

Computer-aided Triage and Notification for Measurement of  
Intracranial Cerebrospinal Fluid Flow

# Annalise Triage – Obstructive Hydrocephalus

ICD-10 Coordination and Maintenance Committee Meeting  
March 2024

- **Obstructive hydrocephalus (OH)** refers to cerebrospinal fluid (CSF) accumulation from blocked CSF flow within ventricular pathway(s). Excessive accumulation in the ventricles can lead to increased intracranial pressure and brain herniation, resulting in tissue damage, autonomic dysfunction, loss of brainstem reflexes, coma and death.
- On non-contrast CT head scans, it is defined as enlargement of one or more ventricles due to obstruction.
- Overall prevalence of hydrocephalus in North America: 33 per 100,000 adults; most common type is obstructive<sup>1</sup>
- The American College of Radiology has classified OH as a “Category 1 actionable finding - Communicate Within Minutes”<sup>2</sup>.

<sup>1</sup> Isaacs, A. M. et al. Age-specific global epidemiology of hydrocephalus: Systematic review, metanalysis and global birth surveillance. PLoS One 13, e0204926 (2018).

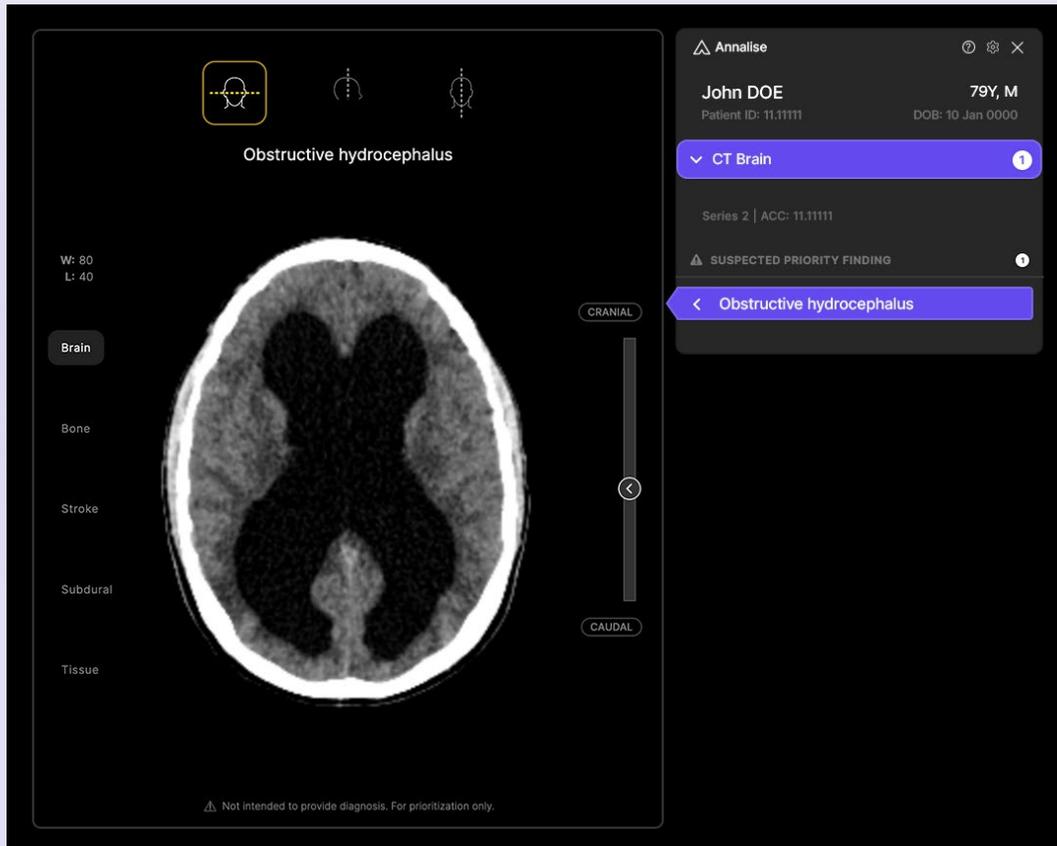
<sup>2</sup> Larson, Paul A., Lincoln L. Berland, Brent Griffith, Charles E. Kahn Jr, and Lawrence A. Liebscher. 2014. “Actionable Findings and the Role of IT Support: Report of the ACR Actionable Reporting Work Group.” Journal of the American College of Radiology: JACR 11 (6): 552–58.

- Without treatment, up to 6 in 10 with any type of hydrocephalus will die<sup>1</sup>.
- Surgical interventions are most common<sup>2</sup>.
- Decisions about clinical management and effectiveness of treatment are time dependent<sup>2</sup>.
- Non-contrast computed tomography (NCCT) brain scans are first line imaging used to diagnose OH, in combination with presenting symptoms and clinical workup<sup>3</sup>.

<sup>1</sup> Kaneshiro, N. K. Hydrocephalus. Medline Plus.(2021).

<sup>2</sup> Koleva, M. & De Jesus, O. Hydrocephalus. in StatPearls (StatPearls Publishing, 2021).

<sup>3</sup> Gibbs, W. N. & Tanenbaum, L. N. Imaging of hydrocephalus. Appl. Radiol.(2018).



- Annalise Triage OH is triage and notification software which uses an AI algorithm to identify suspected OH in non-contrast computed tomography (NCCT) brain scans
- It aids in triage and prioritization of suspected OH within a worklist of radiological imaging studies
- It is compatible with image and order management systems such as PACS and RIS.
- The AI algorithms in the device are convolutional neural networks, trained on over 200,000 CT brain (CTB) scans that are generalizable across a range of patient demographics, characteristics, and CT manufacturers.
- Annalise Triage OH is intended to be used in patients who are 22 years or older.
- First radiology triage device to receive FDA Breakthrough Device designation<sup>1</sup>

<sup>1</sup> FDA website updated as of June 2023

<b>Series A (CT slice thickness ≤ 1.5 mm thick) N=175</b>	
Sensitivity at default operating point	98.7 (95% CI: 96.0, 100.0)
Specificity at default operating point	92.0 (95% CI: 86.0, 97.0)
AUC	0.988 (95% CI: 0.972,0.998)

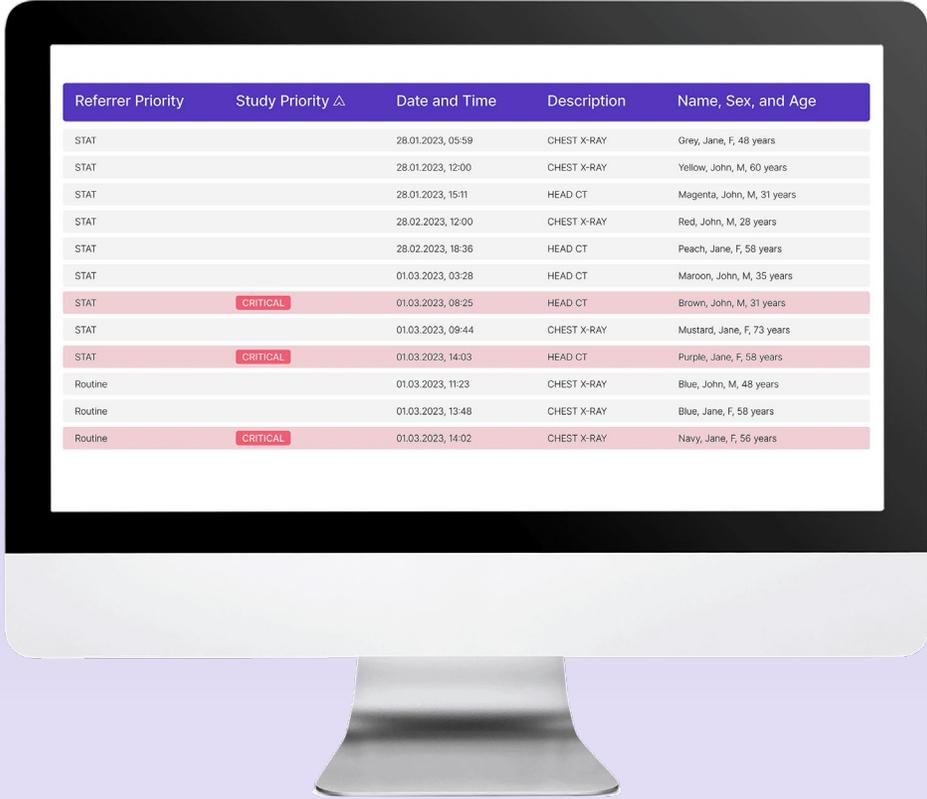
<b>Series B (slice thickness &gt;1.5 mm and ≤ 5 mm thick) N=194</b>	
Sensitivity at default operating point	97.6 (95% CI: 94.0, 100.0)
Specificity at default operating point	95.3 (95% CI: 90.7, 99.1)
AUC	0.987 (95% CI: 0.969,0.997)

Mean time to notification (TTN): 81.6s (95% CI: 80.3-82.9)

<sup>1</sup> Data on file

A typical workflow for Annalise Triage OH:

1. Patient presents symptoms suspicious for OH
2. Provider orders NCCT of head and Annalise Triage OH
3. The PACS/RIS automatically forwards head NCCT studies to the device for processing
4. Algorithm makes prediction as to presence and likelihood of OH; confidence score is compared with customer’s preconfigured threshold to determine whether case is assigned priority
5. Device outputs to the worklist the name of the identified finding, i.e., obstructive hydrocephalus and priority level, and has option to interface with hospital active notification service (e.g., SMS, paging, pop-up notifications) to alert select individuals of prioritized finding
6. Device also has option to output to the non-diagnostic Annalise Viewer when case is opened



- Annalise Triage OH will be ordered concurrently with the NCCT.
- Annalise Triage OH will be used in patients presenting to the emergency department and those already hospitalized.
- Use of the device will be documented either manually or automatically in the NCCT report. Specific details will depend on customer's infrastructure and technical implementation.
  - For manual documentation, users can report use of the device after viewing the device output on the worklist, in the Annalise Viewer, or in the patient study as a secondary capture image.
  - For automatic documentation, device may be configured to output text or secondary output image directly to report.
- Customers will implement systems for documenting use of the device and ensure Radiology providers are trained in its use and appropriate documentation.

- Annalise Triage Obstructive Hydrocephalus is a Breakthrough Designated device that received FDA clearance in Aug 2023.
- Annalise AI applied for NTAP for Annalise Triage Obstructive Hydrocephalus in the FY 2025 cycle.
- There is currently no existing code that describes triage and notification through AI-assisted identification of suspected obstructive hydrocephalus.
- Annalise AI requests the creation of a new ICD-10-PCS code to uniquely describe the use of this new technology.