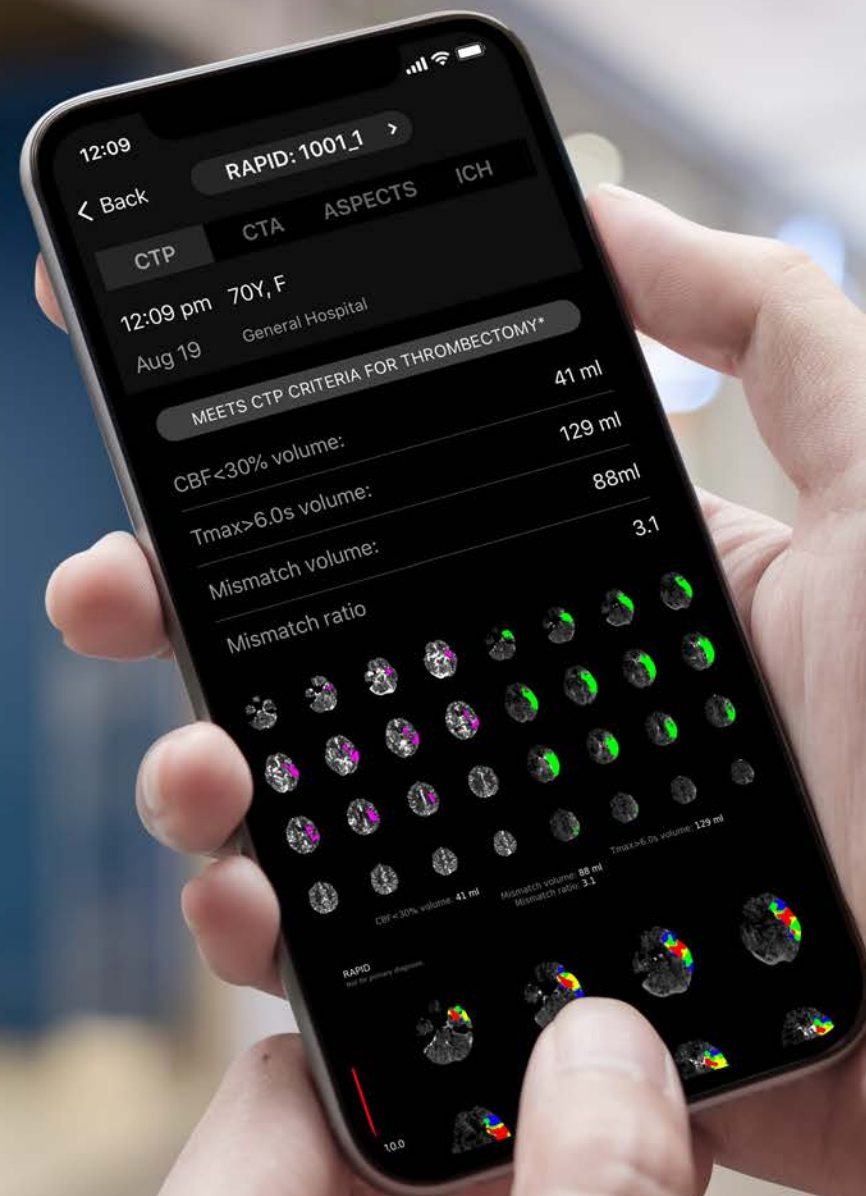


# Computer-Aided Assessment and Characterization Software for Head CT Scan

Prepared for: CMS ICD-10 Coordination  
and Maintenance Committee  
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**RAPID**AI



# Presenters:

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# Background

- Every year, approximately 800,000 strokes occur each year in the United States
- About 87% of these strokes are ischemic infarctions, about 10% are primary hemorrhages, and 3% are subarachnoid hemorrhage.
- Large vessel occlusions (LVOs), the most disabling strokes, account for approximately about 1/3 of acute ischemic strokes and treatment of these strokes has the largest therapeutic benefit
- Treatment with tPA and mechanical thrombectomy is highly effective but time sensitive
- A major predictor of outcomes is time to treatment. Treatment delays are associated with an increase in post-stroke disability.

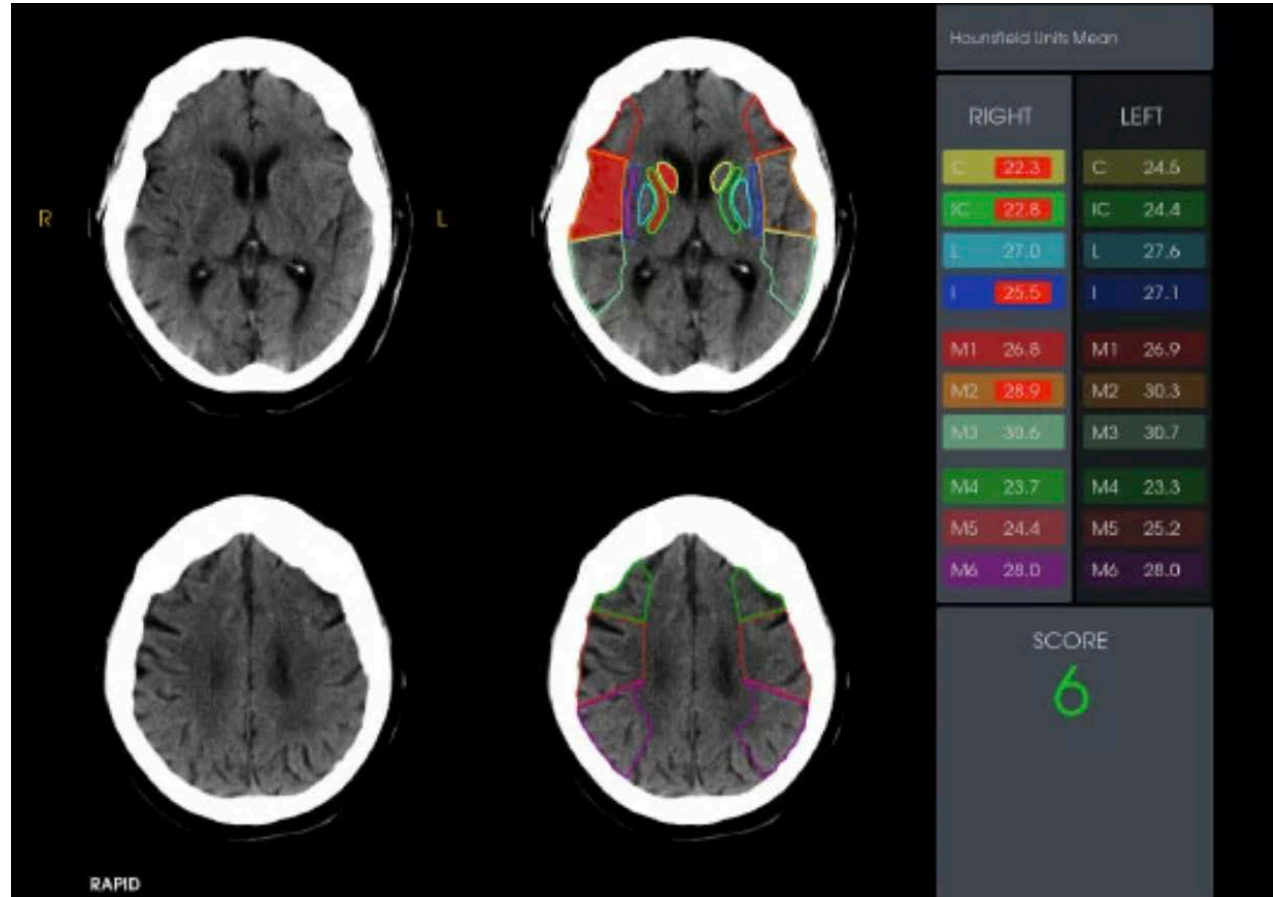
# ASPECTS

- The Alberta Stroke Program Early CT Score (ASPECTS) is a defined standard of care scale used to quantify brain tissue abnormalities that indicate of early irreversible stroke. The score ranges from 0 (worst) -10 (best) based on the extent of tissue involvement.
- Rapid ASPECTS is a computer-aided diagnosis (CADx) software device used to assist the clinician in determining the ASPECT score.
  - The Software automatically registers CT images and segments and analyzes ASPECTS Regions of Interest (ROIs).
  - Rapid ASPECTS extracts image data for the ROI(s) to provide analysis and computer analytics based on morphological characteristics.
  - The imaging features are then synthesized by an artificial intelligence algorithm into a single ASPECT Score.

# Rapid ASPECTS

ASPECTS is based on assessing pre-defined middle cerebral artery (MCA) vascular territories.

These individual regions are assessed for focal hypoattenuation

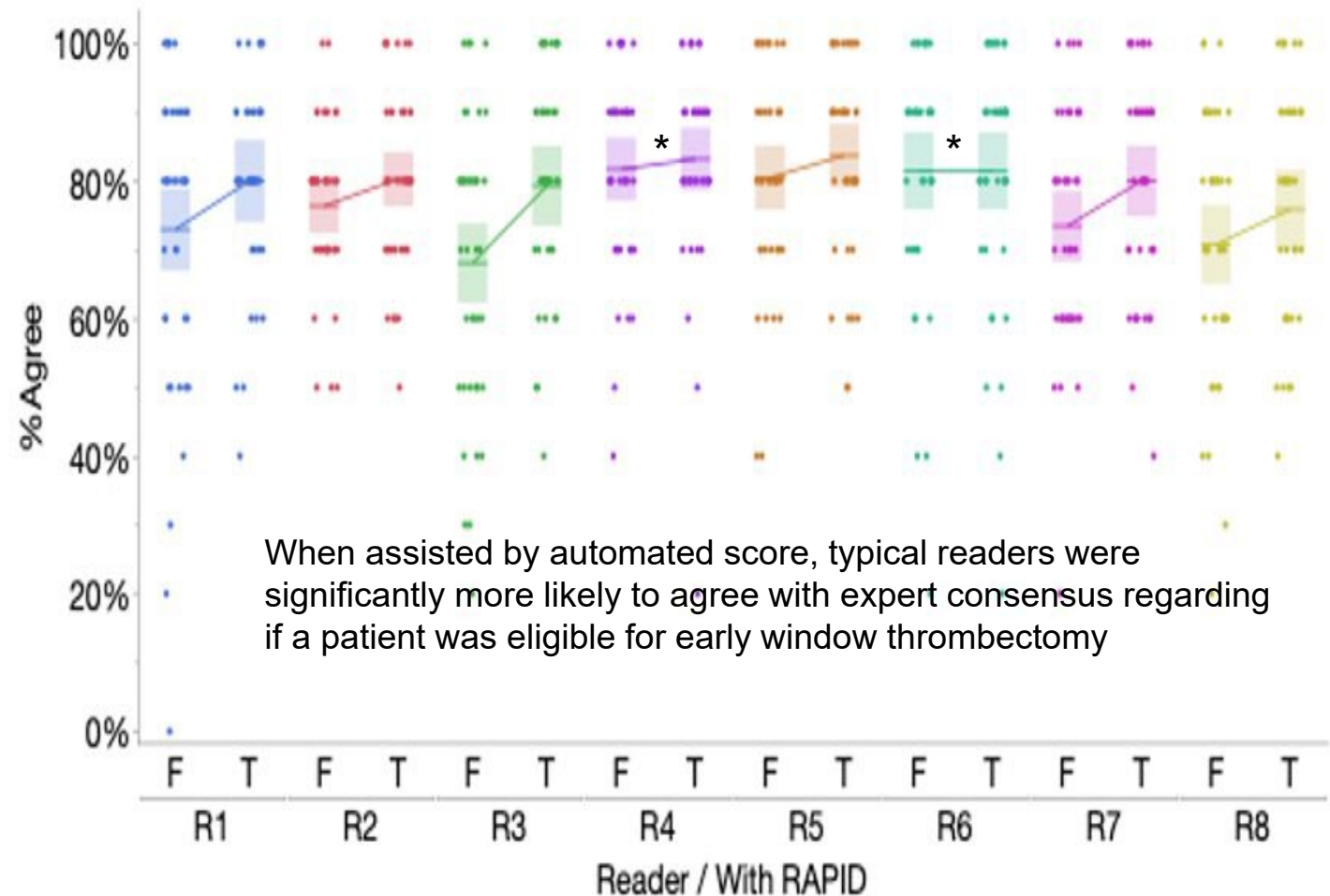


# Rapid ASPECTS Workflow

- The typical workflow for ASPECTS determination is:
  - Patient presents at the Emergency Department
  - If patient is symptomatic for stroke a CT and CTA are ordered
  - The CT scans are evaluated for hemorrhagic stroke and LVO
  - If LVO is identified, then ASPECT score is calculated using Rapid ASPECTS.
  - Results are available within two minutes and help determine if patient is a candidate for thrombectomy (score of 6 or more is required)

# Performance

- Rapid ASPECTS (FDA K200760) has been shown to standardize ASPECTS scoring among typical readers and to provide a more consistent and accurate score.
- Less experienced readers' scores were equivalent to expert neuroradiologists when assisted by Rapid ASPECTS



Typical readers including 2 expert neuroradiologists\*



# Documentation, Setting, and Indications

Rapid ASPECTS is documented in the radiology report, physician notes, Emergency Department (ED) Orders and/or ED notes

Rapid ASPECTS is typically only used in the inpatient setting once an LVO is determined to be likely.

Rapid ASPECTS is indicated for use for both internal carotid artery occlusion and middle cerebral artery occlusion strokes



# Processing / Adverse Events

- Rapid ASPECTS processing occurs based on a CT scan DICOM file typically during the time when a CTA is performed and is immediately available following completion of the NCCT/CTA scan.
- There have been no associated complications/sequela/adverse events with Rapid ASPECTS.

# Summary

- There are currently no unique ICD-10-PCS codes that describe computer-assisted diagnostic software for assessment and characterization of ASPECTS Regions of Interest using CT image data
- RapidAI recommends creating a new ICD10-PCS code for use with this new software