M3 Information™
Transforming Mental Health Care

The M3 Checklist & Clinical Practice

What It Is • Why It's Needed • How to Use It

155 Gibbs Street, Suite 522 Rockville, MD 20850

Version 1

301.444.4400 | M3Information.com

Special Communication | USPSTF Recommendation Statement

Screening for Depression in Adults

US Preventive Services Task Force Recommendation Statement[34]

Sui A, et al, 2016. Screening for Depression in Adults US Preventive Services Task Force Recommendation Statement. JAMA 2016:315(4):380

The USPSTF recommends screening and behavioral counseling interventions to reduce alcohol misuse by adults, including pregnant women, in primary care settings.

Screening Tests

- Treating depressed adults and older adults identified through screening in primary care settings with antidepressants and/or psychotherapy decreases clinical morbidity. USPSTF also found that programs combining depression screening and feedback with staff assisted depression care supports improve clinical outcomes in adults. There is fair evidence that screening and feedback alone without staff-assisted care supports do notimprove clinical outcomes in adults.

- All positive screening results should lead to additional assessment that considers severity of depression and comorbid psychological problems (e.g. anxiety, panic attacks, or substance abuse), alternate diagnoses, and medical conditions. Patients who screen positive should be appropriately diagnosed and treated with evidence-based care or referred to a setting that can provide the necessary care.

- The USPSTF found adequate evidence that the magnitude of harms of screening for depression in adults is small to none.

Measurement & Evidence-Based
Mental Health Care

The M3 Checklist screening assessment & tracking tool is:

Evidence-based

User-friendly

Administered on the web or a mobile device

Instantly interpreted

M3 Detects Risk for:

Depression

Anxiety disorders

Bipolar disorders

Post-traumatic stress disorder

Substance Misuse

Suicidality

Functional Impairment

It fits into practice workflow, yields standardized reports, and connects with most electronic health records (EHRs).

Information developed through the M3 Checklist provides a comprehensive profile of each patient, including functional status, drug use, and thoughts of suicide. The information can be used in measurement-based care, revealing changes in a patient's mental health status, practice patterns, and aggregate population health data.

M3 Checklist — Why It's Needed & How to Use It

Contents

About M3 Checklist

LabCorp is now offering the M3 Checklist, empowering providers with an evidence-based assessment that detects symptoms of mental health conditions: depression, anxiety, bipolar disorders, PTSD and an option for substance misuse. The Checklist is a nationally recognized, peer reviewed and clinically validated tool.[1]

Once the patient completes the assessment, the M3 Checklist computes results and sends a report to the ordering clinician. The report provides a numeric value, the M3 score, indicating the overall level of mental health symptom burden. Functional impairment and symptom severity for each of mental health conditions are also identified. Out of range scores are flagged as "high" so there can be further review with the patient to determine clinical needs.

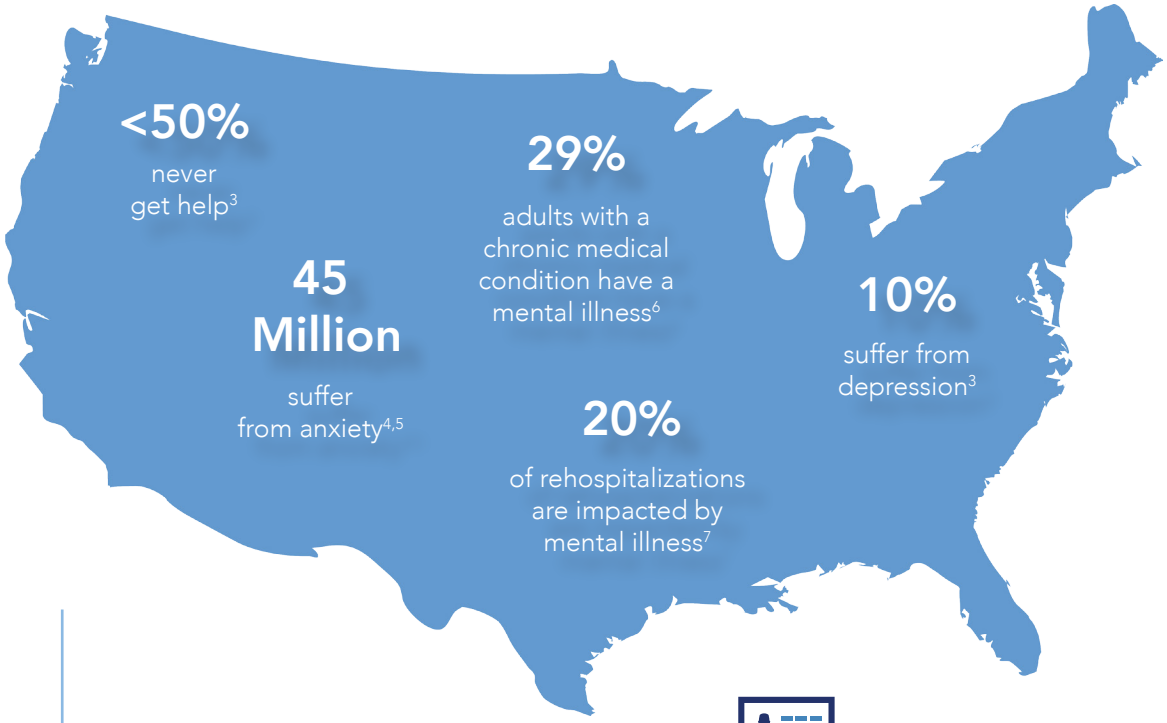
1 in 5

U.S. adults suffer from one or more mental health disorders[2]

7

different disorders and features of mood & anxiety disorders

- Anxiety
- Depression
- PTSD
- Suicide
- Bipolar disorder
- Substance Misuse
- Functional Impairment



27

Questions on the test

EMR

Data is sent directly to the EMR

Who Should Use the M3 Checklist?

- Primary care practitioners
- Specialty care physicians
- Patient centered medical homes
- Accountable care organizations
- Federally qualified health centers
- Mental health professionals
- Behavioral health clinics
- Integrated delivery networks
- Commercial & government payers
- Employee assistance programs

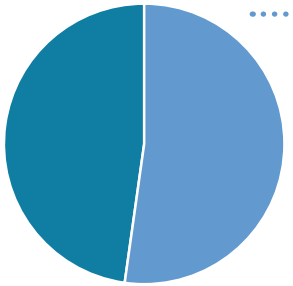
Mental Health: More than Just Depression

Anxiety disorders, depression, and bipolar disorders represent 99 percent of mental health conditions. Research shows that 55 percent of Americans will experience a mental health disorder in their lifetime (see Figure 1).

Anxiety disorders are nearly two times more prevalent than depression. Yet, practices that use screening tools typically assess only for depression. For this reason, and because mental health conditions frequently present together, this common approach often results in under-diagnosis and under-treatment.

The M3 Checklist identifies symptoms of anxiety disorder, bipolar disorder, depression, and PTSD, providing a profile showing the presence of any of these conditions in every screened individual. Figure 2 indicates the diagnoses of the participants in the M3 validation study and shows where many had one or more mental health condition.

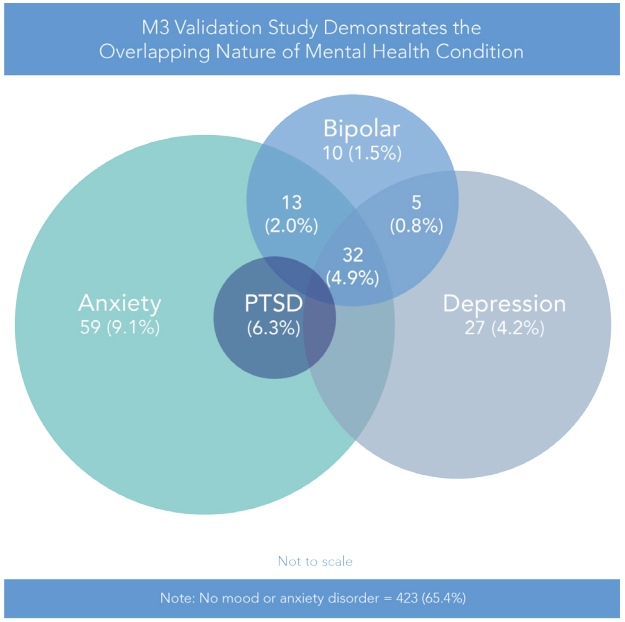
Fig. 1: Lifetime Prevelance[8]



55% of Americans will suffer from a mental disorder during their lifetime.

Disorder	Lifetime Prevalence
Any anxiety disorder	**28.8%**
Panic Disorder	4.7%
Agoraphobia without panic	1.4%
Specific phobia	12.5%
Social phobia	12.1%
Generalized anxiety disorder	5.7%
Obsessive-compulsive	**1.6%**
Separation anxiety	5.2%
Mood disorder	20.8%
Major depression	**16.6%**
Dysthymia	2.5%
Bipolar I or II	**3.9%**
Post-traumatic stress disorder	**6.8%**
Substance misuse disorder	**14.6%**
Alcohol abuse	13.2%
Alcohol dependence	5.4%
Drug abuse	7.9%
Drug dependence	3.0%

Fig. 2: M3 Validation Study Demonatrates the Overlapping Nature of Mental Health Condition[1]



Cost of Mental Illness

Payers	PMPM without MH Diagnosis	Patients with Diagnosis	PMPM with MH Diagnosis	Increase with MH Diagnosis
Commercial	$340	14%	$903	266%
Medicare	$582	9%	$1,409	242%
Medicaid	$381	20%	$1,301	341%
All Insurers	$397	14%	$1,085	273%

Potential Savings in Chronic Condition Care through Treating Co-occuring Mental Illness[9]

Medical Condition	Total Commercial Costs (Million)	Total Medicare Costs (Million)
Arthritis	$36,372	$11,929
Asthma	$30,801	$2,570
Cancer	$16,201	$3,535
Hypertension (without complications)	$27,241	$9,620
Ischemic Heart Disease	$7,208	$7,278

***Please note that the values do not sum to create the total**

$26 to $48 billion can be saved through effective integration of mental health and medical services.[9]

TOTAL SAVINGS

Total Commercial Costs (Million)
$162,366

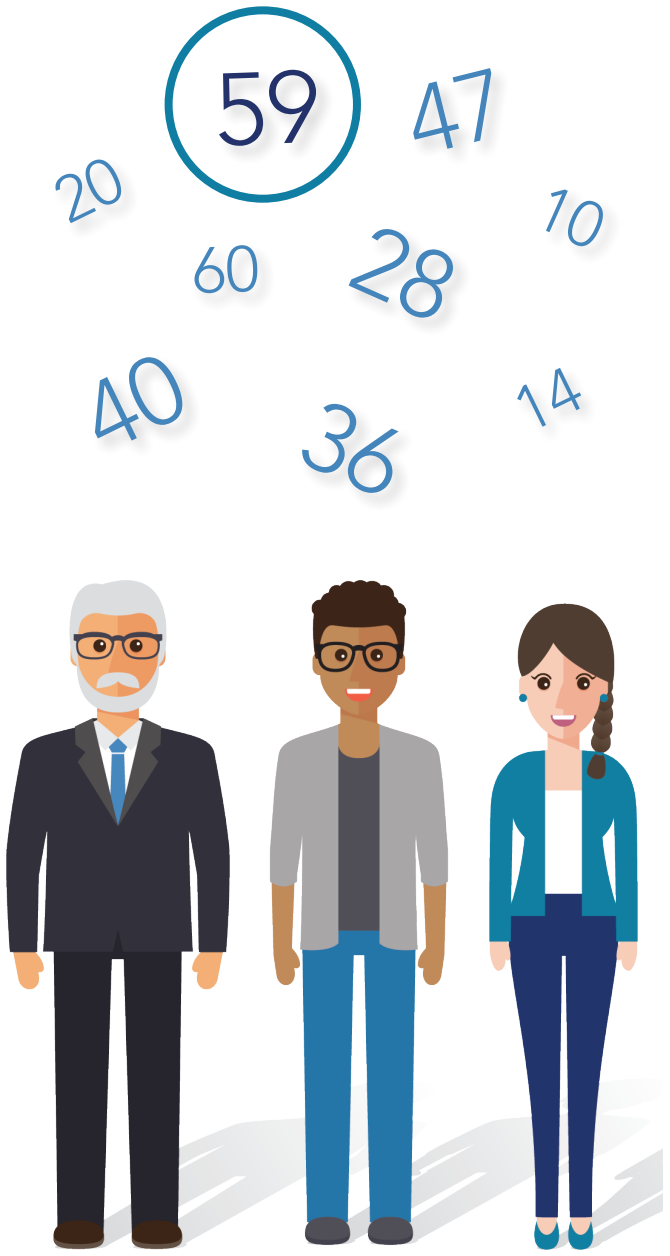
Total Medicare Costs (Million)
$30,803

The M3 Score: One Number for Mental Health

The M3 Checklist captures a comprehensive measure of a patient's overall mental health symptom burden. This is done by assessing a patient's risk of common mental health conditions found in primary care: depression, anxiety, bipolar disorder, and post-traumatic stress disorder. The validation study out of the University of North Carolina[1] identified symptom burden scores for each of the four diagnoses. Of the 647 participants enrolled in the study, any positive M3 sub-score reflects 83% sensitivity and 76% specificity for risk of a diagnosable condition.

Further evaluation of the original study data was performed to determine whether a single number, the M3 Checklist Score or M3 Score, could quickly indicate whether the patient is at significant risk of any mood or anxiety disorder, singly or in combination. This unpublished analysis[10] demonstrated that the optimal screening cut point is a score of 33 and above. With this additional data, the Checklist has a positive predictive value of 71%, indicating patients at risk for four mental health disorders (not merely depression), while 89% of patients with a score of 33 or less are diagnosis free. Consequently, scores of 33 or above are considered out of range and are therefore flagged as "high" on the report. The M3 Score also correlates well with the Short Form Health Survey (SF-12), a standard in the field, which is a brief, functional health survey that assesses limitations on role functioning as a result of physical and emotional health. These correlations are further proof of the M3's ability to find clinically significant cases where there is demonstrable functional impairment.[11]

The National Institute of Mental Health has endorsed a more multi-dimensional approach to psychiatric illness,[12,13] suggesting that symptoms from across a range of common diagnostic categories should be assessed. This is the approach the M3 takes. The first step in using the M3 Checklist is to determine whether the M3 score is in or out of range. Look next to the four subscores, also flagged when results indicate the patient may be at risk for each of the four disorders. Finally, in considering a diagnosis it is important to look at the patient's functional status, reflected in the M3 Gateway responses. A positive Gateway, combined with significant symptom severity, provides the criteria for a mental health diagnosis from which primary care physicians can initiate treatment, whether it be psychotherapy, pharmacotherapy, or both. The M3 also contains two additional questions probing for alcohol and substance misuse. When endorsed by the patient, alcohol use patterns may be further investigated with the AUDIT-C, an instrument available to order along with the M3 Checklist.



How to Review the M3 Checklist Report

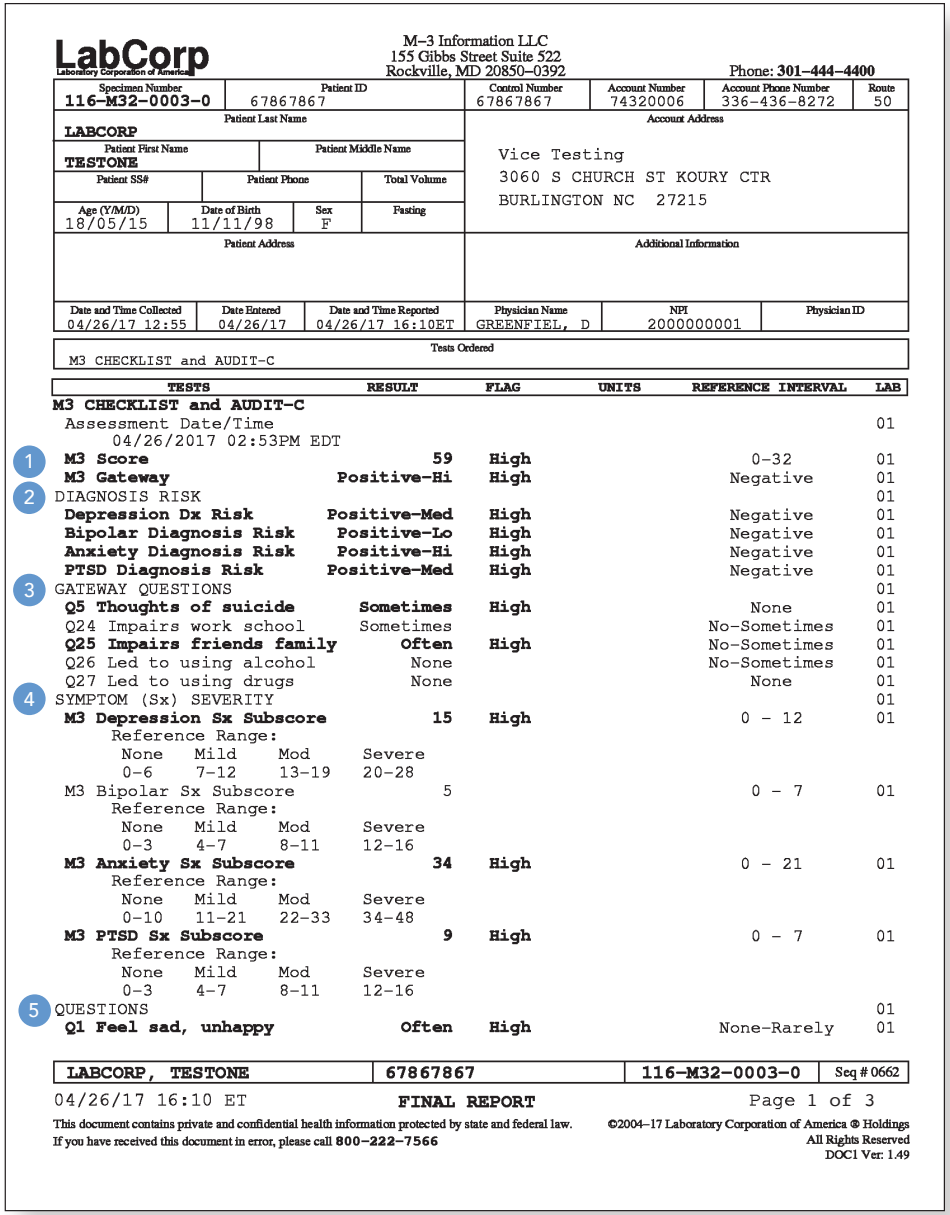
This lab report is organized like any other LabCorp report. The left-hand column entitled "TESTS" shows requested assessment results for the M3 Checklist and/or the AUDIT-C. The "RESULT" column displays overall findings relative to the results of the assessment, e.g. M3 Score, M3 Gateway, Diagnosis Risk by condition, Gateway Questions, Symptom Severity Subscores by condition, and responses to Questions. "FLAG" identifies out-of-range scores, which are either "HIGH" or blank. Items flagged as "HIGH" are bolded and suggest the need for special attention to better understand the nature of the patient's response and how they relate to the relevant mental health condition. The "REFERENCE INTERVAL" identifies the expected baseline range for each item.

1 M3 Score indicates the overall level of mental health symptom burden. 0-32=low; 33-108=high
M3 Gateway, when positive, indicates impairment in functional status. The Gateway is positive if any of the five Gateway questions (Q5 & Q24-27) are positive.

2 Diagnosis Risk A psychiatric diagnosis requires significant impairment in function, which is indicated by a positive Gateway. A sufficient level of symptoms is also required to meet diagnostic criteria for any condition. Generally, each Diagnosis Risk incorporates both requirements into its result.

3 The Gateway Questions (questions 5 and 24 through 27) address functional status, substance use, and thoughts of suicide. Positive answers to these questions should be followed by additional questions to understand what the patient means, if this is a change, and to determine need for further intervention. Suicide assessment is included to minimize risk when treating mood and anxiety disorders.

4 Symptom Severity indicates the severity of symptoms for each of the four clinical conditions and is not impacted by the Gateway result. These subscores are most sensitive to change over time, and their review should be combined with discussing of the responses for each condition.



LabCorp
Laboratory Corporation of America

M–3 Information LLC
155 Gibbs Street Suite 522
Rockville, MD 20850–0392
Phone: 301–444–4400

Specimen Number	Patient ID	Control Number	Account Number	Account Phone Number	Route
116–M32–0003–0	67867867	67867867	74320006	336–436–8272	50

Patient Last Name: LABCORP
Patient First Name: TESTONE
Patient Middle Name:
Patient SS#:
Patient Phone:
Total Volume:
Age (Y/M/D): 18/05/15
Date of Birth: 11/11/98
Sex: F
Fasting:
Patient Address:

Account Address:
Vice Testing
3060 S CHURCH ST KOURY CTR
BURLINGTON NC 27215

Additional Information:

Date and Time Collected	Date Entered	Date and Time Reported	Physician Name	NPI	Physician ID
04/26/17 12:55	04/26/17	04/26/17 16:10ET	GREENFIEL, D	2000000001	

Tests Ordered: M3 CHECKLIST and AUDIT-C

	TESTS	RESULT	FLAG	UNITS	REFERENCE INTERVAL	LAB
	M3 CHECKLIST and AUDIT-C					
	Assessment Date/Time 04/26/2017 02:53PM EDT					01
1	**M3 Score**	**59**	**High**		0–32	01
1	**M3 Gateway**	**Positive–Hi**	**High**		Negative	01
2	DIAGNOSIS RISK					01
2	**Depression Dx Risk**	**Positive–Med**	**High**		Negative	01
2	**Bipolar Diagnosis Risk**	**Positive–Lo**	**High**		Negative	01
2	**Anxiety Diagnosis Risk**	**Positive–Hi**	**High**		Negative	01
2	**PTSD Diagnosis Risk**	**Positive–Med**	**High**		Negative	01
3	GATEWAY QUESTIONS					01
3	**Q5 Thoughts of suicide**	**Sometimes**	**High**		None	01
3	Q24 Impairs work school	Sometimes			No–Sometimes	01
3	**Q25 Impairs friends family**	**Often**	**High**		No–Sometimes	01
3	Q26 Led to using alcohol	None			No–Sometimes	01
3	Q27 Led to using drugs	None			None	01
4	SYMPTOM (Sx) SEVERITY					01
4	**M3 Depression Sx Subscore**	**15**	**High**		0 – 12	01
	Reference Range: None 0–6 / Mild 7–12 / Mod 13–19 / Severe 20–28					
4	M3 Bipolar Sx Subscore	5			0 – 7	01
	Reference Range: None 0–3 / Mild 4–7 / Mod 8–11 / Severe 12–16					
4	**M3 Anxiety Sx Subscore**	**34**	**High**		0 – 21	01
	Reference Range: None 0–10 / Mild 11–21 / Mod 22–33 / Severe 34–48					
4	**M3 PTSD Sx Subscore**	**9**	**High**		0 – 7	01
	Reference Range: None 0–3 / Mild 4–7 / Mod 8–11 / Severe 12–16					
5	QUESTIONS					01
5	**Q1 Feel sad, unhappy**	**Often**	**High**		None–Rarely	01

LABCORP, TESTONE | 67867867 | 116–M32–0003–0 | Seq # 0662
04/26/17 16:10 ET | **FINAL REPORT** | Page 1 of 3

5 The 27 Questions and responses inform how the clinician focuses on further assessment after reviewing the report. Responses flagged as "HIGH" have the highest severity and should be reviewed in more detail with the patient. The following question numbers indicate which questions apply to each condition.

- Depression: 1-7
- Anxiety: 8-19 (GAD 8-9; Panic 10-11; Social 12; OCD 17-19)
- PTSD: 13-16
- Bipolar: 20-23

Sample LabCorp Report Highlighting the M3 Scores (continued)

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155 Gibbs Street Suite 522
Rockville, MD 20850-0392
Phone: 301-444-4400

Patient Name	Specimen Number
LABCORP, TESTONE	116-M32-0003-0

Account Number	Patient ID	Control Number	Date and Time Collected	Date Reported	Sex	Age(Y/M/D)	Date of Birth
74320006	67867867	67867867	04/26/17 12:55	04/26/17	F	18/05/15	11/11/98

TESTS	RESULT	FLAG	UNITS	REFERENCE INTERVAL	LAB
Q2 Can't concentrate/focus	**Sometimes**	**High**		None-Rarely	01
Q3 Nothing gives pleasure	**Sometimes**	**High**		None-Rarely	01
Q4 Tired, no energy	**Sometimes**	**High**		None-Rarely	01
Q6A Difficulty sleeping	**Sometimes**	**High**		None-Rarely	01
Q6B Sleeping too much	Rarely			None-Rarely	01
Q7A Decreased appetite	**Sometimes**	**High**		None-Rarely	01
Q7B Increased appetite	**Sometimes**	**High**		None-Rarely	01
Q8 Tense anxious can't sit	**Often**	**High**		None-Rarely	01
Q9 Worried or fearful	**Often**	**High**		None-Rarely	01
Q10 Panic Attacks	**Sometimes**	**High**		None-Rarely	01
Q11 Dying losing control	**Often**	**High**		None-Rarely	01
Q12 Nervous shaky social	**Often**	**High**		None-Rarely	01
Q13 Nightmares, flashbacks	Rarely			None-Rarely	01
Q14 Jumpy, startled easily	**Sometimes**	**High**		None-Rarely	01
Q15 Avoids places	**Often**	**High**		None-Rarely	01
Q16 Dull numb or detached	**Often**	**High**		None-Rarely	01
Q17 Can't get thoughts out	**Most time**	**High**		None-Rarely	01
Q18 Must repeat rituals	**Often**	**High**		None-Rarely	01
Q19 Need to check/recheck	**Most time**	**High**		None-Rarely	01
Q20 More energy than usual	**Sometimes**	**High**		None-Rarely	01
Q21 Irritable angry	**Sometimes**	**High**		None-Rarely	01
Q22 Excited revved high	Rarely			None-Rarely	01
Q23 Needed less sleep	None			None-Rarely	01

Comments: 01

The M3 Score reflects relative symptom severity. The M3 Gateway, when positive, reflects a negative impact on lifestyle and function. Both are considered when assessing diagnosis risk and when comparing prior scores [1]. The Diagnosis Risk reflects the likelihood of having a diagnosis based on both the Symptom and the Gateway ratings when compared to the MINI [2]. Those who deny role impairment (Q24-25), substance abuse (Q26-27), and suicidal ideation (Q5), will have a negative Gateway and negative Diagnosis Risk, even with higher symptom scores. People with negative Gateways and M3 Scores less than 33 have the lowest likelihood of having a diagnosis.
The highest M3 Score is 108.

A) All proposed categories of Risk (low, med, high) are positive and may be used for risk stratification pending further studies.

B) The M-3 Checklist is a screening test designed to aid in the detection of common mental health conditions. It is not a diagnostic procedure and should not be used as the sole means of detecting these conditions. Both false-positive and false-negative reports do occur [1]. The diagnoses screened for include major depressive, bipolar, posttraumatic stress, and anxiety disorders (generalized anxiety, social anxiety, panic, and obsessive-compulsive disorders).

LABCORP, TESTONE	67867867	116-M32-0003-0	Seq # 0662

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M-3 Information LLC
155 Gibbs Street Suite 522
Rockville, MD 20850-0392
Phone: 301-444-4400

Patient Name	Specimen Number
LABCORP, TESTONE	116-M32-0003-0

Account Number	Patient ID	Control Number	Date and Time Collected	Date Reported	Sex	Age(Y/M/D)	Date of Birth
74320006	67867867	67867867	04/26/17 12:55	04/26/17	F	18/05/15	11/11/98

TESTS	RESULT	FLAG	UNITS	REFERENCE INTERVAL	LAB

C) When the Gateway Questions 24, 25, 26, or 27, or Question 5, are out of range, this suggests a positive impairment, meaning a likely impact on lifestyle.

D) Symptom subscores in the Moderate or Severe range are flagged with a High.

E) Patient instructions are as follows:
For Q1-Q19: 'Over the past two weeks, have there been phases or periods when you have noticed the following?'
For Q20-Q23: 'Since you last took this screen, have there been phases or periods when you have noticed the following?'
For Q24-Q27: 'Have you noticed whether any of the symptoms you described:'

References: 01

[1] Gaynes et al., 2010. Feasibility and Diagnostic Validity of the M-3 Checklist: A Brief, Self-Rated Screen for Depressive, Bipolar, Anxiety, and Post-traumatic Stress Disorders in Primary Care. Ann Fam Med 8(2):160.
[2] Sheehan et al., 1998. The Mini-International Neuropsychiatric Interview (M.I.N.I.): The Development and Validation of a Structured Diagnostic Psychiatric Interview for DSM-IV and ICD-10. J Clin Psych 59(20):22.

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PDF Image	.				01
AUDIT-C	**Positive**	**High**		Negative	01
AUDIT-C Total Score	**5**	**High**		0-2	01
Q1 How often in past year	2-3x weekly				01
Q2 How many on a typical day	3-4 drinks				01
Q3 6+ drinks per occasion	**< Monthly**	**High**		Never	01
Comments:					01

A) AUDIT-C identifies people at high risk for heavy drinking

LABCORP, TESTONE	67867867	116-M32-0003-0	Seq # 0662

04/26/17 16:10 ET **FINAL REPORT** Page 3 of 3

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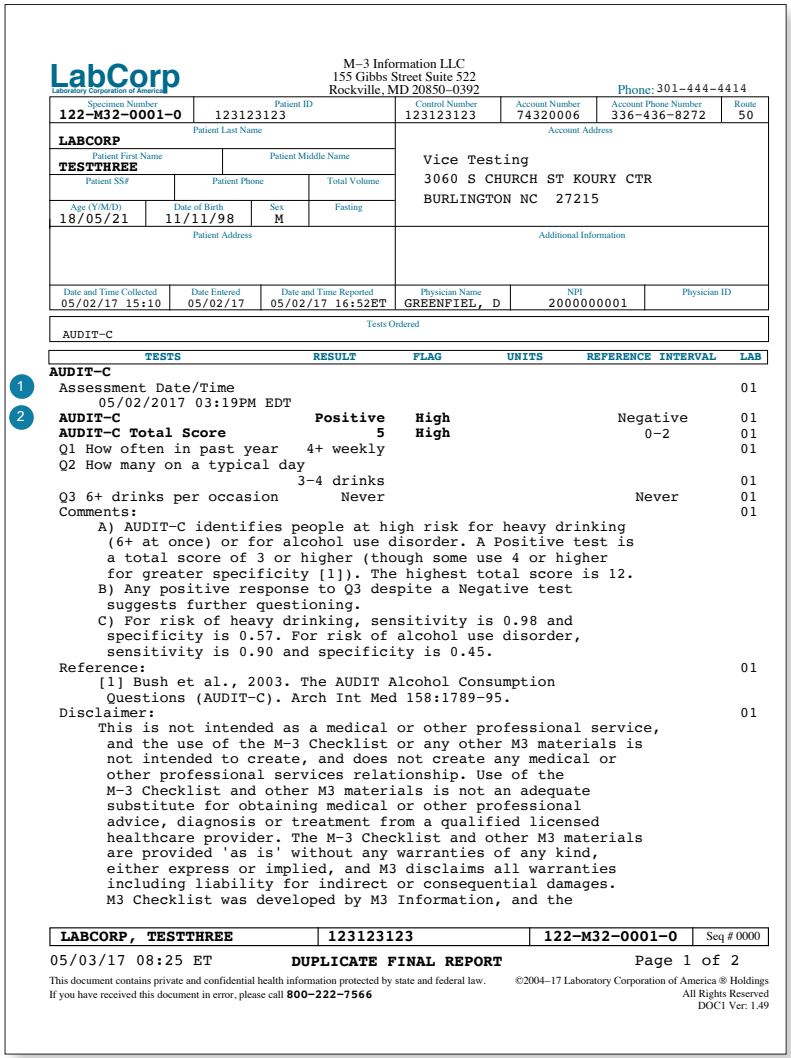
How to Review the AUDIT-C Report

The AUDIT-C identifies people at high risk for Alcohol Use Disorder. This report is organized like any other LabCorp report. The left-hand column entitled "TESTS" lists the queries for the AUDIT-C (e.g. question 1). The "RESULT" column displays overall findings relative to the results of the assessment (e.g. Positive). "FLAG" identifies out-of -range scores, which are either "HIGH" or blank. Items flagged as "HIGH" are bolded and suggest the need for special attention to better understand the nature of the responses and how they relate to alcohol use. The "REFERENCE INTERVAL" identifies the expected baseline range for each item.

1 AUDIT-C Total Score A positive test is a total score of 3 or higher (some use 4 as the threshold for men) or any response to Q3 other than "Never."

2 Questions The response to each question can be reviewed. Responses inform the clinician how to focus further assessment of the patient. These questions relate to frequency, and quantity of alcohol use, and the presence of binging behavior. Any positive response to Question 3, despite a negative overall result, warrants further questioning.



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Rockville, MD 20850–0392
Phone: 301-444-4414

Specimen Number	Patient ID	Control Number	Account Number	Account Phone Number	Route
122-M32-0001-0	123123123	123123123	74320006	336-436-8272	50

Patient Last Name: LABCORP
Patient First Name: TESTTHREE
Patient Middle Name:
Patient SS#:
Patient Phone:
Total Volume:
Age (Y/M/D): 18/05/21
Date of Birth: 11/11/98
Sex: M
Fasting:
Patient Address:

Account Address:
Vice Testing
3060 S CHURCH ST KOURY CTR
BURLINGTON NC 27215

Additional Information:

Date and Time Collected	Date Entered	Date and Time Reported	Physician Name	NPI	Physician ID
05/02/17 15:10	05/02/17	05/02/17 16:52ET	GREENFIEL, D	2000000001	

Tests Ordered: AUDIT-C

TESTS	RESULT	FLAG	UNITS	REFERENCE INTERVAL	LAB
AUDIT-C					
1 Assessment Date/Time 05/02/2017 03:19PM EDT					01
2 **AUDIT-C**	**Positive**	**High**		Negative	01
AUDIT-C Total Score	**5**	**High**		0-2	01
Q1 How often in past year	4+ weekly				01
Q2 How many on a typical day	3-4 drinks				01
Q3 6+ drinks per occasion	Never			Never	01
Comments:					01

A) AUDIT-C identifies people at high risk for heavy drinking (6+ at once) or for alcohol use disorder. A Positive test is a total score of 3 or higher (though some use 4 or higher for greater specificity [1]). The highest total score is 12.
B) Any positive response to Q3 despite a Negative test suggests further questioning.
C) For risk of heavy drinking, sensitivity is 0.98 and specificity is 0.57. For risk of alcohol use disorder, sensitivity is 0.90 and specificity is 0.45.

Reference: 01
[1] Bush et al., 2003. The AUDIT Alcohol Consumption Questions (AUDIT-C). Arch Int Med 158:1789-95.

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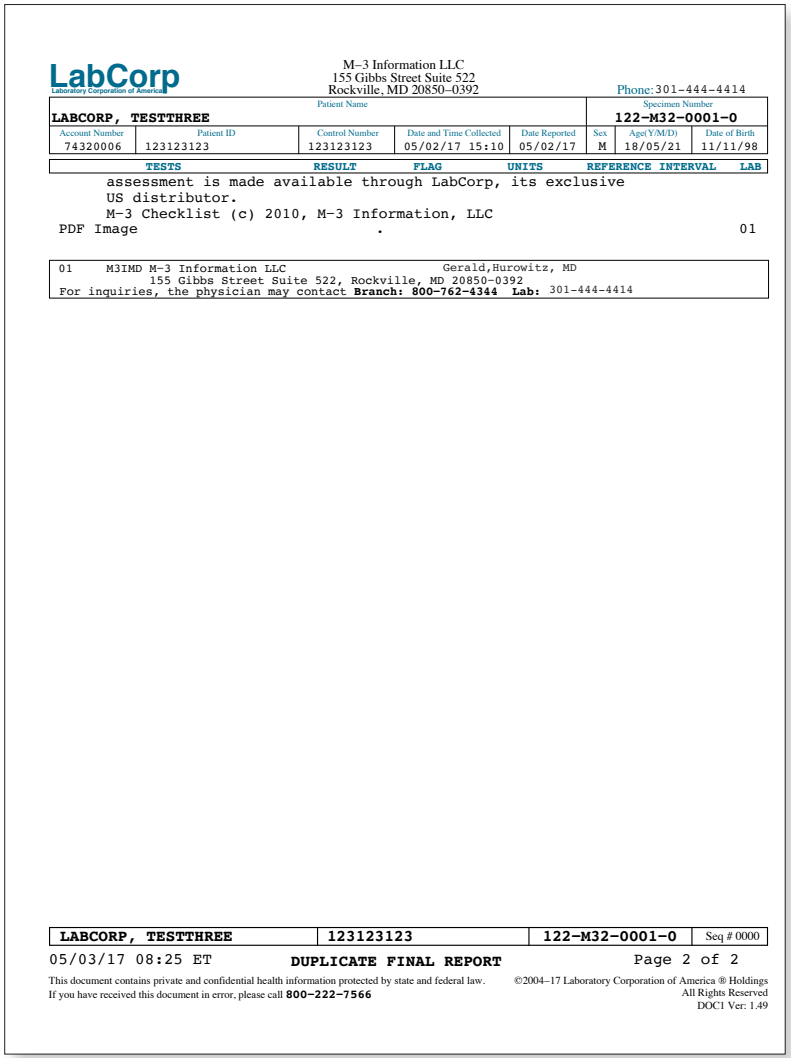
LABCORP, TESTTHREE	123123123	122-M32-0001-0	Seq # 0000

05/03/17 08:25 ET **DUPLICATE FINAL REPORT** Page 1 of 2



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Laboratory Corporation of America

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155 Gibbs Street Suite 522
Rockville, MD 20850–0392
Phone: 301-444-4414

Patient Name	Specimen Number
LABCORP, TESTTHREE	122-M32-0001-0

Account Number	Patient ID	Control Number	Date and Time Collected	Date Reported	Sex	Age(Y/M/D)	Date of Birth
74320006	123123123	123123123	05/02/17 15:10	05/02/17	M	18/05/21	11/11/98

TESTS	RESULT	FLAG	UNITS	REFERENCE INTERVAL	LAB

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US distributor.
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01 M3IMD M-3 Information LLC Gerald,Hurowitz, MD
155 Gibbs Street Suite 522, Rockville, MD 20850-0392
For inquiries, the physician may contact **Branch: 800-762-4344 Lab:** 301-444-4414

LABCORP, TESTTHREE	123123123	122-M32-0001-0	Seq # 0000

05/03/17 08:25 ET **DUPLICATE FINAL REPORT** Page 2 of 2

M3 Mental Health Advisor

M3 Score: 40 (High) *Reference Range: 0-32*

M3 Gateway: Positive-Med *Reference Range: Negative*

Patient Name: Testing, Minnie J
Provider Name: M3 Info. Testing Account

DOB: 03/08/1955 (Age 62) **ID**: 922-729-4355-6
Gender: Female
Collected: 5/17/17, 09:35 **Reported:** 5/17/17

Observations

The M3 Score is 40 (moderate level of symptoms) with medium level impairment due to alcohol use, thoughts of suicide "sometimes," and significant impairment at work, with some at home, too. Minnie has a high positive risk of having a current major depression diagnosis, with a lower positive risk of an anxiety disorder, possibly generalized anxiety disorder. Risk of having bipolar disorder or PTSD is low. He is drinking alcohol heavily. Depression symptoms are at the severe level (M3 Depression score = 20), w mild level of anxiety symptoms (M3 Anxiety score = 11). Intervention strongly advised.

Treatment Options

Guideline recommendations suggested for those with similar symptoms include medication, psychotherapy, and brief intervention and referral for alcohol use. If a prior depression medicine has been effective, this can be considered. Minnie's symptom profile shows anergia and insomnia to be most severe, followed by depressed mood, concentration, anhedonia, and worrying. Medications suggested as first line include SSRIs, SNRIs, and bupropion. Alcohol cessation may carry risk of withdrawal and seizure, so assessment of risk and education on withdrawal symptoms and management with short course of long half-life benzodiazepines may be considered, which may also help with insomnia. Cognitive-behavioral therapy referral is recommended per guidelines.

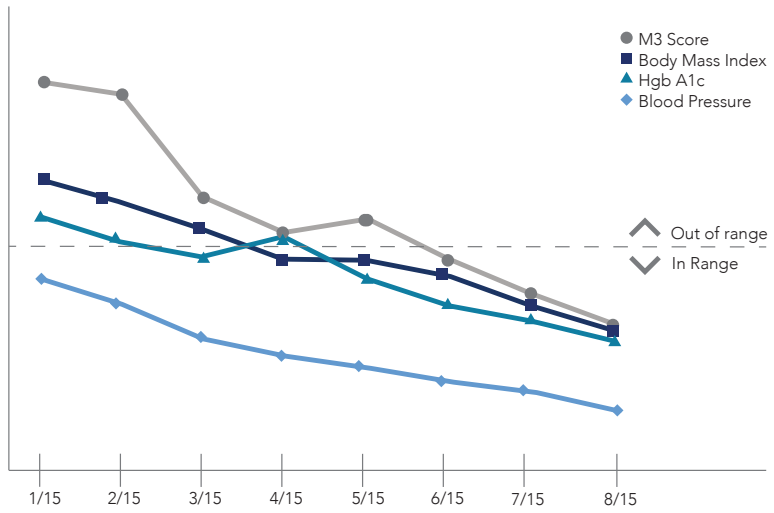
Care Considerations

Assessment of suicide risk is the first priority. With an acceptable safety plan, further diagnostic assessment includes duration of symptoms and ruling out medical causes, including medication side effects. If specialty consultation is available, it should be considered.

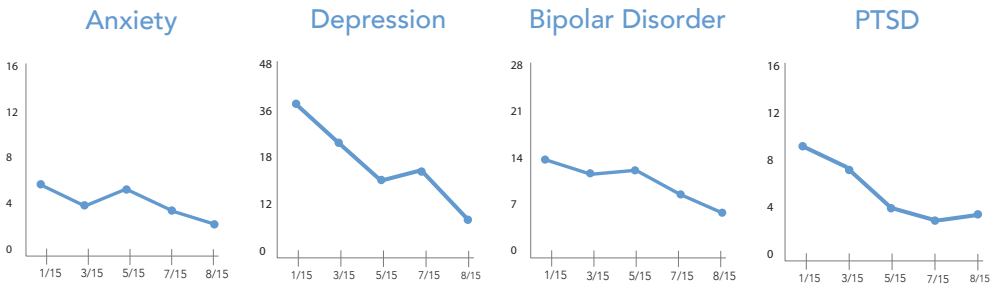
Depression Treatment Timeline

A weekly assessment is recommended until symptom severity begins to decrease. With adequate medication dosage and adherence, symptom subscores may begin to decrease after 2-3 weeks. Goal is M3 Depression score less than 15 within 1-2 weeks, and less than 7 within 4-6 weeks. Monitor for increase in Anxiety or Bipolar Symptom scores, which can be medication side effects.

Relationship Between Mental & Physical Health Indicators



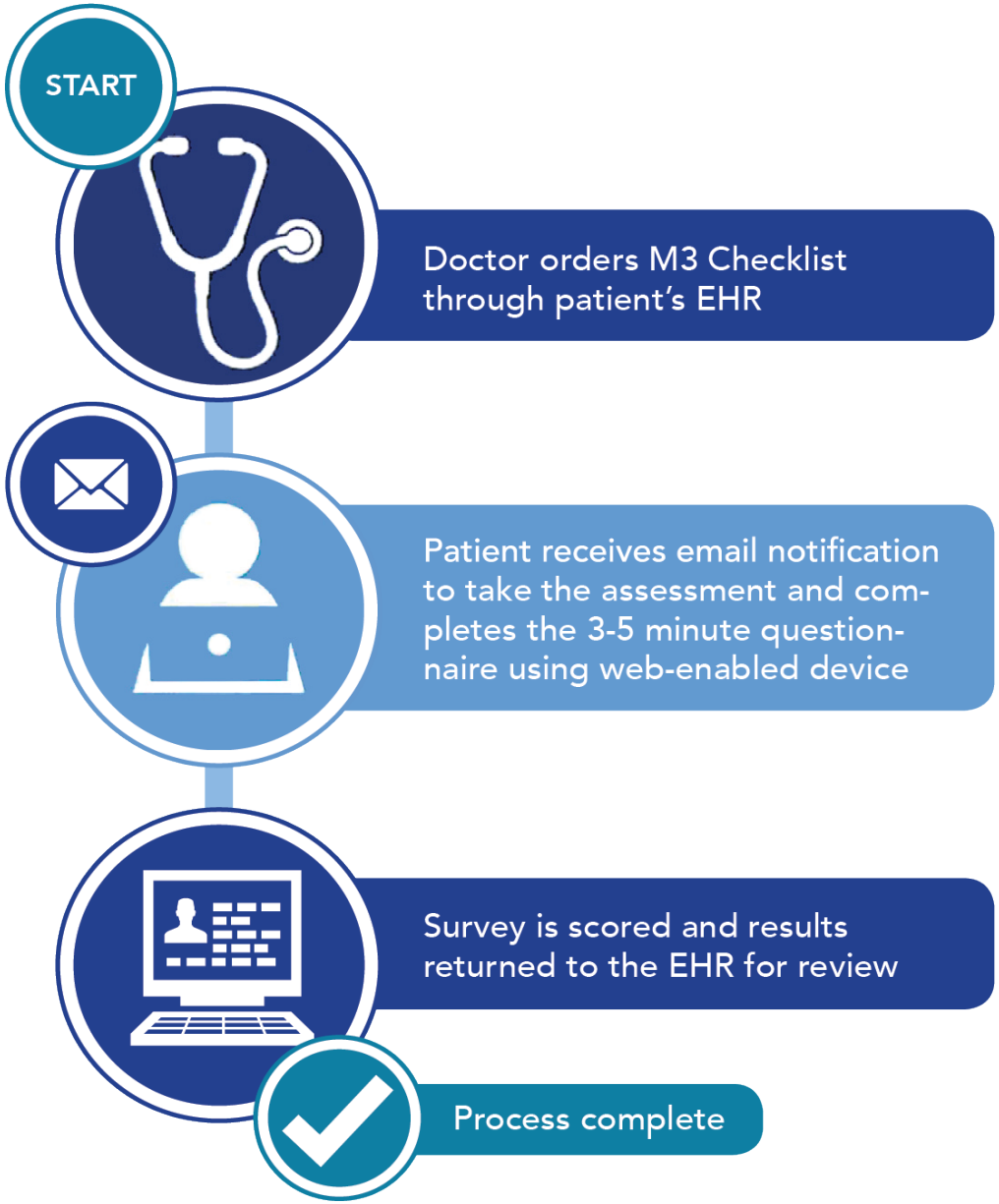
Subscores



M3 Checklist Workflow

These assessments are ordered the same way as any LabCorp specimen test

Primary care physicians do not want to do more work and especially without getting paid for it. The M3 Checklist and the AUDIT-C easily fit into clinical workflow and are reimbursed by Medicare and many commercial insurers. These assessments are ordered the same way as any LabCorp specimen test and, once completed on-line by the patient, the reports are integrated into the electronic health record for review of out of range values by the clinician, with the patient.



Comparison of Assessments

In one assessment, the M3 checklist offers more than other common mental health screens. It assesses for over 5 mental health disorders, is web-based, provides structured data directly to the electronic health record and takes minutes to complete.

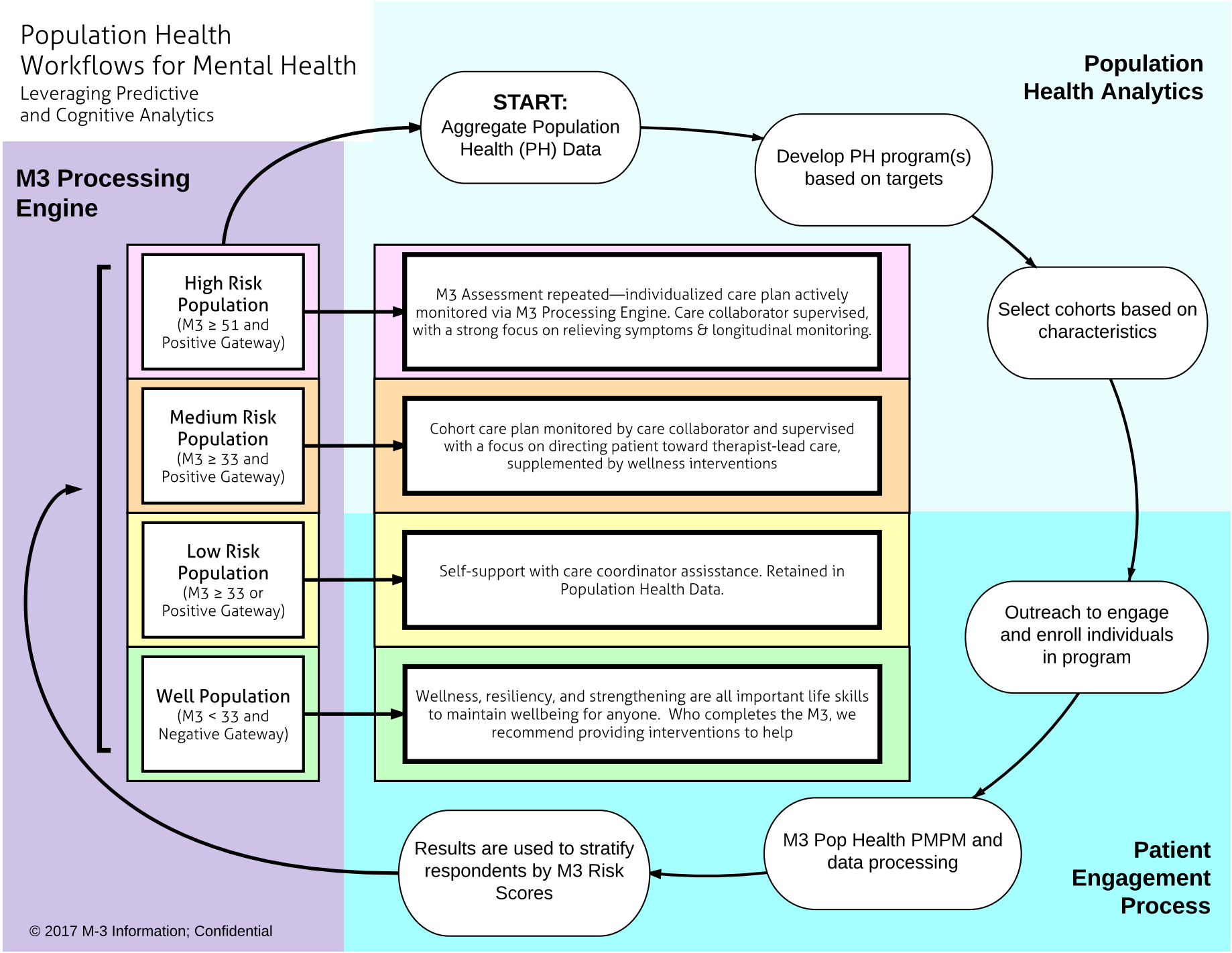
	M3 Checklist	AUDIT-C	GAD-7	PHQ-9,4,2	DAST-10	DASS-21	MDQ	SF-20
No. of Questions	27	3	7	9,4,2	19	21	13	20
Time to Complete	3-5 mins.	1 min.	2 mins.	3,2,1 min(s).	3 mins.	7 mins.	5 mins.	7 mins.
Depression	✓			✓		✓		✓
Bipolar	✓						✓	
Anxiety	✓		✓	4&9 ✓		✓		✓
PTSD	✓							
Substance Misuse	✓	✓			✓			
Functional Impairment	✓							✓
Data sent to EHR	✓	✓						
Suicide	✓			✓				

Comprehensive List of Codes & Reimbursement for Mental Health Assessments

Type of Assessment	Payer	Code Type	Billing Code	Description	Estimated Reimbursement
Mental Health Assessments	Medicare/ Commercial	CPT[22]	96103	Psychological testing, administered by a computer, with qualified health care professional interpretation and report.	$30.95[23]
					$28[24] & $30[25] to $60[25]
	Medicare	HCPCS[26, 27]	G0444	Annual depression screening, 15 minutes. No co-insurance, no co-pay	$21.06[23]
	Medicare/ Commercial	CPT[22]	96127	Brief emotional/behavioral assessment with scoring and documentation, per standardized instrument. Up to 4 units can be billed per day	$6.94[23]
	Commercial	CPT[22]	96160	Administration of patient-focused health risk assessment instrument (e.g., health hazard appraisal) with scoring and documentation, per standardized instrument.	$ 5.62[23]
			96161	Administration of caregiver-focused health risk assessment instrument (e.g., depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument	$ 5.62[23]
Alcohol Assessments	Medicare	HCPCS[26, 28]	G0396	Alcohol and/or substance (other than tobacco) abuse structured screening and brief intervention services (SBIRT); 15 to 30 min	$37.51[23]
	Commercial	CPT[22, 29]	99408		$33.41[29]
	Medicare	HCPCS[26, 30]	G0442	Annual alcohol misuse screening in adults, 15 min. Preventive service: no coinsurance, no deductible for patient.	$21.04[23]
			G0443	Brief face-to-face behavioral counseling interventions for individuals who screen positive for alcohol misuse 15 min. No coinsurance, no deductible, no co-pay	$29.09[23]
Collaborative Care Model Codes	Medicare	HCPCS[26, 31]	G0502	Initial psychiatric care management, 70 min.	$162.80[23]
			G0503	Subsequent psychiatric care management, 60 min	$143.84[23]
			G0504	Initial/subsequent psychiatric care management, additional 30 min	$75.07[23]
			G0507	Care management for behavioral health conditions services, minimum 20 min, directed by a physician.	$54.17[23]

Population Health Workflows for Mental Health

Leveraging Predictive and Cognitive Analytics



M3 Information Use Cases

The multi-condition mental health assessment, the M3 Checklist, can be used to identify and monitor mental health symptoms in many settings, as seen to the right. Alone or in the presence of comorbid medical conditions, mental health disorders often interfere with patients' adherence to treatment and impair their ability to function at home and work. Detection, treatment, and monitoring of patients' mental health conditions in many settings enhances function, improves outcomes, and decreases rehospitalizations.

Use Cases	Logic	How Often to Administer
Annual Physical	Annual review to see if there is a problem[27]	Once a Year unless there are signs during the year[32]
Monitoring those in therapy or receiving medication	Monitor progress to adjust treatment to improve outcomes[33]	43.6 million patients have dealt with a mental disorder in the past year. USPSTF suggests using clinical judgment in consideration of risk factors to determine if additional screening is warrented[34]
Readmission reduction efforts	Mental illness increases the chances of readmissions[35]	Depression and mental illness are responsible for up to 20% of rehospitalizations (at discharge)[35]
Behavioral Health / Employee Assistance	Minimize absenteeism and "presenteeism"[36, 32]	Every 6 to 12 months routinely[36, 32]
Specialty Settings	High rates of mental illness and physical illness comorbidity[7, 37]	• OB/GYN (Post Partum)[6, 34] • Endocrine (Diabetes, Hypothyroid-ism)[7, 37] • Cardiology (Myocardial Infarction)[7, 37] • Neurology (Stroke, TBI, Epilepsy)[7, 37] (Annually)

Sustainability of Mental Health Screening in Primary Care

One in five patients may harbor diagnosable mental illness.[2] Primary care is the first line of defense in identification of these disorders. The majority of mental health visits occur with primary care physicians, and these same professionals write the bulk of antidepressant and antianxiety prescriptions for mood and anxiety disorders.[1] The M3 Checklist, an evidence-based and validated multi-condition mental health screening tool, enables LabCorp to help physicians identify patients that can benefit from treatment.

This schedule uses practice information, annual prevalence rates of behavioral health disorders and current CPT codes to project costs and revenues for primary care practices implementing routine annual mental health and alcohol use disorder assessments. Two billing codes are used in this model:

- 96103 for the M3 Checklist, a computer based multi-condition mental health assessment
- G0442 for an annual preventive service alcohol screen

Patients whose scores are out of range for either assessment would receive follow-up care for three months. Progress is monitored through a monthly follow-up assessment for these three months. Adjustment to care is informed by changes to the M3 Checklist and AUDIT-C scores.

It is estimated that out of a practice of 1,500 patients, approximately 238 would be at risk for a mental health condition and would require further treatment. Implementing annual screens for a panel of patients with serial assessments of those patients with a mental health diagnoses would generate $34,650 in annual income.

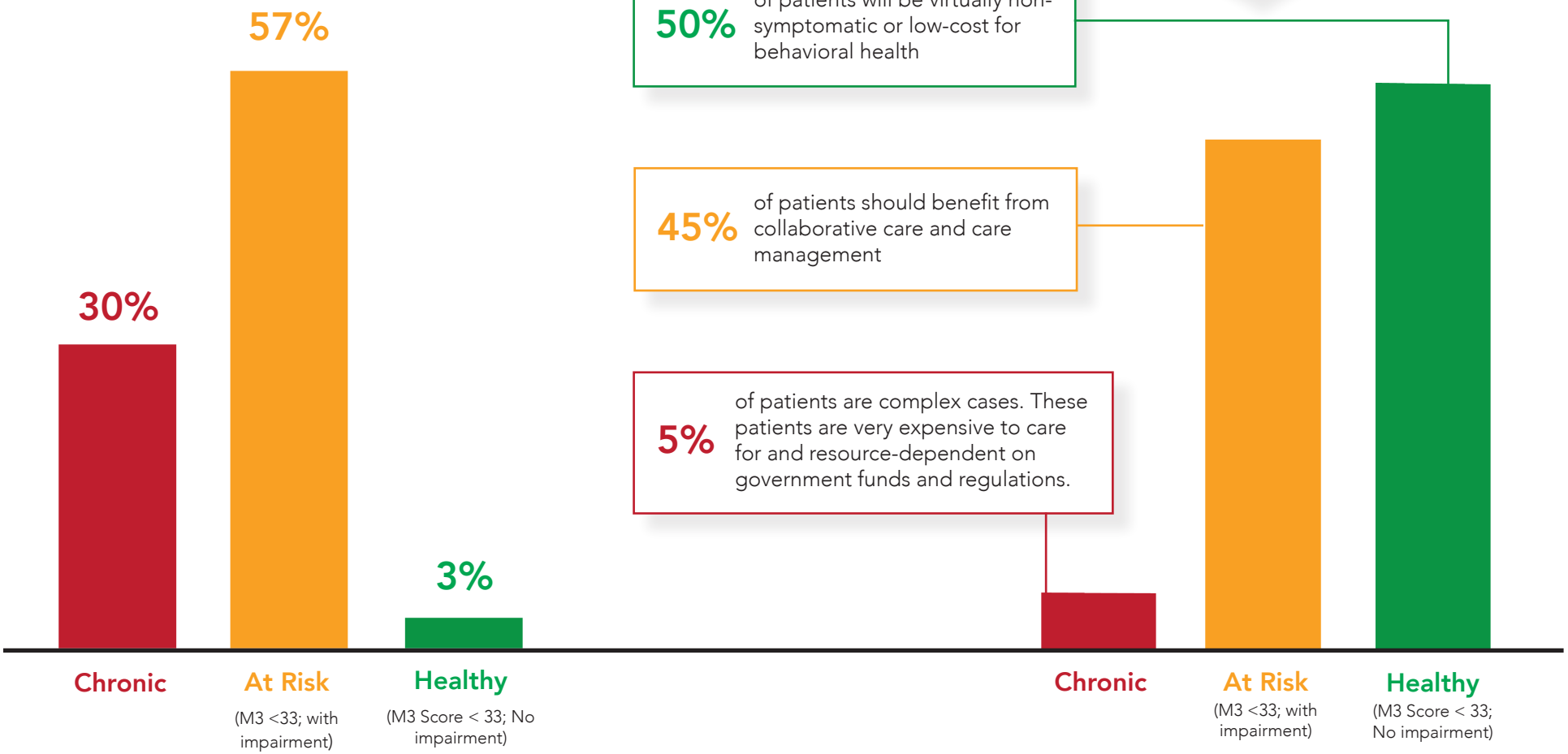
Model Elements	Assumptions Annually	Model
Number of Providers	1	1
Patients in Provider Panel	1,500	1,500
Patients Receiving MH Assessment	70%	1,050
Percent of Patients at Risk of MH condition[2]	16.7%	175
Percent of Patients at Risk for Alcohol Misuse[2]	6%	63
Percent of Patients with Both MI and AUD[2]	3.3%	8
Patients at Risk of BH Conditions	-	238
Number of Assessments for Identification	-	1,050
Reimbursement per review for 96103[3]	$30	$31,500
Reimbursement per review for GO442[3]	$21	$22,050
Total Reimbursement for MH and SUD Review)	$51	$53,550
Cost to Administer Assessments	$18	$18,900
Net Income from Assessment Effort	$33	$34,650

M3 Resource Allocation Map for Behavioral Health:

3 Paths to Direct Care-Management Teams

Target Population

These 45% of patients are responsible for 57% of total costs to the mental healthcare system. They benefit quickly from brief managed care interventions.



Frequently Asked Questions

1. What are Mood and Anxiety Disorders?

A mood disorder[38] is any of several psychological disorders characterized by the elevation or lowering of a person's mood, such as depression and bipolar disorder. There are various anxiety disorders[38], such as panic disorder, obsessive-compulsive disorder, a phobia, or generalized anxiety disorder. These disorders are characterized by excessive or unrealistic anxiety about two or more aspects of life. Changes related to mood or anxiety disorders are typically distressing to the individual and their family and often impair work and school performance.

2. How Many Americans Suffer from Mood and Anxiety Disorders?

According to the most recent national survey by the federal Substance Abuse and Mental Health Services Administration (SAMHSA), 1 in 5 US adults suffer with a mental condition.[2] Annually, anxiety disorders affect 18 percent of adults and depression impacts nearly 10 percent.[3] 20 percent of patients diagnosed with depression are in fact suffering from bipolar disorder.[5] Unfortunately, less than 50 percent of patients receive any help for these mental health conditions.[4]

3. What is the M3 Checklist?

The M3 Checklist is a 27-question, web-based, patient-rated checklist for symptoms of depression, anxiety, bipolar disorder, suicidality, and substance misuse that takes 5 minutes or less to complete. Responses to the Checklist are quantified and calculated into an individual's risk of suffering from a mental health condition. Reports are sent directly to the electronic health record in the typical LabCorp report format, which highlights out-of-range responses. The information provided by the M3 Checklist report facilitates doctor-patient discussion of relevant mental health issues during their office visit. The Checklist directs the clinician toward a diagnosis and helps patients be aware of their mental health needs.

4. What is the AUDIT-C?

The Alcohol Use Disorders Identification Test—Consumption (AUDIT-C)[14] is a brief, 3-question, validated screen for risky drinking and alcohol misuse and dependence.

5. Who can Benefit from Taking the M3 Checklist?

Anyone 18 years or older may complete the M3 Checklist, and the results can help that person identify and track any symptoms it may reveal. Clinicians and health care practices can benefit from the M3 Checklist by gaining access to a more comprehensive understanding of each patient's clinical presentation. This is especially valuable for primary care practices, because undiagnosed or under-treated mood, anxiety, and alcohol use disorders can delay or block responses to medical therapies and often result in worse outcomes for comorbid chronic medical conditions, the costs of which double with comorbid behavioral health conditions (and 80 percent of those excess costs are on the medical side).[37] Within the tight time constraints of a typical office visit, the Checklist provides an algorithm for up-to-date, evidence-based treatment of mood and anxiety disorders that might otherwise go untreated.

6. How Does the M3 Checklist Help Ensure Appropriate Mental Health Care?

The M3 Checklist is not designed to diagnose mental illness on its own. Rather, it is meant to elicit a symptom profile that may indicate a psychiatric illness. Physicians must use the symptoms checklist responses and risk assessment provided as a basis for formulating a diagnosis and treatment.

7. How Often Will Patients Complete the M3?

After patients complete the initial screen and have begun appropriate treatment and/or therapy, they should be screened monthly to monitor changes in the Checklist total score and sub-scores. Subsequent assessments may

be ordered as part of routine check-ups or to inform ongoing treatment decisions.[33,34]

8. How Was the M3 Checklist Validated?

A research group from the University of North Carolina headed by Dr. Bradley Gaynes conducted a study of 650 patients at the UNC Family Practice Clinic.[1] This study confirmed the validity of the M3 Checklist as a diagnostic tool utilizing the Mini International Neuropsychiatric Interview as a standard.

9. Who Created M3?

The M3 Checklist was created in 2003 by Robert Post, MD, head of the Bipolar Collaborative Network and a psychiatrist with the National Institute for Mental Health for 30 years; Bernard Snyder, MD, Assistant Clinical Professor of Psychiatry (retired) at Georgetown University; Michael Byer, President and co-founder of M3 Information; and Gerald Hurowitz, MD, Assistant Clinical Professor of Psychiatry at Columbia University and Chief Medical Officer of M3 Information.

10. Do Other Tools Like the M3 Already Exist?

Several other tests provide some functions present in the Checklist. However, the M3 Checklist is unique in eliciting patient-reported symptoms dealing with depression, anxiety disorders, PTSD, bipolar disorder, suicidality, and substance misuse in one web-based checklist and in integrating the results into a primary practice's workflow and electronic health record. M3 Checklist's exclusive availability through LabCorp's test catalogue also means it is more accessible and more easily reimbursable than other tools.

11. How are the M3 Checklist and AUDIT-C Ordered?

The M3 Checklist and AUDIT-C are found in the LabCorp test catalogue at www.labcorp.com/test-menu/search.

12. What are the Advantages of the Collaboration of M3 Information & LabCorp?

The collaboration between M3 Information and LabCorp brings advantages to patients and clinicians alike. Together, M3 and LabCorp are able to offer a multi-condition assessment tool that is easily accessible to clinicians and patients, seamlessly integrated into EHRs, and reimbursable under billing codes recognized by Medicare and most commercial insurance plans. Availability of assessment under this arrangement furthers the integration of mental health with general health care by providing effective and efficient mental health screening through LabCorp's extensive network of clinical settings. Individuals will receive better care and clinicians will see improved outcomes over a broad range of conditions – from stroke, diabetes, and cancer to targeted mental health conditions including depression, bipolar disorder, anxiety disorders, post-traumatic stress disorder, and alcohol misuse disorder. The aggregated information stemming from the assessments will help improve population health approaches, as well. Through LabCorp's extensive network and high standard of care and M3 Checklist's emphasis on symptom identification and treatment adherence, this collaboration has the potential to produce a quantum leap in the quality of mental health treatment, which could lead to better patient outcomes, increased efficiency for practices, and significant savings for the healthcare system at large.

13. How do you implement the M3 Checklist through LabCorp?

Two steps need to be completed by the practice, LabCorp and M3 Information. First, M3 will establish the practice as a "client bill," and the secondly the order needs to be in a "stand-alone" order. When orders are placed through electronic health records (EHRs), the EHR will need to collect the order date and time and the patient's (or clinic's) email address. The email information is collected through an "Ask at Order Entry" prompt. The LabCorp support team will work with practices to complete these two data elements, identifying which fields to place in the order message.

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Appendix A

Feasibility and Diagnostic Validity of the M-3 Checklist: A Brief, Self-Rated Screen for Depressive, Bipolar, Anxiety, and Post- Traumatic Stress Disorders in Primary Care[1]

Abstract

PURPOSE Mood and anxiety disorders are the most common psychiatric conditions seen in primary care, yet they remain underdetected and undertreated. Screening tools can improve detection, but available instruments are limited by the number of disorders assessed. We wanted to assess the feasibility and diagnostic validity of the My Mood Monitor (M-3) checklist, a new, 1-page, patient-rated, 27-item tool developed to screen for multiple psychiatric disorders in primary care.

METHODS We enrolled a sample of 647 consecutive participants aged 18 years and older who were seeking primary care at an academic family medicine clinic between July 2007 and February 2008. We used a 2-step scoring procedure to make screening more efficient. The main outcomes measured were the sensitivity and specificity of the M-3 for major depression, bipolar disorder, any anxiety disorder, and post-traumatic stress disorder (PTSD), a specific type of anxiety disorder. Using a split sample technique, analysis proceeded from determination of optimal screening thresholds to assessment of the psychometric properties of the self-report instrument using the determined thresholds. We used the Mini International Neuropsychiatric Interview as the diagnostic standard. Feasibility was assessed with patient and physician exit questionnaires.

RESULTS The depression module had a sensitivity of 0.84 and a specificity of 0.80. The bipolar module had a sensitivity of 0.88, and a specificity of 0.70. The anxiety module had a sensitivity of 0.82 and a specificity of 0.78, and the PTSD module had a sensitivity of 0.88 and a specificity of 0.76. As a screen for any psychiatric disorder, sensitivity was 0.83 and specificity was 0.76. Patients took less than 5 minutes to complete the M-3 in the waiting room, and less than 1% reported not having time to complete it. Eighty-three percent of clinicians reviewed the checklist in 30 or fewer seconds, and 80% thought it was helpful in reviewing patients' emotional health.

CONCLUSION The M-3 demonstrates utility as a valid, efficient, and feasible tool for screening multiple common psychiatric illnesses, including bipolar disorder and PTSD, in primary care. Its diagnostic accuracy equals that of currently used single-disorder screens and has the additional benefit of being combined into a 1-page tool. The M-3 potentially can reduce missed psychiatric diagnoses and facilitate proper treatment of identified cases.

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