Get With the Guidelines Stroke®

Mechanical Endovascular Reperfusion Therapy

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American Heart Association | American Stroke Association. life is why™

GET WITH THE GUIDELINES. STROKE

Heart.org/Quality

Speaker

Lee H. Schwamm, MD

Executive Vice Chairman and Director of Stroke/TeleStroke Services, Department of Neurology and Director of TeleHealth, Massachusetts General Hospital
Professor of Neurology, Harvard Medical School

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Disclosures

- Clinical trials consultant to Medtronic (Steering Committee VICTORY AF, REACT AF; Co-PI Stroke AF)
- DSMB member for Novo-Nordisk DeVOTE trial, Penumbra Separator 3D trial
- Chair, Stroke Clinical Workgroup AHA GWTG-Stroke

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Overview and Objectives

- Review AHA/ASA recommendations for endovascular interventions in the management of acute ischemic stroke
- Review the new Mechanical Endovascular Reperfusion measure set developed by the American Heart Association
- Review updates to the Get With the Guidelines-Stroke Patient Management Tool®

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Optimal Initial Treatment for Ischemic Stroke

Patients eligible for IV tPA should receive IV tPA even if endovascular treatments are being considered - Class 1; Level of Evidence A

Recommendation unchanged from 2013 Guideline.

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Additional Treatment (666)

Clinical trials show some patients will benefit from additional treatment if proximal (large) artery occlusion is present, symptoms are severe (NIHSS≥6), imaging looks favorable (ASPECTS≥6) and time to treatment is ≤6 hr of last known well

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Randomized Clinical Trials Of Endovascular Stroke Treatment

Primarily IA Fibrinolysis and/or First Generation Mechanical Embolectomy Devices	Trials with Primarily Stent Retrievers
SYNTHESIS Expansion	MR CLEAN
IMS III	SWIFT-PRIME
MR RESCUE	ESCAPE
	EXTEND-IA
	REVASCAT

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Comparison of the 3 predominantly non-stent retriever trials

	SYNTHESES EXPANSION	IMS111	MR RESCUE
Treatment groups	IA/Any device/both vs IV tpa	0.6mg/kg IV+IA tpa / any or both	Standard IV tpa + MERCI or PENUMBRA
Territory	Any	Any	Anterior circulation
Age	18-80	18-82	18-85
IV tpa	Required	Required < 3 hours	Not required
Time to IAT (hrs)	6	5	8 stop by 9
Severity (NIHSS)	≤ 25	≥ 10 or 8-9 with occlusion	6-29
ASPECTS	No	< 4	No
Vascular imaging	No	No	CTA/MRA occlusion
Other imaging	No	> 1/3 MCA infarction excluded	Multimodal/CT/MRI for stratification
Stent retrievers used	14%	IA 41%, IA + device 59%, stent retrievers 1.5.%	MERCI/PENUMBRA

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Summary of 5 MER Trials

Table. Summary of Data From the 5 Trials

Trial N IAT+/CTL	NIHSS Range CTL	 IAT+	r-tPA	TICI 2B/3	LSN to Groin Mdn	mRS 0–2 at 90 d CTL	 IAT+	sICH CTL	 IAT+	Device Complications	Mortality CTL	 IAT+
MR CLEAN[12] 500 233/267	18 (14–21)	17 (14–22)	90%	59%	260	19%	33%	6.4%	7.7%	Embol. 13	22%	21%
ESCAPE[13] 315 165/150	17 (12–20)	16 (13–20)	76%	72%	200	29%	53%	2.7%	3.6%	Perfor.1	19%	10%
EXTEND IA[14] 70 35/35	13 (9–19)	17 (13–20)	100%	86%	210	40%	71%	6%	0%	Perfor.1 Embol.2	20%	9%
SWIFT PRIME[15] 196 98/98	17 (13–19)	17 (13–20)	98%	88%	224	36%	60%	3%	0%	SAH 4	12%	9%
REVASCAT[16] 206 103/103	17 (12–19)	17 (14–20)	73%	66%	269	28%	44%	1.9%	1.9%	Perfor. 5 Embol. 5	16%	18%

"Stroke Neurologist's Perspective on the New Endovascular Trials. - NCBI." 5 May. 2015, https://www.ncbi.nlm.nih.gov/pubmed/25944328.

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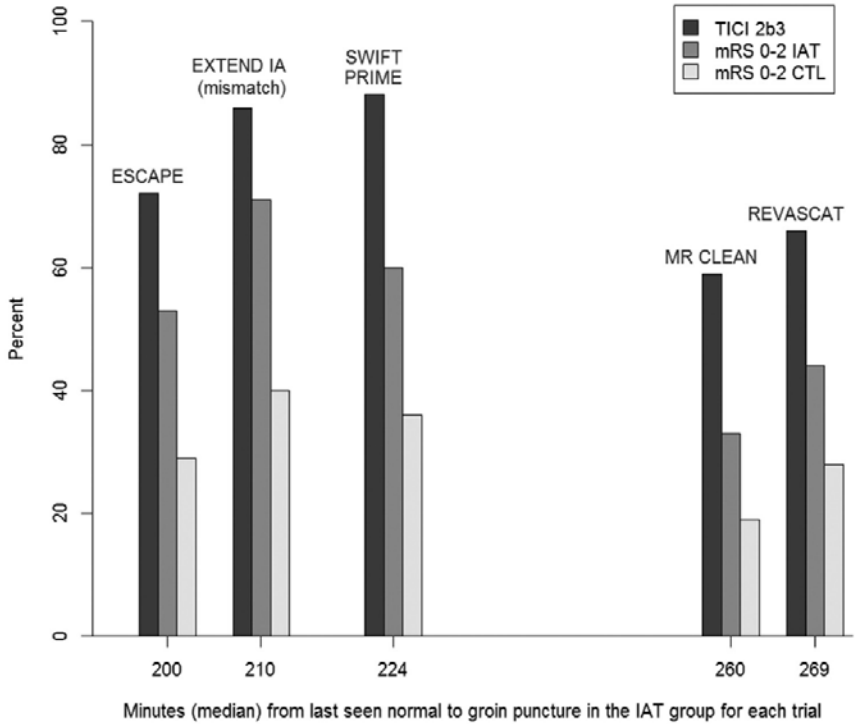
Median Minutes from LKW to Groin Puncture



"Stroke Neurologist's Perspective on the New Endovascular Trials. - NCBI." 5 May. 2015, https://www.ncbi.nlm.nih.gov/pubmed/25944328.

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Conclusions from Trials

- Five published studies have shown consistent and persuasive benefits for IAT using advanced technology in patients with stroke because of intracranial large artery occlusion.
- Stroke teams, including practicing neurologists caring for patients with stroke, should now provide the option for IAT for the subset of patients with acute ischemic stroke with persistent distal ICA or M1 occlusions who can be treated within 6 hours.
- Further research to enhance these gains is needed.
- Further work is ongoing to develop prehospital triage routing algorithms for patients with LVO and determining if additional PMT Elements.

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Endovascular Recommendations – Eligibility

Recommendation	Class and Level of Evidence
Patients eligible for IV tPA should receive IV tPA even if endovascular treatments are being considered.	Class I; Level of Evidence B-R (***recommendation unchanged from 2013 Guideline***)
Patients should receive endovascular therapy with a stent retriever if they meet all the following criteria: • Pre-stroke modified Rankin Score (MRS 0-1) • IV tPA within 4.5 hrs of LKW • Causative occlusion of the ICA or MCA • Age 18 years and over • NIHSS score ≥ 6 • ASPECTS ≥ 6 • Treatment can be initiated w/in 6 hours of sx onset	Class I; Level of Evidence A (***New Recommendation***)

Stroke. 2015;46:3020–3035

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Endovascular Recommendation – Timing

Recommendation	Class and Level of Evidence
Reduced time from symptom onset to reperfusion with endovascular therapies is highly associated with better clinical outcomes. To ensure benefit, reperfusion to TICI grade 2b/3 should be achieved as early as possible and within 6 hours of stroke onset	Class I; Level of Evidence A (***Revised from 2013 Guideline***)
Observing patients following IV tPA to assess for clinical response before pursuing endovascular therapy is not required to achieve beneficial outcome and is not recommended.	Class III; Level of Evidence B-R (***New Recommendation***)

Stroke. 2015;46:3020–3035

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Endovascular Recommendation – Imaging

Recommendation	Class and Level of Evidence
Emergency imaging of the brain is recommended before initiating any specific treatment for acute stroke. In most instances, non-enhanced CT will provide the necessary information to make decisions about emergency management.	Class I; Level of Evidence B-R (***New Recommendation***)
If endovascular therapy is contemplated, a noninvasive intracranial vascular study is strongly recommended.	Class I; Level of Evidence A (***New Recommendation***)

Stroke. 2015;46:3020–3035

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Patient Management Tool Updates

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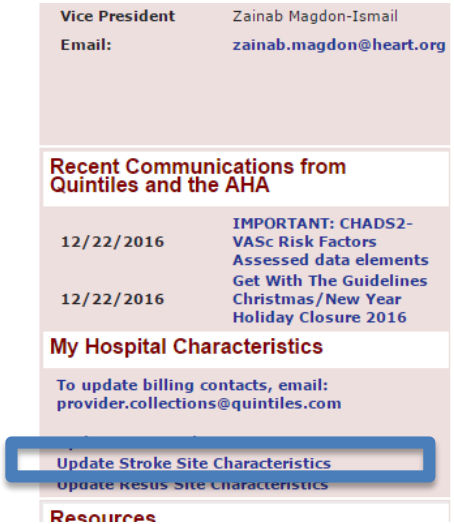
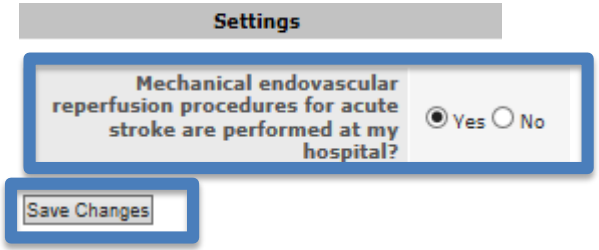
New data elements that support the MER measure set will be added to the PMT for hospitals performing mechanical endovascular reperfusion therapy procedures.

*MER is an optional form group, but **we encourage all sites who are performing endovascular procedures to activate it,** so you can begin to track and benchmark care in this population.*



To add these elements to your tool:

1. Visit the community page
2. Select “Update Stroke Site Characteristics”
3. Select “Yes” to Mechanical endovascular procedures under settings.



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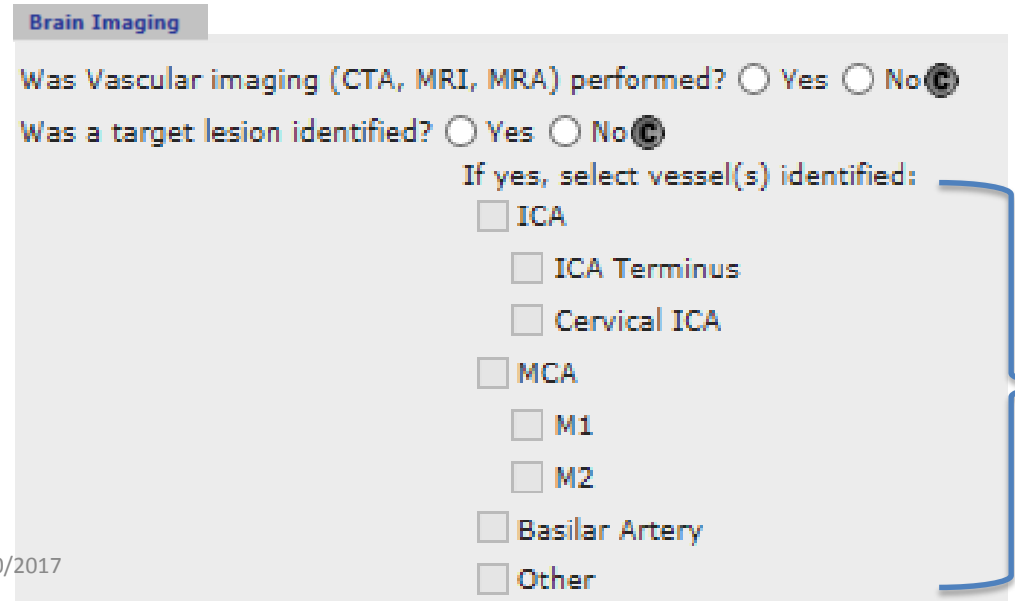
Hospitalization Tab

NEW MER Elements added to Brain Imaging section of the Hospitalization tab to determine:

- Whether advanced imaging was performed
- Location of Target Lesion if identified (eligible for endovascular therapy).



Elements only visible for sites who activate the MER form group.

Multi-select to capture detailed and varied locations when documented/available.

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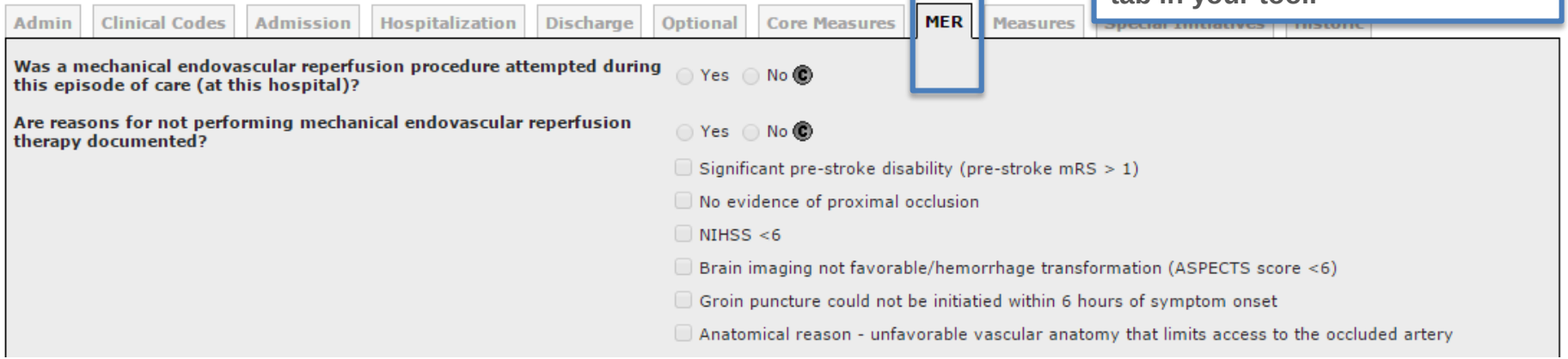
MER Tab

Once turned on, the MER tab will appear in before the “Measures” tab in your tool.



- If you are using the Comprehensive Stroke version of the PMT®, overlapping MER elements will auto-populate based responses in the Hospitalization tab. You still need to visit the MER tab to complete remaining variables.
- If you are NOT using the Comprehensive version, you will complete all variables on the MER tab.
- In future versions we are looking to harmonize MER and Comprehensive version so they can appear once in the tool.

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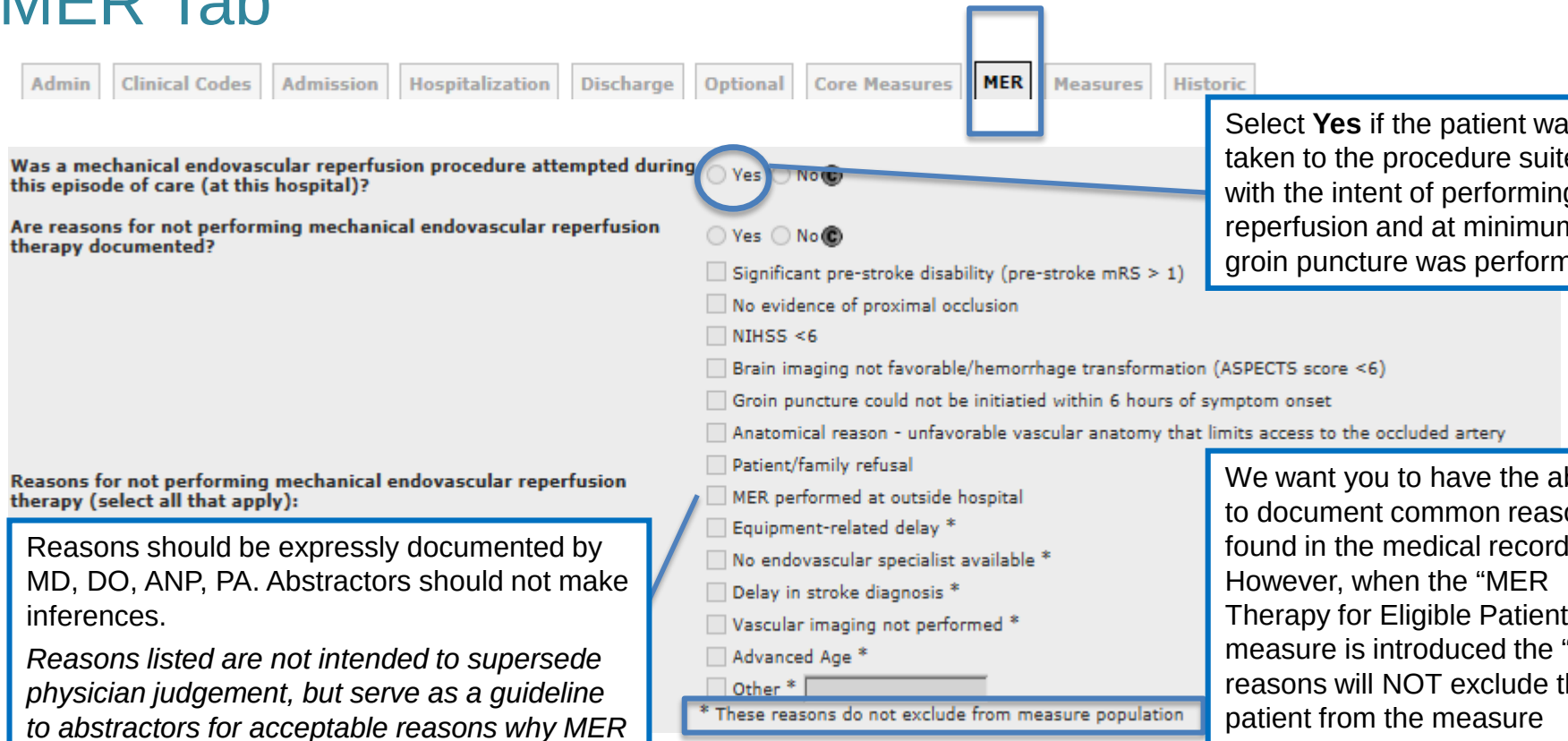
MER Tab



Select **Yes** if the patient was taken to the procedure suite with the intent of performing a reperfusion and at minimum a groin puncture was performed.

Reasons should be expressly documented by MD, DO, ANP, PA. Abstractors should not make inferences.

Reasons listed are not intended to supersede physician judgement, but serve as a guideline to abstractors for acceptable reasons why MER was not initiated.

We want you to have the ability to document common reasons found in the medical record. However, when the “MER Therapy for Eligible Patients” measure is introduced the “*” reasons will NOT exclude the patient from the measure population.

Coding Instructions

REQUIRED: Was a mechanical endovascular reperfusion procedure attempted during this episode of care (at this hospital)?

- Mechanical endovascular reperfusion procedures include the use of retrievable stent and other clot retriever devices, clot suction and intracranial angioplasty.
- Select **Yes** if the patient was taken to the procedure suite with the intent of performing a reperfusion and at minimum a groin puncture was performed.
- **Notes for abstraction:**

  Examples of a mechanical endovascular devices include, but not limited to:

  – Solitaire
  – Trevo
  – Merci Retrieval System
  – Penumbra Stroke System
  – A Direct Aspiration First Pass Technique (ADAPT)

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Coding Instructions

REQUIRED: Are reasons for not performing mechanical endovascular reperfusion therapy documented?

- Yes: There is a documented reason for not initiating mechanical endovascular reperfusion during this episode of care.
- No: There are no specific reasons documented in the medical record why mechanical endovascular reperfusion therapy was not initiated during this episode of care.
- This can be documented by a physician/ANP/PA. Abstractors should not make inferences as to the reasons.
- Source for abstraction: operative notes and radiology reports.

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Coding Instructions

REQUIRED: Reasons for not performing mechanical endovascular reperfusion therapy (select all that apply):

- Select the specific reason(s) documented in the medical record. The following reasons are not intended to supersede physician judgement, but serve as a guideline to abstractors for acceptable reasons why MER was not initiated. As always, the physician must exercise due caution in providing treatment, given the risks and benefits to the individual patient and the available information at the time of treatment decision.

  - Significant pre-stroke disability (pre-stroke mRS > 1)
  - No evidence of proximal occlusion
  - NIHSS <6
  - Brain imaging not favorable/hemorrhage transformation (ASPECTS score < 6)
  - Groin puncture could not be initiated within 6 hours of symptom onset
  - Anatomical reason- unfavorable vascular anatomy that limits access to the occluded artery
  - Patient/family refusal
  - MER performed at outside hospital
  - Equipment-related delay *
  - No endovascular specialist available *
  - Delay in stroke diagnosis *
  - Vascular imaging not performed*
  - Advanced Age *
  - Other *

For guidance on the criteria for initiating mechanical endovascular procedures, 2015 American Heart Association/American Stroke Association Focused Update of the 2013 Guidelines for the Early Management of Patients with Acute Ischemic Stroke Regarding Endovascular Treatment, refer to https://goo.gl/i5tTCr

* These reason does not exclude from measure population

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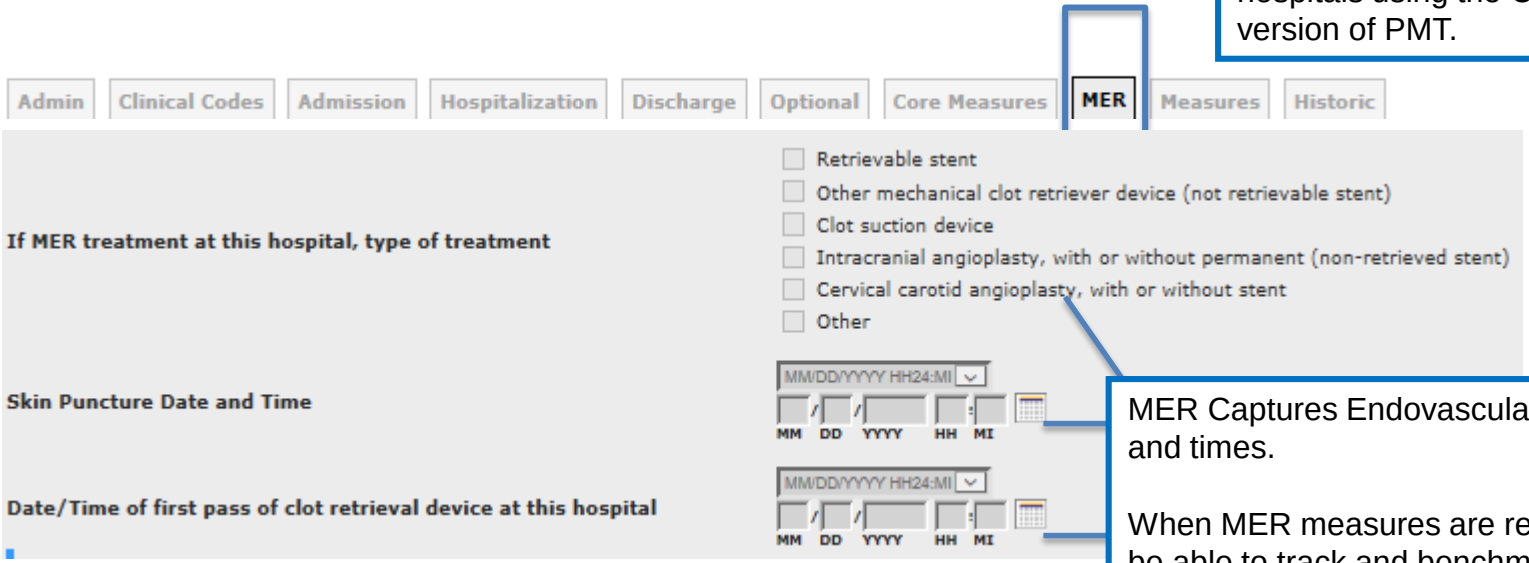
MER Tab

These elements will auto-populate from the Hospitalization Tab for hospitals using the Comprehensive version of PMT.



MER Captures Endovascular treatment type and times.

When MER measures are released, sites will be able to track and benchmark treatment times.

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Coding Instructions

REQUIRED: Skin puncture Date/Time

- This is the date and time when a needle was placed into an artery for a MER procedure. If the puncture time is not documented, select the **MM/DD/YYYY** format. If both the date and time are not documented, select **Unknown**.

REQUIRED: Date/Time of first pass of clot retrieval device at **this hospital**

- This is the date and time of the first pass of a clot retrieval device. If the first pass/deployment time is not documented, select the **MM/DD/YYYY** format. If both the date and time are not documented, select **Unknown**.
- If the timing of the first pass is uncertain, record the earliest time of definitive evidence of device deployment.

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MER Tab

Select ‘Yes’ if there is a documented cause for delay in initiating MER therapy greater than 120 minutes after hospital arrival.

Selections are in process of being updated

If there is a documented cause for delay, select all reasons that apply.

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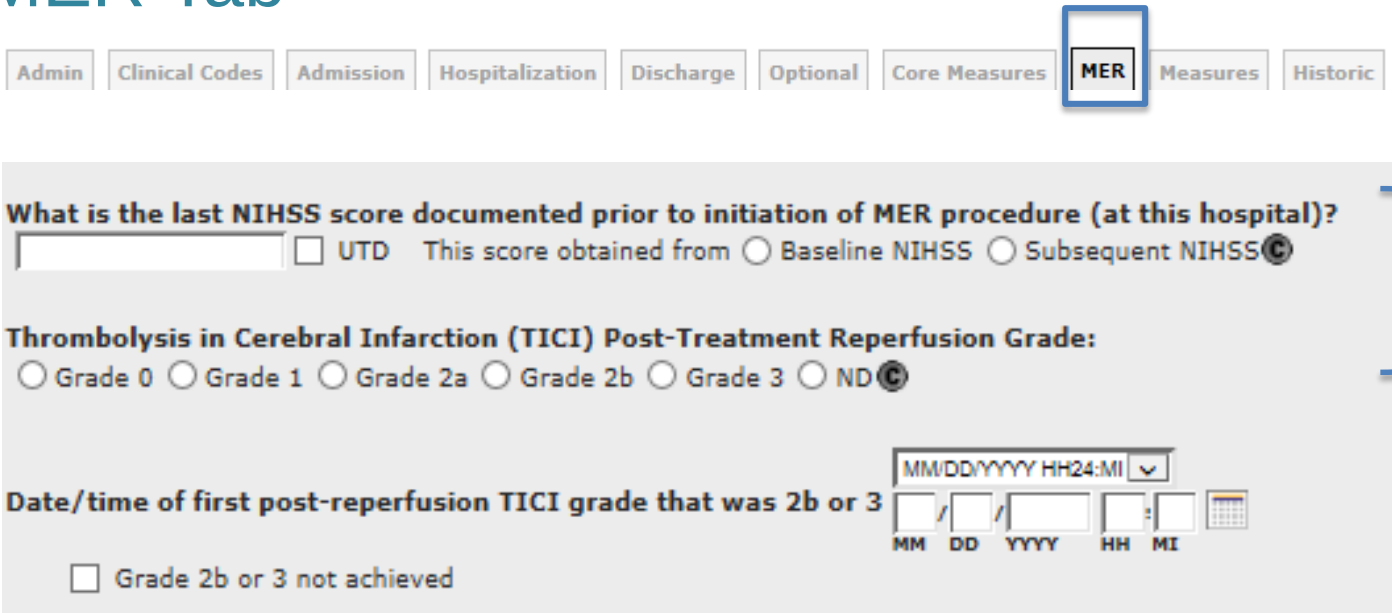
MER Tab



These elements will auto-populate from the Hospitalization Tab for hospitals using the Comprehensive version of PMT.

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Coding Instructions

REQUIRED: What is the last NIHSS score documented prior to initiation of MER procedure (at this hospital)?

- This is the documented NIHSS score performed closest to the time before MER was initiated at this hospital. Enter a value of 0-42. If more than one enter or if not done ever, select UTD (unable to determine) if score is not documented. Enter value done on presentation.
- If a score is entered, also select **Baseline NIHSS** if the score entered is the baseline obtained upon presentation. Select **Subsequent NIHSS** if the score was obtained following a baseline/initial score and prior to MER procedure.
- **Notes for Abstraction:**
  - If more than one NIHSS is performed prior to MER, enter the score obtained closet to the time of MER initiation time.
  - If no NIHSS is available from time of ED arrival to time of MER, select UTD.

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Coding Instructions

REQUIRED: Thrombolysis in Cerebral Infarction (TICI) Post-Treatment Reperfusion Grade:

Modified TICI grading system[1]

- Grade 0: No Perfusion. No antegrade flow beyond the point of occlusion.
- Grade 1: Penetration With Minimal Perfusion. The contrast material passes beyond the area of obstruction but fails to opacify the entire cerebral bed distal to the obstruction for the duration of the angiographic run.
- Grade 2a: Partial tissue reperfusion in < 50% of the occluded artery.
- Grade 2b: Partial reperfusion in ≥50% of the occluded artery territory.
- Grade 3: Essentially complete Perfusion. Antegrade flow into the bed distal to the obstruction occurs as promptly as into the obstruction *and* clearance of contrast material from the involved bed is as rapid as from an uninvolved other bed of the same vessel or the opposite cerebral artery.

[1]*Sang Hyun Suh, Harry J. Cloft, Jennifer E. Fugate, Alejandro A. Rabinstein, David S. Liebeskind and David F. Kallmes Stroke. 2013;44:1166-1168.*

- Notes for Abstraction:
  - If a TICI reperfusion grade was not done post treatment or cannot be determined from medical record documentation, select “ND.”
  - TICI grade must be documented by a Physician/APN/PA.

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Coding Instructions

REQUIRED: Date/time of first post-reperfusion TICI grade 2b or 3

- This is the date and time of the first TICI score obtained following reperfusion that was grade 2b or 3. If the time is not documented, select the MM/DD/YYYY format. If both the date and time are not documented, select Unknown.
- Select **Grade 2b or 3 not achieved** when applicable.

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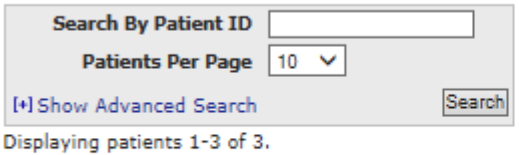
Stroke Post-Discharge Follow-up Form



90 day outcomes are captured in the Post Discharge Follow-up form.

This form provides valuable insight on outcomes post-hospitalization.

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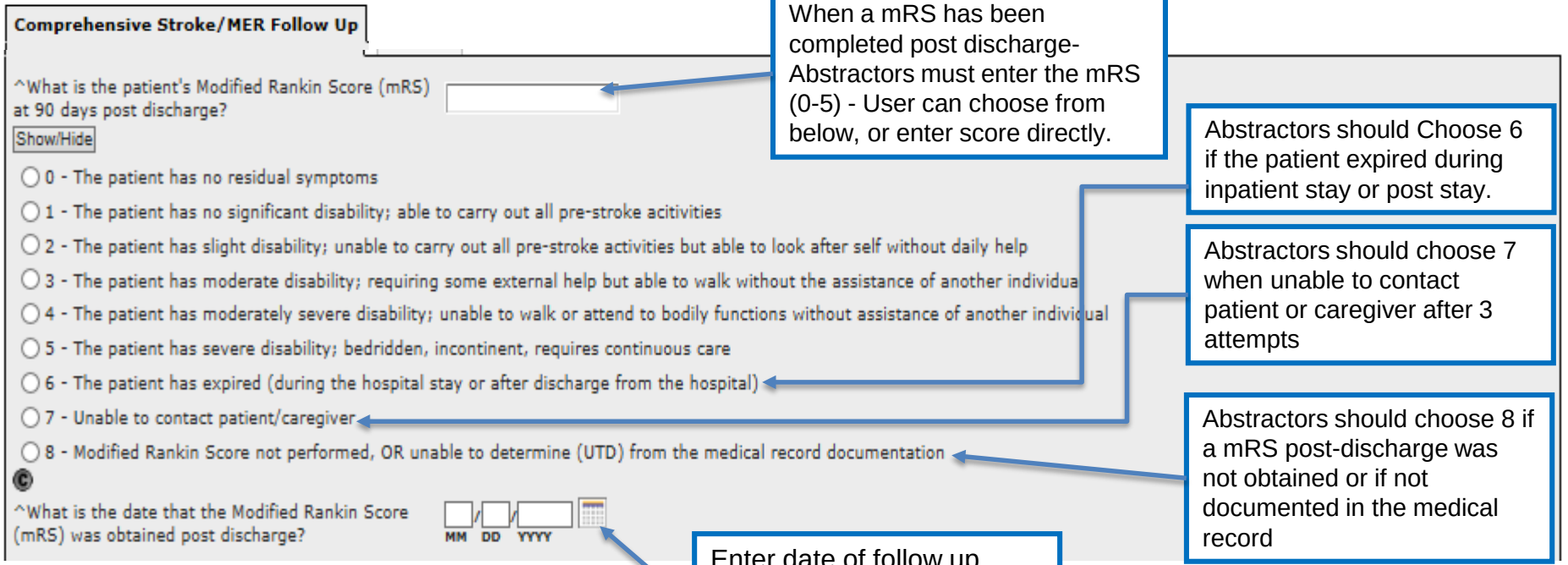
Stroke Post-Discharge Follow-up Form



When a mRS has been completed post discharge- Abstractors must enter the mRS (0-5) - User can choose from below, or enter score directly.

Abstractors should Choose 6 if the patient expired during inpatient stay or post stay.

Abstractors should choose 7 when unable to contact patient or caregiver after 3 attempts

Abstractors should choose 8 if a mRS post-discharge was not obtained or if not documented in the medical record

Enter date of follow up score here.- Required for Measure Inclusion.

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MER Measures

- MER Measures will be launched in Q2 2017
- They are available for all sites using the MER tab and will allow you to track valuable aspects of endovascular care

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MER Measures

Mechanical Endovascular Reperfusion Therapy for Eligible Patients with Ischemic Stroke
Door to Start of Revascularization (DTR) within 120 minutes
Door to Puncture (DTP) Time within 90 minutes
Picture to Puncture (PTP) Time within 60 minutes
Median Puncture to Start of Revascularization (PTR) Time
Median Puncture to Recanalization/Reperfusion (PTRp) Times

Door to Recanalization/Reperfusion (DTRp) within 120 Minutes
Rate of Substantial Reperfusion
Thrombolysis in Cerebral Infarction (TICI) Post-Treatment Reperfusion Grades for Successful Mechanical Endovascular Clot Retrieval procedures
90-Day Modified Rankin Scores (mRS) following Mechanical Endovascular Reperfusion Therapy
Discharge Disposition following Mechanical Endovascular Reperfusion Therapy

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Questions

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Thank you for your participation in Get With the Guidelines Stroke

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