – 1993 (AHCPR + APA)
- (MBC + Algos) vs TAU(outpts) – 1997-2004 (TMAP)
- MBC details defined – 2006 (STAR*D)
- (MBC + Algos) vs TAU (inpts), GAP (2006-2015)
- MBC vs. TAU - Guo, et al. (2015)

Rationale for MBC with Mood Disorders

- **Communication & Collaboration**
- Quality of Care & Outcomes
- Care Delivery & System Management

MBC Enhances Communication & Collaboration

- Focuses clinical interaction on key goals **to enhance shared clinical decision-making**
- Shared, **more precise metric** for “mild, moderate or severely ill”; response, remission, partial responses, etc.
- Provides **clear evidence and history** for when a “second opinion” or transfer to another service provider is needed
- **Educates patients** about depression (e.g. helps differentiate depression from other comorbid conditions)
- **Documents outcomes with “standard” care** thereby supporting “off label” medication use if needed

Rationale for MBC with Mood Disorders

- Communication & Collaboration
- **Quality of Care & Outcomes**
- Care Delivery & System Management

MBC Enhances Quality of Care & Outcomes - 1

- More **reliable diagnoses**
- Greater detection of concurrent comorbidities
- Better detection of inadequate response / residual symptoms
- Allows for **tailored dose adjustments**
- Earlier detection of impending relapse
- **Better symptomatic/functional outcomes**

MBC Enhances Quality of Care & Outcomes - 2

- **Minimize under-dosing**
- Reveals symptom changes patients do not globally report
- Regular and systematic evaluation of important symptoms (e.g., sleep, suicide)
- Early detection of side effect burden that can trigger timely dose revisions or antidotes
- Objective trajectory of outcomes **reduces biased recall** by patient and doctor

MBC Enhances Quality of Care & Outcomes - 3

- Focuses patient-doctor interaction on key metrics (e.g. symptoms, function, side effects) **to enhance shared clinical decision-making**
- Consistent with the clinical procedures used to establish efficacy and safety in regulatory trials
- May reduce patient anxiety
- May increase patient adherence and collaboration
- May reduce premature attrition

MBC Enhances Care Delivery & System Management

- Can be used at home (remotely) in lieu of a visit or with telemedicine
- Provides **documentation of outcomes** to care systems, patients and families
- Allows learning by clinicians and the system across patients over time
- **Reduces cost**
- **Saves clinician time**

Does MBC Improve Diagnosis?

Diagnosis Depends on Elicitation of Signs, Symptoms, Course & Comorbidities

- Structured interviews have the advantage of greater thoroughness & reliability
- They can be initially administered by staff and confirmed by diagnosticians
- They add to time required to establish a diagnosis
- They may be cost-effective if routine diagnoses are deficient

Does a Structured Interview (SCID) Help in Diagnosis?

Gold standard: SCID + chart + diagnostician interview = diagnosis

Patients: Outpatients from a Texas Community Mental Health Center

Comparisons: Routine (chart) diagnoses; SCID diagnoses; SCID + chart review

Source: Basco MR, et al. Am J Psychiatry 2000;157:1599-1605

Performance of Diagnostic Methods vs. Gold Standard by Disorder

Diagnosis	Source	Sensitivity	Specificity
BPD-I (N=50)	Routine	54%	92%
	SCID	76%	93%
	SCID + Chart	88%	93%
MDD (N=38)	Routine	50%	96%
	SCID	84%	91%
	SCID + Chart	82%	96%

Basco MR, et al. Am J Psychiatry 2000;157:1599-1605

Do Structured Interview Results Change Diagnosis?

SCID informed psychiatrists over 3 months were:

- 10x more likely to make clinically-significant change in diagnosis ($p < .0001$)
- 2x more likely to update diagnosis ($p < .0001$)
- Altogether 20.5% of psychiatrists with SCID feedback versus 2.3% of psychiatrists with no SCID feedback changed diagnosis from one to another severe mental disorder

Kashner TM, Rush AJ, et al. Impact of structured clinical interviews on physicians' practices in community mental health settings. *Psychiatr Serv* 2003, May;54(5):712-8.

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Conclusions on Structured Interviews

- Routine clinical diagnoses are inaccurate enough that...
- they can lead to incorrect treatment
- Structured-interview information does change both diagnosis AND treatment in a meaningful proportion of cases
- Wouldn't structured interviews be useful in the cases of inadequate response to standard care based on routine diagnostic procedures?

Habits Are Powerful



Rationale for MBC with Mood Disorders

- Communication & Collaboration
- **Quality of Care & Outcomes**
- Care Delivery & System Management

**Does MBC Improve Treatment Quality
or Outcome?**

MBC: Helps to Balance Dose and Side Effects

- Establish the maximal tolerable dose
- Optimal duration to declare no response
- Optimal duration to define max benefit
- Dosing at a rate to achieve tolerable dose
- Can self-reports suffice? (AN ASIDE)



Treatment Entails Both Strategies & Tactics

Strategies: Treatments or treatment sequences

Tactics: Initial dose, dose titration, duration of trial; management of side effects

BOTH Strategies (**what** is delivered) & Tactics (**how** it is delivered) affect outcomes and adverse effects

Tactics Affect Treatment Efficacy & Tolerability

- What is an adequate trial?
- When to continue or discontinue?
- When is maximal effect expected to occur?
- What side effects occur? When? For how long?
- What is the side-effect burden in those for whom the treatment works?
- What is the optimal dose titration schedule for this patient?

MBC in Efficacy Trials But Not Practice













	Efficacy Trials	Clinical Practice
Structured diagnostic interviews	+++	-
Std outcome assessments at visits	+++	+/-
Frequent, preplanned visits	+	+/-
Follow-up missed appointments	++	+
Treat to measured outcome	++	+/-
Doses adjusted based on measurement of outcomes at visits	+++	+/-
Concomitant medications	+/-	++

Ways to Measure Symptomatic Outcomes

- Clinician global (S or I)
- Patient global (S or I)
- Itemized symptom self-report
- Itemized symptom clinician rating
- 0-100 global rating scale
- Penny-dollar rating scale

Measure the Target of Treatment

COMPARATIVE PAIN SCALE CHART (Pain Assessment Tool)

											
0 Pain Free	1 Very Mild	2 Discomforting	3 Tolerable	4 Distressing	5 Very Distressing	6 Intense	7 Very Intense	8 Utterly Horrible	9 Excruciating Unbearable	10 Unimaginable Unspeakable	
No Pain	Minor Pain		Moderate Pain			Severe Pain					
Feeling perfectly normal	Nagging, annoying, but doesn't interfere with most daily living activities. Patient able to adapt to pain psychologically and with medication or devices such as cushions.		Interferes significantly with daily living activities. Requires lifestyle changes but patient remains independent. Patient unable to adapt pain.			Disabling; unable to perform daily living activities. Unable to engage in normal activities. Patient is disabled and unable to function independently.					

Depressive Symptoms: **PHQ, QIDS-SR**

Daily Function: **SDS**

Medication Side Effects: **FIBSER**

Self-Reports

- Often correlate well with clinical ratings
- Easy to use; can be gathered via telephone
- May be somewhat less sensitive than clinical rating to change (e.g., BDI versus HAM-D)
- When C and SR items match, SR is as sensitive to change as C rating (e.g., IDS-C vs. IDS-SR)

QIDS-SR₁₆

During the past seven days...

1. Falling Asleep:

- 0 I never take longer than 30 minutes to fall asleep.
- 1 I take at least 30 minutes to fall asleep, less than half the time.
- 2 I take at least 30 minutes to fall asleep, more than half the time.
- 3 I take more than 60 minutes to fall asleep, more than half the time.

During the past seven days...

5. Feeling Sad:

- 0 I do not feel sad
- 1 I feel sad less than half the time.
- 2 I feel sad more than half the time.
- 3 I feel sad nearly all the time.

Rush, et al. *Int J Meth Psychiatr Res.* 2000;9:45-59

Rush, et al., *Bio Psychiatry.* 2003;54(5):573-583.

FIBSER

Frequency (Circle one)

Choose the response that best describes the frequency of the side effects of the treatment you are now taking for your depression (last week).

1. No side Effects	2. Present 10% of the time	3. Present 25% of the time	4. Present 50% of the time	5. Present 75% of the time	6. Present 90% of the time	7. Present all the time
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Intensity (Circle one)

Choose the response that best describes the intensity of side effects that you believe are due to treatment(s) that you are taking now for your depression (last week).

1. No side effects	2. Trivial	3. Mild	4. Moderate	5. Marked	6. Severe	7. Intolerable
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Describe **the degree to which the side effects** that you have had over the last week, from treatment(s) for your depression, have **interfered with your day-to-day functions**.

1. Not at All	2. Minimal impairment	3. Mild impairment	4. Moderate Impairment	5. Marked Impairment	6. Severe Impairment	7. Unable to function due to side effects
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Wisniewski SR, et al. *J Psychiatr Pract.* 12:71-79, 2006

Tracee – any questions yet??



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- Communication & Collaboration
- **Quality of Care & Outcomes**
- Care Delivery & System Management

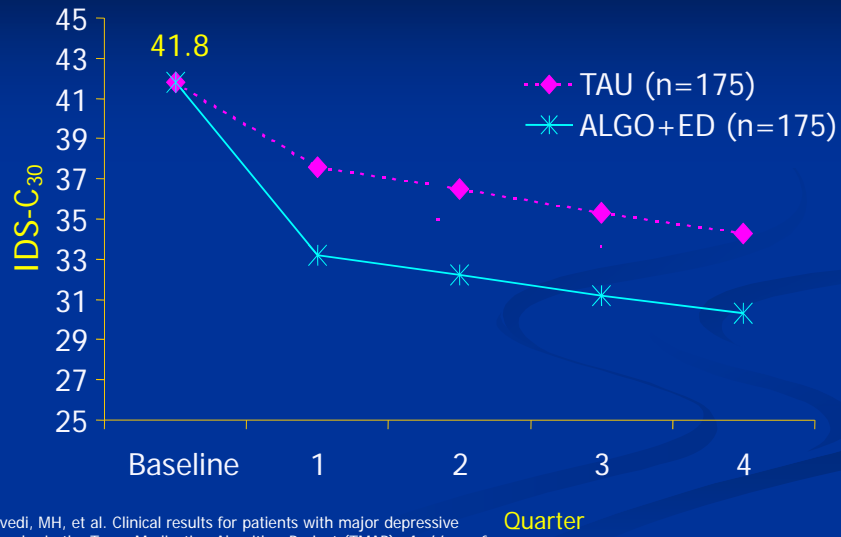
Does MBC Improve Quality of Care & Outcomes?

Texas Medication Algorithm Project (1999-2006)
(included algorithms + MBC procedures)

German Algorithm Project (2004-2015)
(included algorithms + MBC procedures)

Guo et al. (2015): Single Site RCT of MBC in China (includes only MBC)

MBC Better Than TAU in MDD in TNAP



Trivedi, MH, et al. Clinical results for patients with major depressive disorder in the Texas Medication Algorithm Project (TMAP). *Archives of Gen Psychiatry*, 61(7):669-680, 2004.

MBC Promoted Adequate Dosing in STAR*D

Medication	Step	Use	Exit Dose (mg/d)
Citalopram	1	Monotherapy	42
Bupropion	2	Switch	283
Sertraline	2	Switch	135
Venlafaxine	2	Switch	194
Bupropion	2	Augment	268
Buspiron	2	Augment	41
Citalopram	2	(With Aug)	54

Rush et al., *Am J Psychiatry*. 2006;163(11):1905-1917

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MBC Promoted Adequate Dosing in STAR*D

Medication	Step	Use	Exit Dose (mg/d)
Nortriptyline	3	Switch	97
Mirtazapine	3	Switch	42
Lithium	3	Augment	860
T ₃	3	Augment	45
Tranlycypromine	4	Switch	37
Venlafaxine	4	Switch	210
Mirtazapine	4	Switch	36

Rush et al., *Am J Psychiatry*. 2006;163(11):1905-1917

PHQ-9 Feedback Changed Clinical Decisions (2,185 Visits)^{a,b}

Action Taken	N	%
Change dosage of antidepressant	927	44
Add another medication to treat depression	570	26
Start or increase psychotherapy	347	16
Switch antidepressant	273	12
Initiate antidepressant	225	10
Additional suicide risk assessment	61	3
Reassess depression diagnosis	28	1
Make mental health consultation or referral	22	1

^a Reprinted from Duffy et al¹ with permission from Psychiatric Services, © 2008. American Psychiatric Association

^b More than 1 treatment change per visit may have occurred. Data for this analysis were missing for 382 patient visits, hence 2,185 visit data were used.

¹ Duffy FF, et al. *Psychiatr Serv* 2008;59(10):1148-1154.

Gelenberg, AJ. *J Clin Psychiatry* 2010;71(suppl E1):e01

Guo et al. (2015) (Outpatients)

- Single site (Beijing)
- Adult outpatients with non-psychotic MDD
- Only paroxetine or mirtazapine
- 120 subjects
- Time to HAM-D response and remission = primary outcomes
- Blinded raters
- 24-week trial (12 weeks in MBC)

Guo et al. *Am J Psych* 2015; 172:1004-1013

MBC vs. Std. Care: Efficacy Outcomes

Measure	Standard Care (N=59)		MBC (N=61)		P-value
% Response	62.7		86.9		0.002
% Remission	28.8		73.8		<0.001
	Mean	95% CI	Mean	95% CI	p-value
Est. weeks to response	11.6	9.2, 14.1	5.6	3.9, 7.4	<0.001
Est. weeks to remission	19.2	17.2, 21.3	10.2	8.0, 12.3	<0.001
Change in HAM-D₁₇	13.6	12.1, 15.0	17.8	16.3, 19.2	<0.001
Change in YMRS	0.6	0.3, 1.1	0.6	0.2, 1.0	0.73
Change in QIDS-SR	NA	NA	9.7	8.2, 11.3	NA

Guo et al., *Am J Psychiatry*. 2015;172(10):1004-13

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MBC vs. Std. Care: Adverse Effects

Adverse Effect	Standard Care (N=59)	MBC (N=61)
	%	%
Checklist of common side effects		
Dry mouth	13.6	9.8
Diarrhea or constipation	10.2	8.2
Dizziness or drowsiness	8.5	8.2
Loss of appetite or nausea	6.8	4.9
Headache	5.1	4.9
Excessive sweating	5.1	3.3
Total	49.2	39.3

Guo et al., *Am J Psychiatry* 2015;172(10):1004-1013

MBC vs. Std. Care --ADM Dosages¹

Time Point and Measure	Standard Care	MBC	p-value
	Mean (SD)	Mean (SD)	
Baseline (n=59/61)			
Dosage (mg/day)			
HAM-D score	22.2 (4.1)	22.5 (4.2)	0.74
2 weeks (n=59/61)			
Dosage (mg/day)	106.7 (21.6)	118.0 (28.9)	0.02
HAM-D	15.2 (4.8)	12.4 (5.0)	0.002
Visits from baseline to week 2	2.0 (0.0)	2.0 (0.0)	
4 weeks (n=58/60)			
Dosage (mg/day)	106.7 (21.6)	118.0 (28.9)	0.02
HAM-D	12.1 (3.9)	9.3 (4.1)	<0.001
Visits from week 3 to week 4	1.0 (0.0)	1.0 (0.0)	

¹Amitriptyline Equivalents (50 mg AMI = 10 mg paroxetine or 15 mg mirtazapine)

Guo et al., *Am J Psychiatry* 2015;172(10):1004-1013

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MBC vs. Std. Care –ADM Doses¹

Time Point and Measure	Standard Care	MBC	p-value
	Mean (SD)	Mean (SD)	
8 weeks (n=55/57)			
Dosage (mg/day)	107.6 (24.2)	119.6 (35.6)	0.03
HAM-D	9.9 (3.3)	6.3 (3.9)	<0.001
Visits from week 5 to week 8	1.1 (0.3)	1.9 (0.2)	<0.001
12 weeks (52/49)			
Dosage (mg/day)	109.3 (27.0)	122.1 (35.9)	0.03
HAM-D	8.9 (3.5)	5.4 (3.7)	<0.001
Visits from week 9 to week 12	1.2 (0.5)	1.7 (0.5)	<0.001
24 weeks (n=37/44)			
Dosage (mg/day)	106.7 (21.6)	122.1 (35.9)	0.006
HAM-D	8.6 (3.6)	4.8 (3.6)	<0.001
Visits from week 13 to week 24	2.5 (1.1)	1.6 (1.1)	<0.001

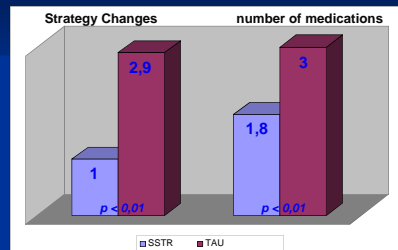
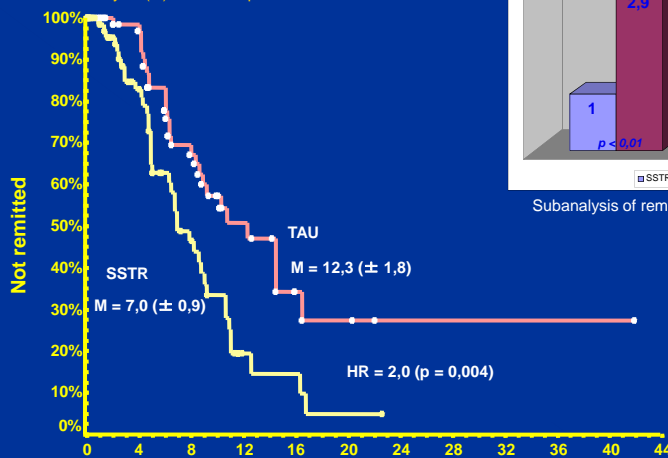
¹Amitriptyline Equivalents (50 mg AMI = 10 mg paroxetine or 15 mg mirtazapine)

Guo et al., *Am J Psychiatry* 2015;172(10):1004-1013

GAP 2: ALGO + MBC vs. TAU

N = 148, SSTR = 74, TAU = 74

Survival Analysis (ITT) of Total Population Intended to Treat



Subanalysis of remitted patients of both groups

Bauer, Pfennig, ... Adli, *J Clin Psychopharmacology* 2009
(John Mitchell Balter Award 2009)

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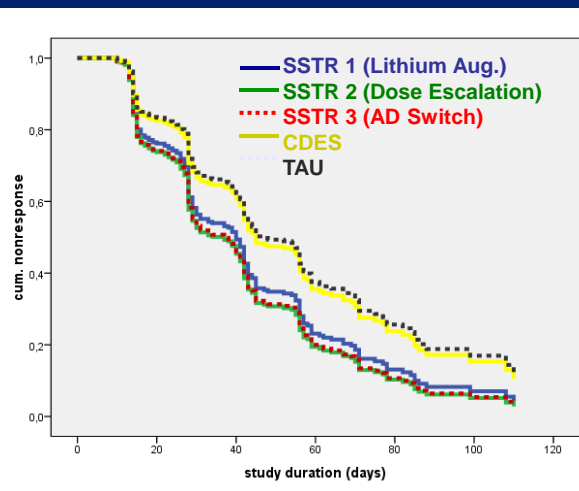
MBC Reduced Treatment Costs -GAP 2 (inpatients)

Cost-effectiveness analysis for time in study (ITT)

	SSTR (n=74)	TAU (n=74)		TOTAL (n=148)
Inpatient treatment costs	10 862 € (± 8 658)	15 247 € (± 12 520)	p 0,014** (T -2,478)	13 055 € (± 10 950)
remission rate	0,54	0,39		0,47
costs per remission	20 115 €	39 097 €		27 776 €

Ricken et al. 2012, *J Affect Disord*

German Algorithm Project - GAP 3



	Hazard-Ratio	p
SSTR 1 vs. TAU	1.494	.055
SSTR 2 vs. TAU	1.671	.014
SSTR 3 vs. TAU	1.643	.018
CDES vs. TAU	1.055	.811

Adli et al., submitted

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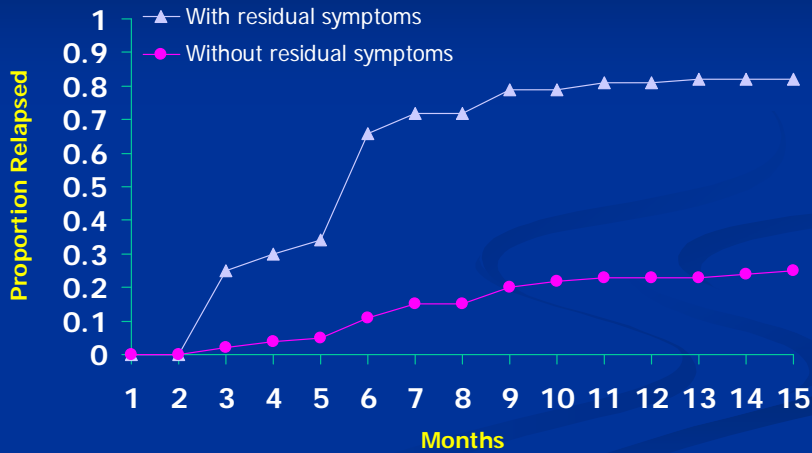
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Rationale for MBC with Mood Disorders

- Communication & Collaboration
- Quality of Care & Outcomes
- **Care Delivery & System Management**

**MBC Can Also Provide Important
Prognostic or Other Patient Level
Clinical Indicators That Can
Tailor/Personalize Care Delivery**

Which Remitted Patients Will Relapse?

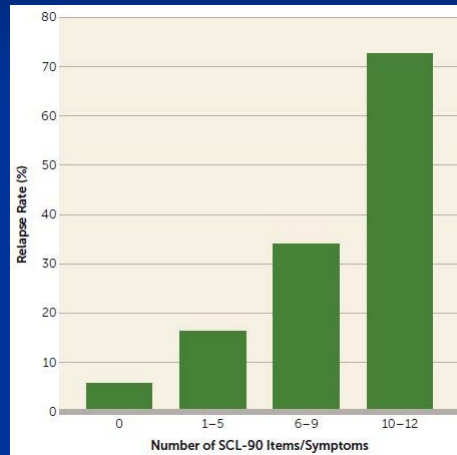


Paykel ES, et al. *Psychol Med.* 1995;25:1171-1180. Reprinted with the permission of Cambridge University Press.

Individuals With Higher Ratings in Remission Are at Higher Risk of Relapse

SCL-90 Symptoms

- Feeling blocked
- Feeling pushed
- Tense / keyed up
- Having ideas/beliefs others do not
- Feeling inferior to others
- Low in energy / slowed down
- Very self-conscious with others
- Headaches
- Crying easily
- Feelings easily hurt
- Worrying too much
- Trouble concentrating



Judd LL et al. *Am J Psychiatry* 2016;173(11):1140-1146

MBC Provides Program Evaluation Metric

- If MBC data enters EHR, programmatic success is easily analyzed
- Hypotheses about indicators of treatment selection can be developed
- Patients with high side effects or poor therapeutic effects can be identified
- Performance of individual providers can be assessed
- Need for second opinions can identified earlier

Why Don't Psychiatrists Use Scales to Measure Depression Outcomes? (N=248)*

Reasons	%
Do not believe it would be clinically helpful	28
Do not know what measure to use	21
Takes too much time	34
Too disruptive of clinical practice	19
Was not trained to use them	34
Other	29

* Only Ss who never, rarely, or sometimes used scales responded to this question. Ss could check off more than one response.

Zimmerman M, McGlinchey JB, Chelminski I. *Primary Psychiatry* 2008;15(6)

Opposition to MBC:

Blog response to recommendation for MBC

"For how long do we have to keep bending over and taking it from the regulators and insurers. Only we physicians provide the care, and the system is useless without us. I'm tired of spending my time "accounting," "justifying," "proving," and "measuring" as a data collector for some other business's purposes. I'd rather just treat my patients and spend the time with them."

beachwoodshrink



MBC Can Address Multiple Clinical Tasks



QUESTIONS ??



Shall We Talk?



Thank You