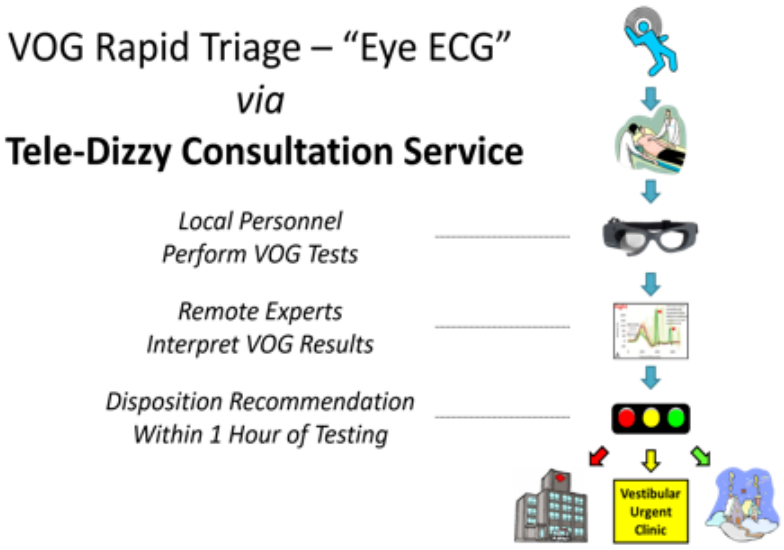
LOOKING FOR INTERESTED SITE PARTNERS FOR A CLINICAL TRIAL PROPOSAL TO IMPROVE DIZZY DIAGNOSIS

We are actively recruiting hospital/ED partners to participate in a grant proposal for a 27-site comparative effectiveness trial we are submitting to the Patient-Centered Outcomes Research Institute (PCORI) in 2026. The proposed **V.E.R.T.I.G.O. Trial** (**V**estibular **E**mergency **R**oom **T**eleconsults vs. **I**maging for better dia**G**nostic **O**utcomes) compares video-oculography (VOG)-enabled teleconsults to a neuroimaging-first strategy to improve diagnosis of stroke vs. inner ear disease and associated health outcomes for adult ED dizzy patients. The full proposal is due May 5, 2026, and the trial is scheduled to run from March 2027 to February 2032.

Why? We know the diagnosis of acute dizziness with a low/normal NIHSS presents a challenge. These patients are resource-intensive and can slow down busy ED clinicians. It is also not feasible to emergently obtain MRIs on all these patients. We want to help.

How? Portable VOG is a technology that facilitates remote video interpretation of bedside eye findings by expert neuro-vestibular consulting physicians. Our goal is to use VOG-enabled teleconsultation to improve diagnostic accuracy, health outcomes, and ED workflow for patients presenting with acute dizziness who lack any obvious acute stroke symptoms.



Trial Hypothesis: VOG-enabled tele-neurology consultation is superior to a neuroimaging-first strategy for accurately differentiating posterior strokes from inner ear disease in dizzy patients who are not candidates for acute intervention with thrombolysis/thrombectomy.

We are looking for hospital and ED partners who…

1. are interested in learning more and are open to considering participation in the trial (*note that the trial design is flexible enough to accommodate local needs/differences in trial implementation logistics*);
2. can identify local personnel who would be interested in learning to perform VOG testing in the ED; and
3. wish to explore this novel technology, which has the potential to improve quality of care, speed patient throughput/reduce ED length of stay, avoid unnecessary tests, reduce excess admissions to observation or inpatient units, decrease cognitive load for clinicians, and improve both patient and provider satisfaction.

Please join us for a VERTIGO Trial information session in conjunction with the Maryland Stroke Center Consortium (MSCC) meeting on March 27th, 2026 (*times TBA*). We will review details of clinical trial design, describe patient enrollment procedures, discuss site participation parameters, and answer questions.

Study PI: David E. Newman-Toker, MD, PhD

Submitting Organization: Johns Hopkins University School of Medicine

Contact Information: VERTIGO@jh.edu

V.E.R.T.I.G.O. Trial: Vestibular Emergency Room Teleconsults vs. Imaging for better diaGnostic Outcomes

PFA: PCORI PLACER Cycle 1, 2026; full submission due May 5, 2026 (by invitation only, LOI #47881 offer extended)

Submitting Organization: Johns Hopkins University School of Medicine

Leadership Team: David Newman-Toker, MD, PhD (PI); Kathryn McDonald, PhD, MM (Co-PI); Daniel Hanley, MD (DCC PI)

Background: Rapidly differentiating peripheral from central vestibular disorders is a major public health problem. Vertigo and dizziness are challenging symptoms to diagnose clinically, because strokes can mimic inner ear diseases closely with very low NIH stroke scores (0-5). Often the only distinguishing bedside features are subtle differences in pathologic eye movements unfamiliar to most frontline clinicians (and sometimes even stroke teams). Patients with inner ear conditions such as vestibular neuritis and benign paroxysmal positional vertigo (BPPV) are often imaged and admitted over concern for stroke, instead of being treated and discharged. Patients with evolving brainstem or cerebellar strokes are occasionally sent home without critical stroke treatments, potentially resulting in serious harm. ED physicians rank vertigo a top priority for developing new evidence to optimize diagnostic choices. ED workups for the ~5 million ED vertigo/dizziness visits cost over $10B per year nationally. Increased use of neuroimaging has increased costs and ED length-of-stay but has not improved diagnosis. Improved diagnosis will reduce imaging overuse and excess admissions in patients with inner ear disorders, improving care quality; it could potentially save the US healthcare system ~$1B per year (half on inappropriate CT imaging).

TRIAL SYNOPSIS (*Timeline: Feasibility Phase March 1, 2027, to February 29, 2028; Full Trial March 1, 2028, to Feb 29, 2032*)

This study seeks to provide critical evidence to address a key diagnostic dilemma for patients and emergency physicians alike: "***Is this patient's vertigo/dizziness from a potentially dangerous stroke or a self-limited inner ear disease***?"

Study Phases: The PCORI PLACER PFA calls for a 12-month feasibility phase that precedes a 5-year clinical trial phase. Feasibility will optimize trial logistics, ensure site readiness to implement, and confirm Consortium recruitment capacity.

Study Population: ED patients with a presenting/chief symptom of acute vertigo or dizziness who are deemed ineligible for thrombolysis/thrombectomy. Key subgroups are those with stroke or inner ear disease (mostly BPPV or vestibular neuritis).

Trial Hypothesis: We hypothesize that a strategy of video oculography (VOG)-enabled teleneurology consultation to help differentiate subtle stroke from inner ear disease will yield superior patient outcomes to a strategy of neuroimaging first.

Study Design: Proposed is a multi-site, stepped-wedge, cluster randomized comparative effectiveness trial (Figure).

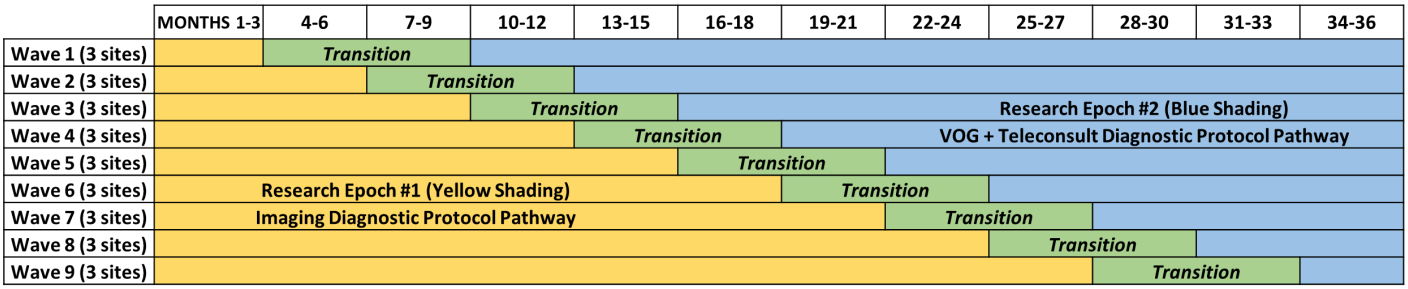


Figure. Proposed VERTIGO Trial Design. Proposed is a stepped-wedge, cluster randomized trial. Epoch #1 is "imaging" (standard care pathway for ED dizziness is neuroimaging, based on site-specific preference: CT or CT/A or MRI). Epoch #2 is "teleconsults" (standard care pathway for ED dizziness is real-time teleconsultation by neurology dizziness/stroke specialty consultants – based on site preference, these can be specialists at the coordinating center or competency-certified local clinicians).

Pathway-Eligible Cohort: Patients with critical illness (ESI level 1) or clear stroke (NIHSS >5 or already placed in an acute stroke care treatment pathway) will be excluded from the trial. Eligible are adults (≥18 yo) with new (or newly worse) dizziness, vertigo, or unsteadiness in the past 7 days with more-than-minimal vascular risk factors by $ABCD^2$ score >2.

Interventions: Comparator interventions will be two different clinical diagnostic pathways. During Epoch #1, sites will select their preferred, locally determined initial imaging protocol for evaluating vertigo/dizziness (CT or CT/A or MRI). All eligible patients without contraindications will undergo imaging as part of their routine clinical care. During Epoch #2, sites will be transitioned over to VOG-enabled teleneurology vertigo/stroke specialty consultations. Consults will be facilitated by a standard bedside exam using a portable eye movement recording device (i.e., VOG) operated by local site personnel (e.g., ED technicians/nurses) who are trained remotely by the clinical coordinating center. Specialists at the clinical coordinating center will be available for teleconsultations, but, if preferred, sites may opt for training and certification of local clinicians.

Outcomes: Primary outcomes are strokes correctly diagnosed and health-related quality of life for dizziness. Secondary outcomes include short-term stroke hospitalizations post treat-and-release ED visit and ED length of stay/resource use.

Sample Size: Feasibility Phase: ~150 pathway-eligible patients across ~6 sites; Full Trial: ~5,212 patients across ~27 sites.

Target Sites: Geographically, demographically, and clinically diverse sites (i.e., different routine imaging capabilities). Site PI with (1) passion/interest in neurologic emergencies, stroke, or bedside diagnosis; (2) comfort with technology-based interventions; and (3) ability to rally ED and institutional support for implementing new quality improvement pathways.

PCORI VERTIGO Trial FAQs

1. **What are the inclusion criteria?** The pathway eligible cohort is adult patients (≥18 years of age) with new (or newly worse) dizziness, vertigo, or unsteadiness in the past 7 days who have more-than-minimal vascular risk factors (as assessed by ABCD2 score >2) and diagnostic uncertainty.

2. **Are there any exclusion criteria?** As this is a pragmatic, comparative effectiveness trial, the goal is for the trial to be as inclusive as possible. However, to ensure safety, patients with critical illness (ESI level 1) or clear stroke (NIHSS >5 or already placed in an acute stroke care treatment pathway) will be excluded from the trial. Patients who cannot participate in their care (e.g., due to dementia) or with contraindications to bedside vestibular testing using video-oculography (VOG) (e.g., unstable cervical spine) will also be excluded, as will be those with obvious medical causes (hypoglycemia, cardiac arrhythmia, anemia, systemic infection, etc.). We will make efforts to track these exclusions.

3. **Can patients with limited English proficiency (LEP) participate?** Our intent is for LEP patients to participate if there are translation services available in the emergency department (ED) that permit patients to follow instructions during VOG testing. Enrollment of such patients will be encouraged. During the feasibility phase, we will assess follow-up procedures for such patients.

4. **How will the study protocol interact with existing stroke/care pathways and neurology consults?** Patients who are "on" the existing stroke pathway will stay on the stroke pathway (see Figure below on "ED Workflow"). For the study, flow of patients with dizziness will be unidirectional with respect to stroke—it will be possible for them to join the stroke pathway, but not possible for them to leave the pathway unless stroke has been definitively ruled out by on-site consultants and neuroimaging. During Epoch #1 (imaging-first pathway care), neurology consultants (on-site or remote) will be engaged, as determined by ED clinicians. During Epoch #2 (VOG-first pathway care), patients who are initial stroke suspects (based on obvious clinical features) will involve a call to the usual stroke care consultants and stroke pathway care. Those patients with dizziness who would normally induce either a general neurology consult or neuroimaging will instead first undergo VOG teleconsultation.

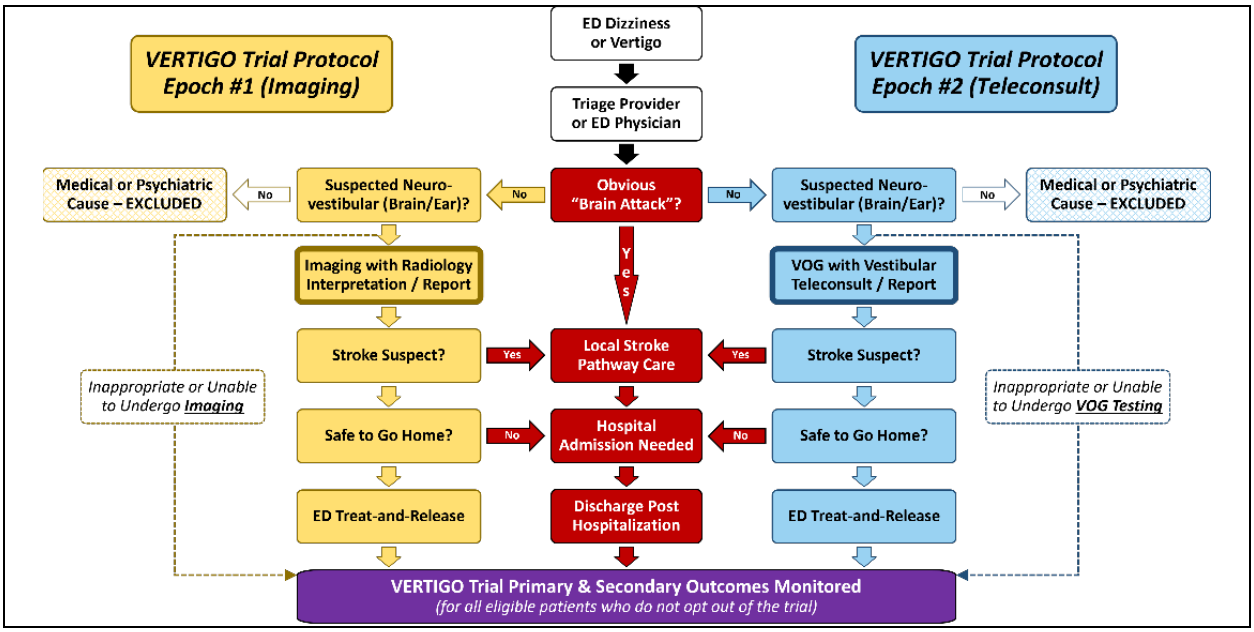


Figure. ED workflow for the VERTIGO trial comparing Epoch #1 (imaging-first pathway care) to Epoch #2 (VOG-first pathway care). Note that there is a unidirectional flow of patients onto the stroke care pathway. No patient can be removed from the stroke care pathway once placed on it, until they have been formally cleared by the usual care process involving ED clinicians, stroke care team, imaging, or any other aspects of typical decision making with respect to stroke pathway care. ED clinicians are always empowered at any point in either Epoch to make protocol deviations for patient safety.

5. **How will the study protocol impact ED physician decision-making with respect to imaging?** At all times, patient safety will take priority over study procedures, so ED physicians can override study procedures for safe patient care. In Epoch #1 (imaging first), enrolled patients with dizziness (non-stroke, non-medical/psychiatric) with uncertainty as to an ear vs. brain cause will be assigned to the local "best available imaging" pathway. Each site will standardize their approach to "best available imaging." Sites will be stratified in the stepped wedge according to their primary self-selected predominant imaging modality (CT, CT/A, or MRI), but standardized "best imaging" protocols may be more complex. For example, at some sites, "best available imaging" might be MRI during the day but CT/A at night or on weekends (or for patients with MRI contraindications). Patients discharged without imaging (e.g., those for whom imaging is deemed unsafe or inappropriate) with "benign dizziness" will be included among the study enrolled patients during both Epochs.

6. **What will be the impact of the study protocol on ED length of stay (LOS)/throughput?** It is expected that during Epoch #1 (imaging first) there will be little or no change in ED LOS, as this phase merely standardizes and protocolizes the current care model. It is expected that in Epoch #2 (VOG first), there will be a reduction in ED LOS. This is estimated on the basis of prior experience with the Tele-Dizzy service at Johns Hopkins and Allegheny Health Network where throughput has improved with implementation of VOG-based care.

7. **Who will do the VOG testing in the ED?** This is at the discretion of the local ED site PI, but it is expected that most sites will want emergency technicians, nurses, paramedics, or advanced practice providers to be trained in performing the VOG procedures. VOG training will occur remotely via standardized procedures used previously (online modules, direct instruction, case supervision). The VOG diagnostic process uses a standardized battery of vestibular tests and takes roughly 10-20 minutes. As noted below, the time required for testing is considered a billable procedure.

8. **How will time for VOG testing by local ED personnel be reimbursed?** PCORI does not generally allow PLACER clinical trial funds to be used to support the patient care intervention under study (and studies requesting such support must then justify future scalability). Local EDs will bill hospital facility fees for this clinical procedure, which can be reimbursed by insurance. Additional support will be provided to cover the costs associated with trial engagement (e.g., initial VOG training).

9. **Who pays for the VOG goggles?** PCORI does not generally allow PLACER clinical trial funds to be used to support the patient care intervention under study (and studies requesting such support [regardless of whether it is for fixed or variable costs of care] must then justify future scalability). Sites will purchase VOG goggles for the study, but the manufacturer will offer a plan in which the costs can be spread over time so they can be recouped by facility fee billings without substantial capital outlay. The VOG goggles will be owned by the hospital/ED at the end of the trial. Depending on the specific software package purchased, goggles prices as of 2025 are in the ballpark of ~$40K.

10. **What is the nature of the VOG-based vestibular teleconsultation?** The "default" pathway for the trial is a standardized teleconsultation by a neurologist with expertise in vestibular disorders (the majority of whom will be Johns Hopkins oto-neurologists, but all of whom will be affiliated with the Clinical Coordinating Center [CCC] at Hopkins). VOG results will be transferred to the vestibular consultant, who will review them and then provide a Level 1, 2, or 3 teleconsult, as appropriate:

    a. **Level 1 consultations (standardized recommendations)**—For patients with normal VOG results, the consultant will offer a standardized recommendation that clarifies the diagnostic significance of a normal VOG in the ED context. A level 2 consult is available on request.
    b. **Level 2 consultations (peer-to-peer remote consultation)**—For patients with abnormal VOG results, the consultant will offer a patient-specific peer-to-peer consultation incorporating information from the clinical team, integrated with VOG findings, and offering a VOG-informed, patient-specific consult note. A level 3 consult may* be available on request.
    c. **Level 3 consultations (direct-to-patient plus peer-to-peer teleconsultation)**—For patients undergoing Level 2 consultations, if the appropriate clinical services arrangements have been made,* the treating ED clinician and consultant may agree to pursue a direct-to-patient teleconsultation in ambiguous cases requiring direct examination.

    * *The final determination about whether Level 3 consultations will be available as an option during the study period will be made during the Feasibility Phase*.

    In the event of connectivity issues, communication may occur by phone rather than video/internet. A note with recommendations will be provided. The linked URL provides a video with additional details describing the VOG-based teleconsultation process.

    Under consideration during the feasibility phase is the possibility of training local clinicians (e.g., stroke neurologists, general neurologists, or emergency physicians) to interpret local VOG results in lieu of remote teleconsultation to the CCC at Hopkins. This approach is under consideration because (a) some sites under consideration have expressed a preference for this approach; (b) this would reduce some aspects of inter-institutional contracting complexity to speed trial implementation; and (c) it would enhance the generalizability and scalability of results. Please note that if this approach were adopted at some (or all) trial sites, certain aspects of what is described in this FAQ document would likely require modifications.

11. **Can local site personnel (e.g., local neurologists) serve as consultants?** Yes, if they can demonstrate competence in reading VOG procedures (a "test" will be performed using cases from the Phase II AVERT clinical trial). However, it is expected that most of the consultants in the central (but fully virtualized) vestibular teleconsultation pool (n=~20) will be located in states other than where the treating ED is located. Physicians in the teleconsultation pool will be licensed in all states where consortium EDs are located. In general, approved local providers will offer only local consultations.

12. **How will teleconsultants be accessed?** The FDA-approved portable VOG device (ICS Impulse, Natus) will operate using a local laptop computer running an FDA-approved thick-client VOG software platform (Otosuite®). The computer will be managed by the local IT department. A secure, web-based platform developed by Johns Hopkins and running in a HIPAA-compliant Microsoft Azure instance will be accessed by the ordering clinicians using an electronic health record order for "Tele-Dizzy" that directly notifies central teleconsultants as soon as a patient is entered in the system.

Once VOG recordings have been transferred to the clinical data warehouse, consultants will review images and communicate with the treating clinical team via note, voice, or video, as appropriate.

13. **How will the VOG recordings be stored and accessed?** A link to a specialized TLS-encrypted, web-based file transfer software will be installed on portable VOG laptop computers. This software securely transfers all files to a HIPAA-compliant clinical trials data warehouse where they can be accessed remotely by vestibular consultants. Data loss is prevented by a secure digital handshake before local files are removed from the local device (before or after local storage, at the discretion of the requesting site's IT department). This procedure has been used successfully in a prior Phase II clinical trial and the clinical Tele-Dizzy consultation service deployed at Allegheny Health Network. Clinical teams can also review VOG recordings from the local laptops or transfer them to the patient's health record (if that is permitted/expected by local IT rules).

14. **How will the consultation notes get into the electronic health record (EHR)?** Signed "Tele-Dizzy" consultant notes will be delivered in a .pdf report to the requesting clinical team via the web-based interface. These reports will incorporate an interpretation and suggested plan, as well as the raw device output printout; in some cases they may also include relevant disease-based summaries. Depending on local IT rules, push functions (e.g., emailing, faxing, or other means of secure digital transfer of the .pdf) to a particular address/phone number may be possible.

15. **How will time for teleconsultants be reimbursed?** PCORI does not generally allow PLACER clinical trial funds to be used to support the patient care intervention under study (and studies requesting such support must then justify future scalability). If the "default" pathway (see FAQ #10) is used, then CCC Tele-Dizzy consultants will bill professional fees for this clinical service, which can be reimbursed by insurance. The process by which this occurs will involve a legal/business clinical services arrangement between Johns Hopkins and the hub or spoke sites. All teleconsultants will be licensed and credentialed at participating hub and spoke sites. If sites are instead approved for local consultations (in lieu of CCC consultants), then billing procedures would be according to usual rules.

16. **How will the IRB be handled?** We plan for a single IRB (sIRB) coordinated through Johns Hopkins.

17. **How will consent be handled?** The trial is a cluster randomized trial using a stepped wedge design. For Epoch #1, the preferred local imaging pathway at each site ED will become the standard of care. For Epoch #2, the VOG pathway care will become the standard of care. As such, the clinical care delivered will not be considered research, per se. There will be no additional data gathered during the ED visit that are not part of the care pathway. Thus, we will seek both a HIPAA waiver and a waiver of individual patient consent for the ED clinical care pathway. For study follow-up, we plan a delayed eConsent via mobile phone with an explicit opt-out option. Patients will be given a standard description of the study and an explanation that they can opt out of follow-up contact.

18. **Who will be involved in the screening and recruitment process?** There will be no dedicated study personnel on site. For on-site clinical personnel, the screening process will involve no effort beyond identifying patients who are appropriate to the standardized diagnostic pathway (i.e., patients with a presenting symptom of dizziness or vertigo who have neither an obvious stroke nor an obvious medical cause, and who would normally undergo a neurology consultation, neuroimaging, or be

treated and released as benign inner ear disease). A standardized "VERTIGO Trial" clinical pathway order set will be incorporated into the local electronic health record system (e.g., Epic or Cerner). This order set will be adjusted in Epoch-specific fashion and will include standard orders for site-specific imaging (Epoch #1) or VOG pathway care (Epoch #2). The order set will be prompted automatically as an option for all patients with a presenting symptom of dizziness or vertigo, and clinicians will determine whether patients are eligible for this standard care pathway or not. All patients for whom the standard dizziness-diagnosis pathway is selected will be part of the trial's study cohort. The order set will include a trial information sheet that bears a QR code that allows patients to download the VERTIGO Trial study app to their mobile phone for the purposes of delayed eConsent (and, if consent is granted, for phone-based data collection). The trial information sheet can be printed with discharge paperwork for ED treat-and-release or hospital admitted patients. If consenting patients lack access to a study-approved smartphone at home (i.e., theirs or a family member's), the study will provide them with alternative means of capturing follow-up data. The precise digital workflow for these steps will be established during the trial's feasibility phase.

19. **How will research data be gathered and follow-up occur for patients recruited into the trial?** There will be two separate procedures for assembling ED encounter and follow-up data. One will involve digital data transfer from either the electronic health record, PCORnet database, or both; funding from the trial will support local personnel in conducting these activities. The other will involve digital patient-reported outcomes and eye recordings with a mobile app; follow-up assessments will be conducted by the central coordinating centers at Johns Hopkins, without need for local personnel. This will include an escalation protocol to phone calls for those who fail to check in via mobile app.

20. **How are sites organized?** Recruiting sites (n=6 during the feasibility phase and n=27 during the full trial phase) will be organized in a hub-and-spoke model. Hubs (n=3 during the feasibility phase and n=~6 during the full trial phase) will be involved in oversight of all spoke site activities, including the selection of site PIs, implementation of subcontracts, sIRB procedures, and patient recruitment. If the "default" pathway (see FAQ #10) is used, this process will also include business/legal clinical services agreements, including provider credentialing, provider enrollment, and delegated billing procedures for teleconsultants. It is understood that hubs with administratively/financially linked spoke sites may have an ease-of-implementation advantage. If sites are instead approved for local consultations (in lieu of CCC consultants), then local rules will guide these clinical relationships.

21. **What are ideal hubs?** Ideal hubs will be larger health systems (academic or non-academic) with at least 3-5 partner hospitals (sites) representing a range of capabilities with respect to access to both neurology consultants and neuroimaging. Both the hubs and their network sites would ideally be located in states that participate in the Interstate Medical Licensure Compact to streamline the central process of obtaining state medical licenses for out-of-state teleconsultants. The hubs will also ideally have an existing legal or compliance relationship with sites that facilitates the sIRB and contracting processes for all affiliated spokes. On a case-by-case basis, we will consider hubs that have a smaller number of affiliated sites (e.g., 1-2) if all sites are willing and eager to participate.

22. **Who are ideal hub PIs?** Hub PIs must be paired–one from emergency medicine and the other from neurology. Either may take the lead (or they may share duties), but, regardless, they must work together collaboratively to ensure the success of the trial at all affiliated spoke sites. Ideal hub PIs

will have a track record of successful participation as site PIs in large clinical trials and a strong working knowledge of their existing stroke care pathways, telestroke networks, and affiliated EDs.

23. **What are ideal sites?** We seek geographically, demographically, and clinically diverse ED sites (i.e., different routine imaging capabilities). In general, very low volume EDs (e.g., <10,000 visits per year) may not have a sufficient number of patients with dizziness to develop proficiency in study procedures. Larger EDs are welcomed, but we will limit the number of academic or other sites whose use of MRI in dizziness substantially exceeds the current national average rate (~4%) to maintain representativeness with current care processes for most ED patients with dizziness in the US. All participating sites must be willing to standardize their imaging protocol pathway care during Epoch #1 and make VOG pathway care their standard care diagnostic protocol during Epoch #2.

24. **Who are ideal site PIs?** ED +/- neurology champion(s) with (1) passion/interest for neurologic emergencies, stroke, or bedside diagnosis; (2) comfortable with technology-based interventions; (3) and able to rally ED/institutional support for implementing new care pathways.

25. **Can specific hospital EDs participate in both the feasibility and full trial phases?** It is generally expected that specific sites participating in the feasibility phase (i.e., making the transition to VOG-based care) will not be eligible for full trial participation. Exceptions may be considered on a case-by-case basis, based on the extent of VOG care implementation at the site during the feasibility phase. Feasibility phase hubs are expected to contribute new ED sites during the full-trial phase.

26. **What will happen to EDs that have transitioned to VOG care after the trial ends?** Sites may elect to continue providing VOG care after their trial engagement has ended (whether feasibility or full trial). A pathway for continuing to provide remote teleconsultation will be made available to sites who wish to do so. It may involve continued contractual relationships with remote teleconsultations or an “incubator” approach (graded exit of remote consultants) to elevate local capabilities in VOG interpretation. Details of this pathway will be co-produced during the feasibility phase of the study.