PREHOSPITAL ACUTE STROKE TRIAGE TIME: A PRAGMATIC TRIAL

StrokeNet SC Call

November 8, 2017

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STATUS UPDATE

- Original presentation to ASWG 6/2017
- Reviewed at and returned by ESC 8/2017
- Re-submitted to and approved by ESC 10/2017
- Goal submission 2/2018

AHA/ASA Policy Statement

Interactions Within Stroke Systems of Care

A Policy Statement From the American Heart Association/American Stroke Association

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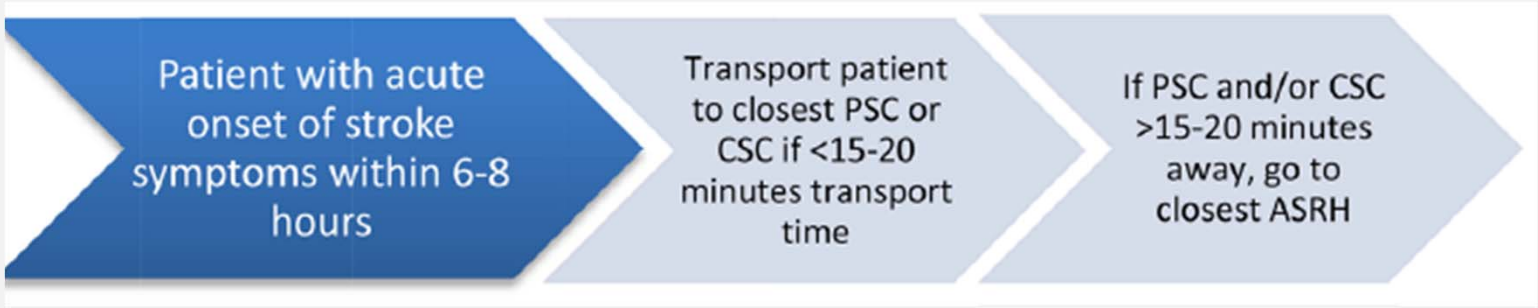
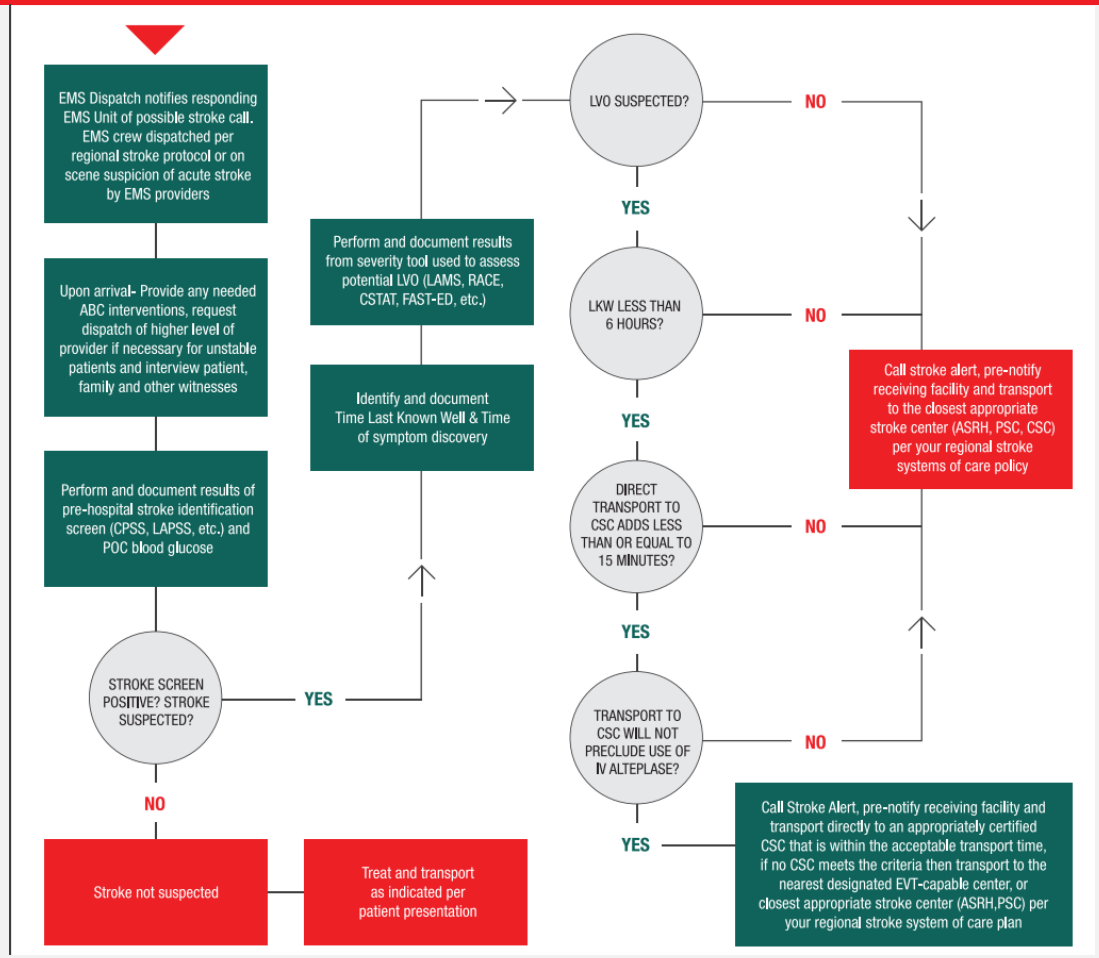
Lee Schwamm, MD, FAHA; Debbie Summers, RN, MSN, ACNS-BC, FAHA;
Lawrence Wechsler, MD, FAHA; Joseph P. Wood, MD, JD;
on behalf of the American Heart Association Advocacy Coordinating Committee



SEVERITY-BASED STROKE TRIAGE ALGORITHM FOR EMS

American Heart Association | American Stroke Association
life is why
Together to End Stroke
MISSION: LIFELINE



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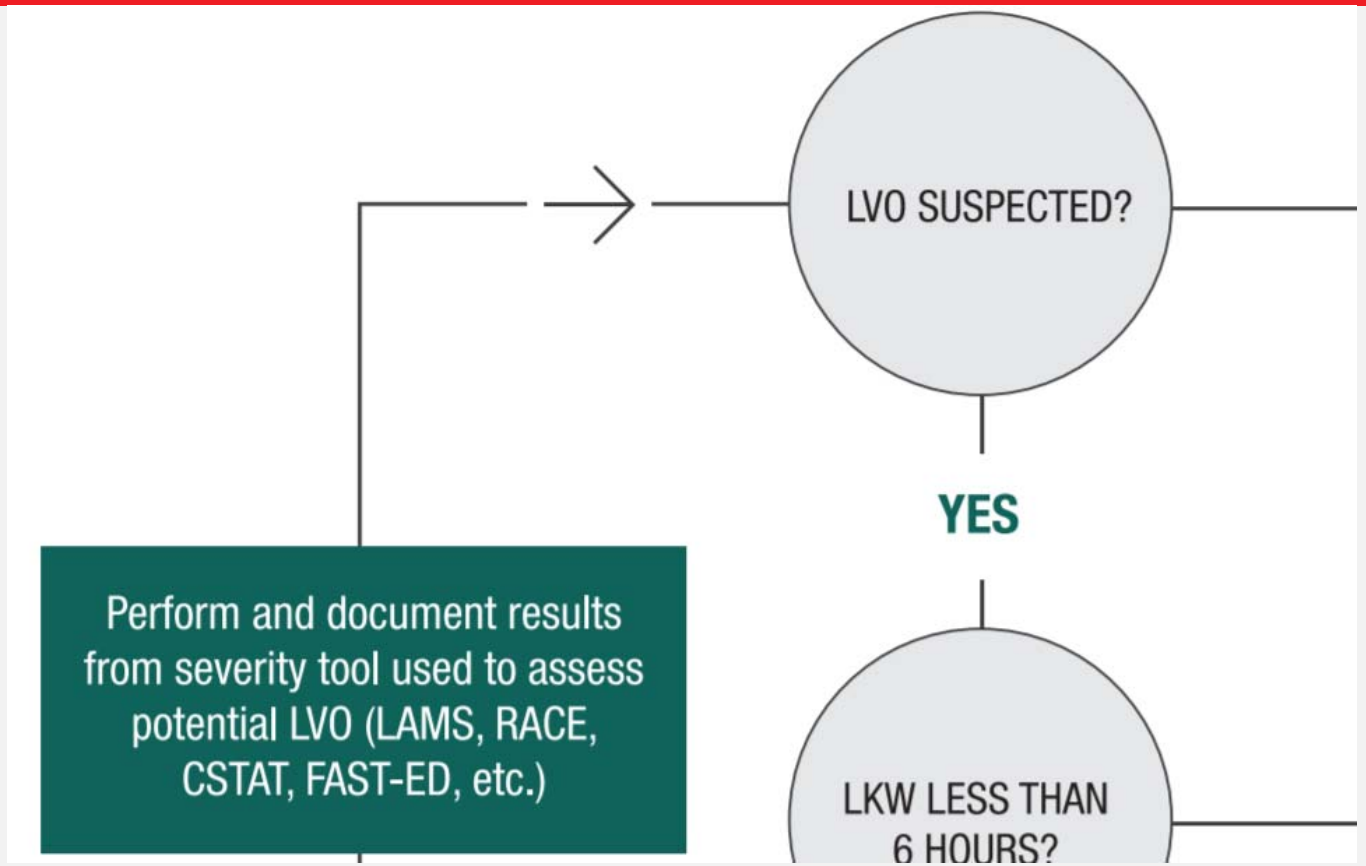


	LAMS	FAST-ED	RACE	C-STAT
Derivation n	119	727	654	624
Goal of scale	LVO	LVO	LVO	Severe Stoke LVO
Independently Validated	Yes (Abstract)	No	Yes	Yes
Validation n			357	650
Sensitivity/specificity (severe stroke)	N/A	N/A	N/A	NIHSS 15 89%/72%
Sensitivity/specificity (LVO)	81%/89%	60%/89%	85%/65%	83%/40%
Prehospital Evaluation	Yes	No	Yes	Yes

	Screen	FAST-ED	LAMS	RACE	CSTAT
Facial Droop	y/n	0-1	0-1	0-1-2	
Arm Drift	y/n	0-1-2	0-1-2	0-1-2	0-1
Speech	y/n	0-1-2		0-1-2	
Grip Strength	y/n		0-1-2		
Eye Deviation		0-1-2		0-1	0-2
Denial/Neglect		0-1-2		0-1-2	
Leg Strength				0-1-2	
Questions/Commands					0-1

PRIMARY AIM

Validate the performance of four AHA/ASA-endorsed prehospital stroke triage tools to identify ischemic stroke patients with LVO during initial EMS evaluation

SECONDARY AIMS

- Compare the performance of the tools to identify Comprehensive Stroke Center (CSC)-appropriate stroke patients during initial field evaluation by EMS providers
  - LVO ischemic stroke patients and intracranial hemorrhagic (ICH) stroke patients
- Determine if a novel combination of items from the tools can be identified with superior accuracy at predicting LVO ischemic stroke patients

RESOURCE AIM

Create a de-identified dataset of:

- prehospital tool diagnoses
- observed routing destinations and distances
- observed prehospital and in-hospital onset to treatment intervals
- imaging
- patient functional outcomes

Will enable further development of evidence-based practice and guidelines.

METHODS—TRIAL DESIGN

- Pragmatic
- Prospective
- Observational
- Multi-center

- Not more than minimal risk
- Waiver of consent

- EMS and regional hospital collaboration required

METHODS—SETTING

- Up to 10 StrokeNet Hubs
- EMS systems must already:
  - use of one of the four tested tools (C-STAT, FAST-ED, LAMS, RACE)
  - preferentially route select patients to CSCs and/or TSCs, rather than PSCs,

METHODS—SUBJECTS

- PAST-Time will specifically enroll adult subjects with prehospital suspicion for stroke, regardless of final diagnosis.
- Inclusion Criteria:
  - Age ≥18
  - EMS clinical suspicion for stroke
  - Presence of facial droop, arm drift, speech difficulty, or grip weakness on EMS assessment
- Clinical Exclusion Criteria:
  - Coma/complete unresponsiveness
  - Acute head trauma
  - Last known normal time exceeds EMS agency time threshold for direct CSC routing

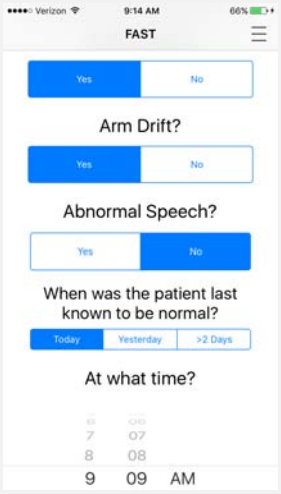
METHODS—INTERVENTION

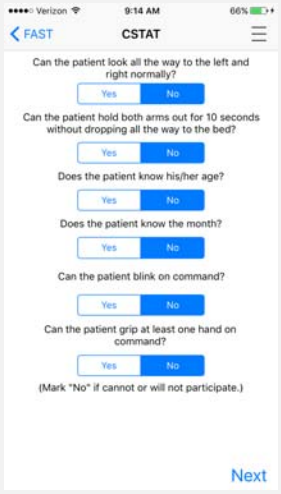
- EMS will perform physical exam findings needed to score all four triage tools
- A prehospital assessment program will systematically record those findings.
  - smartphone/tablet/web-accessible
- EMS agencies will follow current protocols to direct hospital destination and care.

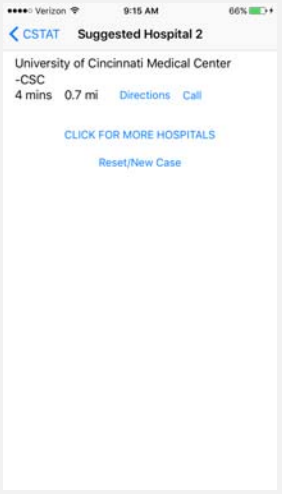
METHODS—THE PAP

- PAP will inform the EMS provider whether the score meets a threshold for escalated level triage as per local clinical policy.
  - Ex: Cincinnati Fire will see the C-STAT result for decision-making
- The PAP will also collect scored elements of the 3 other prehospital triage tools for later analysis.
  - Ex: Cincinnati Fire will not see LAMS, RACE, or FAST-ED results
- The PAP will notify the local study team of enrollment

SAMPLE PAP







1) EMS performs stroke screening scale and collects baseline inclusion criteria information
2) EMS performs components of ALL severity scales
3) Protocol Assist Program displays score used to triage; PAP notes closest appropriate destination

METHODS—OUTCOME ASSESSMENTS

- The primary outcomes (presence/absence of LVO) are imaging based.
- A central neuroimaging core will over-read clinically obtained studies to systematically categorize LVO and ICH.
- The resulting imaging repository will further strengthen the clinical de-identified database for future investigations.

METHODS—OUTCOME ASSESSMENTS

- Additional outcomes will be primarily accomplished through abstraction
  - Clinical EMS and hospital records
  - Quality registries (such as Get With the Guidelines—Stroke).
- Focused post-arrival data collected will include:
  - Final discharge diagnoses,
  - Types of treatments performed (ex: IV tPA, EVT, anticoagulation reversal, hematoma evacuation),
  - Occurrence of subsequent inter-facility transfer to higher level of acute care
  - Discharge destination (home, acute rehabilitation center, skilled nursing facility, death/hospice).
- Where available
  - mRS and ambulation status at discharge
  - mRS at 90 days

SAMPLE SIZE AND POWER

- N=3900
  - 12% LVO prevalence = 468 LVO
  - 80% power to detect 5% change in sensitivity (71% v 76%)
  - 80% power to detect 3% difference in specificity (70% v 73%)

WORK FLOW

Tasks	Staff	Enrollment	Day 2 (+/- 24hrs)	Day 10 or DC (+/-24 hrs.)	30 day (+/-7 days) phone contact	90 day (+/- 10 days) follow-up
Screen + 8 item EMS score	EMS N/C	SOC				
App entry & randomization	EMS N/C	SOC				
Obtain EMS records and review	SC		x			
Obtain Hosp DC MR & review	SC			x		
	MD			x		
Medical Record/Registry Review	SC					x
Data entry & corrections: 1 hour; 2 hours; .5 hour;. 5 hour	SC		x	x	x	x
Subject log maintenance	SC					x

LIMITATIONS

- Non-randomized approach
- Anticipated incomplete 90-day follow-up assessments