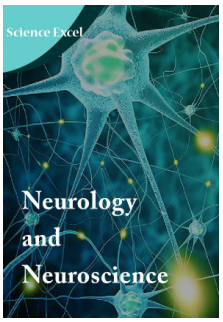
Neurology & Neuroscience

Original Article



Implementation of CT perfusion as The Ancillary Test of Choice for Neurological Determination of Death: A Qualitative Approach

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- Received Date: 23 Jan 2025
- Accepted Date: 20 Feb 2025
- Publication Date: 04 Mar 2025

Abstract

Background: *Accurate neurological determination of death (NDD) is essential in healthcare and often requires several ancillary tests in patients with an ambiguous clinical examination or confounding factors. In the absence of a widely accepted ideal in terms of ancillary tests, this study aims to establish computed tomography perfusion (CTP) as the gold standard test to minimize variability in practice guidelines.*

Methods: *After approval from the institutional research ethics board, the study was conducted in 3 phases: In the first phase of six months, barriers, facilitators, and general attitudes towards CTP were identified among neuroradiologists and critical care physicians, and tailored strategies were developed. After the protocol's implementation for twelve months in phase 2, final evaluations of strategies were conducted in phase 3 for six months. Family members were also interviewed to discuss their views on NDD and CTP's role in the decision.*

Results: *Discussions with neuroradiologists and critical care physicians uncovered a general sense of unfamiliarity with CTP, citing the technology's novelty. However, these feelings of unfamiliarity were found to have reduced after the modality's implementation for a year. The family members also expressed their desire for certainty regarding NDD and a test with decisive results.*

Conclusion: *With continued open discussions and dedicated education to its adopters, this study indicates CTP to be a promising ideal ancillary test for NDD in the future.*

Keywords

CT perfusion; brain death; neurological determination of death

Introduction

Neurological determination of death (NDD), or brain death, is pivotal. Accurate NDD has implications for patients and the health care system including patient prognostication for continued life support and decision about organ donation. NDD is based on clinical examination of brain stem reflexes, performed at the bedside [1,2]. In certain situations, confounders like sedative medications, traumatic injuries, or therapeutic hypothermia prevent appropriate neurological examination, rendering clinical NDD impossible. In circumstances in which a complete and accurate clinical evaluation is hindered, clinicians must use "ancillary" or supplementary tests [3,4] Currently available imaging tests like computed tomography angiography (CTA), 4-vessel angiography, and nuclear medicine studies raise diagnostic challenges including the potential persistence of intracranial blood flow in patients with clinical NDD. These ancillary tests are also limited in resolving the blood flow to specific regions of the brain like the brainstem. None of the currently accepted ancillary tests are ideal, which results in wide variation in hospital policies and practices regarding their use, and lead to disagreement among physicians [5–9]. In the absence of an accepted gold standard ancillary imaging test, these patients often undergo multiple ancillary tests, which may amplify uncertainty as well as cost burden to the healthcare system.

A systematic review of ancillary tests demonstrated significant methodological limitations, with the majority of studies unable to compute specificity because of their exclusion on non-NDD patients [10]. Since the gold standard for NDD (clinical examination) is not always feasible (between 14% and 87% of the time) [11] and because there is no ideal ancillary test, evaluation of new techniques of brain imaging is imperative [12]. Computed tomography perfusion (CTP) has been shown to be the only ancillary imaging technique to demonstrate isolated brainstem death [13–15]. CTP has very high sensitivity and specificity as well as very high inter-observer agreement for diagnosis of NDD [16,17]. Compared to all other currently available ancillary tests, CTP appeared to be the most promising modality for NDD. The aim of our study was to identify

Citation: Trivedi R, Huang B, Green R, Shankar J. Implementation of CT perfusion as The Ancillary Test of Choice for Neurological Determination of Death: A Qualitative Approach. Neurol Neurosci. 2025;6(2):0187.

barriers and facilitators among neuroradiologists, critical care physicians and patients' families to implement CTP as the ancillary imaging of choice when required for NDD in our hospital.

Method

This study was approved by our institutional research ethics board (REB File #: 1021919). Informed consent was obtained from all willing participants in the study. The study employed a mixed-method design [18] with a cross-sectional analysis of existing use of ancillary tests for NDD, subsequent focus groups with end users to identify implementation challenges and strategies, implementation of strategies and evaluation. This was conducted in 3 phases with phase 1 for six months, phase 2 for twelve months and phase 3 for six months.

Phase 1: Assess barriers/facilitators and develop tailored strategies

Guided by the Ottawa Model of Research Use,[19] a planned change theory, the study was initiated by assessing the current environment for barriers and facilitators in establishing CTP as the standard of care ancillary imaging test for NDD. This assessment involved a short one-page survey about ancillary imaging tests for NDD (Appendix 1). It also involved discussion of current practice of ancillary imaging tests for NDD with physicians from neuroradiology and critical care, including the reasons for ordering ancillary imaging tests. This discussion were based on our retrospective review [17]. The plan was to identify potential barriers and facilitators at three levels:

- the *innovation* (i.e., a protocol with CTP as the ancillary imaging modality of choice),
- the *potential adopters* (i.e., staff in neuroradiology and critical care medicine), and
- the *practice environment* (i.e., factors at the hospital and external socio-political levels, such as referral/scheduling processes related to CTP, family understandings and preferences, professional society guidelines, and societal laws and norms).

This was aimed to identify the perceptions and attitudes of potential adopters toward CTP and thereby helped identify strategies to overcome the identified barriers and increase use of the ancillary imaging protocol as part of routine practice to determine NDD at our hospital. This assessment was done through 2 focus groups, one with five fellowship trained neuroradiologists and the other with ten critical care physicians in their respective departmental rounds. The format of the focus group involved a brief presentation of CTP and its evidence base, followed by a discussion structured to address the topics identified above (Appendix 2). The focus group questions and probes were based on Patton [20] and Rubin and Rubin [21] practical guidance to draw information gained during the initial barriers and facilitators assessment, and the experience of establishing the protocol. Each focus group had up to 10 target participants. Each focus group was audio recorded to capture and retrieve the data in true form, and transcribed verbatim.

Based on the knowledge gained through the two focus group assessments, strategies were developed and tailored to facilitate use of CTP as the ancillary imaging modality of choice for NDD and reduce use of other imaging modalities for NDD.

Phase 2: Establish CTP protocol

The tailored strategies were implemented through in-person meetings with the staff neuroradiologist involved in the NDD process. The use of the ancillary imaging protocol was facilitated using tailored strategies. The data on the use of CTP and other imaging modalities for NDD were acquired in this phase.

Phase 3: Evaluation of ongoing post-establishment of CTP protocol

Process evaluation

Two additional focus groups were held in this phase, one each with neuroradiology and critical care residents and staff. The aims of these focus groups were to understand how the protocol was used, assess which strategies to increase use of CTP for NDD were working (or not) and why, explore perceived impacts of using CTP (e.g., reduced uncertainty), and identify continued (and new) barriers to protocol use. This data was critical for monitoring our strategies, understanding whether the strategies require adaptation and/or whether additional ones were required, and to optimize sustainability.

The Framework Method [22,23] was used to analyze the focus group data. Research team meetings were held to review, question, and clarify findings.

Outcomes evaluation

Three outcomes were evaluated in this study: staff knowledge and attitudes, family member experience, and health service use.

Staff knowledge and attitudes: The staff involved in the NDD process (neuroradiologists and critical care physicians) were surveyed at two time points (phase 1 and phase 3). A short questionnaire (Appendix 1) was distributed at the beginning of the focus groups to assess their knowledge of and attitudes towards ancillary imaging tests for NDD. The survey results were compared between phase 1 and phase 3. This was to demonstrate whether knowledge of CTP for NDD increases over the course of the study, whether attitudes have changed, and whether staff increasingly order it as an ancillary test for NDD.

Family member experience: We interviewed 2 family members/next of kin to explore their views on how providers discussed NDD, and their experiences with CTP for NDD. These participants were recruited with the help of the organ donation program. They were contacted for interviews in the time period of 3-6 months after the patient has NDD. Each interview was audio recorded and transcribed verbatim.

Health service use: The use of both CTP and other ancillary imaging tests for NDD was tracked over the course of the study. These rates were compared to retrospective data (published separately) [17] to determine any change.

The performance indicators of success were decided as the number of staff participating in the barriers/facilitators assessment; increased use of CTP for NDD and evidence of staff and health service impact in the comparative surveys.

Statistic

Data analysis was initiated after data was collected in phase 1. A thematic analysis using constant comparative analysis [21] were employed, involving coding, categorizing, and theme identification and refinement. Coding and analysis of interview transcripts were performed.

Results

The focus group discussions with neuroradiologists and critical care physicians brought forward important barriers and facilitators for implementation of CTP for ancillary imaging of choice for NDD. The results are shown in Table 1.

Table 1. *Summary of themes from the focus group discussions among neuroradiologists and critical care physicians.*

Group	Barriers	Facilitators
Neuroradiologists	Limited understanding of process of NDD Limitations of CTP Uncertainty about CTP in practice Inconsistent international practice.	The ability to quantify.
Critical Care Physicians	Preference to angiogram. Uncertainty about CTP. Sensitive and conservative nature of NDD decision.	Limitations of angiogram. Advantages of CTP. Desire for standardization Dependence on neuroradiologists.

Focus group discussion among neuroradiologists

Barriers

Limited understanding of process of NDD: Although the neuroradiologists were experienced in their understanding of radiological findings of ancillary tests for NDD, they were skeptical about how the ancillary test results were used for NDD decision making. Their suspicion was that their reports of ancillary tests findings consistent with NDD result in declaration of death without correlation with the clinical findings. They were very hesitant to use ancillary tests as the neuroradiologists have limited clinical information of the patients at the time of ancillary tests. They were unsure if ancillary test results are just one of the pieces of the clinical puzzle in NDD decision making or the only piece of information that result in NDD.

Limitations of CTP: Though CTP is superior to other imaging tests, it had some limitations that might impede its wider application. Neuroradiologists were uncertain about interpreting the CTP results for NDD, suggesting that establishing a standard protocol and interpretation template were required along with further education for the same for the neuroradiologists. CT scans from different vendors might have different perfusion values, posing difficulties in determining a single threshold for NDD for all scanners. Additionally, as CTP is a relatively new test for NDD, more evidence was needed. However, this limitation is not specific to CTP as high level of evidence for all ancillary tests for NDD are insufficient as all the studies are small and retrospective in nature.

Uncertainty about CTP in practice: Among the neuroradiologists who recognized CTP as an effective test for NDD, some were also unsure if they could trust CTP alone to make the decision or just "use CTP in addition to other ancillary tests to support what we were trying to do".

Inconsistent international practice: There are international variations in acceptance of isolated brainstem death as brain death and practice of using CTP as the ancillary test. Some countries accept brainstem death as NDD such as UK, while Canada does not. Some physicians were resistant to use it, as they were unsure if they "can equate death and brainstem death".

Facilitators

The ability to quantify. CTP's ability to be quantified was one of its most favorable advantages as it could detect perfusion up to 2 mL/min/100gm of cerebral blood flow, and NDD could be determined based on the perfusion value. Most physicians prefered quantification to reduce variability among neuroradiologists, hospitals, and even countries. However, no threshold had been confirmed.

Focus group discussion among critical care physicians

Barriers

Preference to catheter angiogram: In the group discussion among critical care physicians, there was a clear preference to catheter angiogram, and it was more acceptable as the potential standard test, partly due to its wide application. The next best test to most was a CTA and they were somewhat reluctant to turn to another relatively new test for NDD.

Uncertainty about CTP: Critical care physicians expressed their uncertainties and doubts on the current evidence of CTP for the decision of NDD, focusing on (a) reported sensitivity and specificity, (b) generalizability of the results, and (c) limitations of the retrospective study design. However, they recognized that all studies on ancillary tests in this field are retrospective in nature.

Sensitive and conservative nature of NDD decision: NDD is a rather sensitive and ethical decision, and most physicians tend to be conservative when they make death declarations, to minimize false positives. This made it difficult to proceed solely with CTP results if a patient is likely breathing (not sure if spontaneous or not) but had an absent perfusion in the brainstem on CTP.

Facilitators

Limitations of angiogram: Catheter angiogram and CT angiogram are currently the most used and accepted ancillary tests among physicians. However, there was very limited high level evidence for their sensitivity and specificity for NDD. In many cases, the angiogram did not have enough sensitivity for NDD, thus missing the optimal time window for potential organ donation and increasing healthcare costs.

At times, the angiogram may add more uncertainty, as the images could be inconsistent across different time points. This was found in a patient with more than one CTA with inconsistent reports.

Advantages of CTP: CTP had higher sensitivity than the commonly used DSA and CTA particularly in patient with small flow on CTA thus not qualifying for NDD by CTA criteria. Moreover, CTP also provide CTA information as an additional test.

Desire for standardization: (1) Reliable ancillary test. Most physicians expressed a strong desire for a reliable ancillary test as the gold standard when clinical confounders were present. The desired qualities of the ideal test included: (a) high positive predictive rate, (b) high specificity, and (c) consistency. These demands would hopefully drive the implementation of CTP as the standard test for NDD considering that it fulfills most of

these criteria. (2) Standard protocol. In addition to a standard test, a standard and practical protocol was also highly demanded among both neuroradiologists as well as critical care physicians.

Dependence on neuroradiologists: In the discussion among critical care physicians, there was clear dependence on neuroradiologists to make the decision about the choice of ancillary imaging test, as well as their interpretation.

Phase 2

One year observation of use of ancillary imaging test showed use of only CT based imaging tests. This also showed overall increase in use of ancillary tests over the period of 10 years and increasing use of CTP as the ancillary imaging test for confirmation of brain death [17].

Phase 3

Focus group discussion among neuroradiologists

Perceived impacts of ancillary tests on NDD process

Decreased uncertainty: Through the process of the study, the neuroradiologists were reassured that their ancillary imaging tests report is not taken in isolation for NDD. They were reassured that ancillary tests results were always put into the clinical context and were a part of the larger clinical process.

Perceived impacts of using CTP

Decreased uncertainty: CTP decreased uncertainty and strengthened physicians' confidence as it had higher sensitivity in NDD, can quantify, and provided CTA information as well. CT technologists were comfortable with CTP acquisition without any additional training. With more information and exposure, the neuroradiologists became comfortable using CTP for NDD decision.

Continued and/or new barriers of using CTP

Technical issues in interpretation: Some neuroradiologists were still reluctant about the quantification of CTP and uncertain of NDD in scenarios when CTP results were inconsistent with other tests such as CTA.

Focus group discussion among critical care physicians

Perceived impacts of using CTP

Decreased uncertainty: Critical care physicians expressed higher acceptance of CTP and wider use of CTP in NDD process with decreased uncertainty.

Benefits to organ donation: Due to the sensitive and conservative nature of NDD decision, many NDD patients would miss the time window for organ donation because of the uncertainty surrounding other alternative ancillary tests. This improved with the increase in the use of CTP. With high sensitivity and accuracy, CTP identified brain dead patients early, facilitating efficient use of healthcare resources.

Continued and/or new barriers of using CTP

Preference of other tests such as CTA and MRI: Still, some critical care physicians were more comfortable with CTA, likely for historical reasons and the difficulties associated with changing widely accepted practice and attitudes in such a short time frame.

Sensitivity and conservative nature of NDD decision: The sensitive nature of NDD was not a barrier itself, but some critical care physicians tended to be very conservative and were reluctant to make the declaration, even if the patient was indicated brain dead by CTP results. This highlighted the need for more and stronger evidence for the validity and reliability of CTP to increase the physicians' confidence.

Family member interview

Two family members of NDD patients were interviewed to gain insight regarding how they felt when their loved ones were in hospital and what their suggestions were on improving the NDD process. Three main themes were summarized through thematic analysis: desire for certainty, communication, and emotional support.

Desire for certainty: Both family members expressed a strong desire for a reliable test for NDD decision, with high accuracy and sensitivity. They both wanted "100% certain" results. One family member remembered the uncertainty of NDD due to presence of trickle of flow on CTA in their loved one.

Communication: The most emphasized aspect of the whole process was communication. There was a lack of sufficient and effective communication between healthcare workers and patient families, and families required more explanations on the imaging test results and the NDD results. They expressed their wish to look at the images themselves, as they expressed that the images may aid them in understanding the circumstances in a more objective way and may improve their confidence in the results.

One family member mentioned that they would prefer more "one on one" communication as they were not used to "ask questions in front of everybody"; they also expressed their preference to be informed by a doctor instead of a nurse. The same family member emphasized more training for newer and younger healthcare workers, regarding communication of sensitive patient information to families.

Discussions

We assessed local context and identification of barriers and facilitators for use of ancillary tests for NDD prior to design of strategies, which represents best practice in implementation science. Ours is the first study in literature to assess the attitude of neuroradiologists towards NDD. Our study highlights the sense of unfamiliarity of the NDD process and role of ancillary tests in the whole process among the neuroradiologists. The neuroradiologists became more familiar with the process of NDD and were more reassured about their role in the process of NDD through the course of the study.

One of the primary barriers to the deployment of CTP in clinical care, as noted by neuroradiologists and critical care physicians in phase 1, was a general sense of unfamiliarity with the technology of CTP in NDD. In phase 3, neuroradiologists and critical care physicians expressed decreased uncertainty with the test, likely facilitated by further educational sessions. During the interview with family members, an overarching theme of wanting more certainty and clarity in communication was observed. They expressed their desire for a reliable test with quicker results and effective communication once the verdict is known.

The exploration of the nuances and challenges of using different ancillary tests for NDD is not a novel concept. Most recent Canadian guidelines highlight that CT perfusion has an acceptable false-negative rate and low undesirable effects due to an acceptable false-positive rate, however there is immense variability in its acceptability [2]. As also noted by our study, the recent Canadian guidelines reinforce that one of the primary barriers of putting CT perfusion in widespread use is its novelty for NDD and variation in operator training, leading to a lack of certainty about its results [2]. However, our study shows that the uncertainty decreased among neuroradiologists and

critical care physicians after implementing the test for twelve months, signifying this uncertainty to simply be a product of unfamiliarity with the test. We also found that once the feelings of unfamiliarity were overcome and CTP was implemented, the critical care physicians perceived to have benefits to organ donation, as it provided decisive results more rapidly, allowing organ donation to occur in the optimal time frame following NDD. Although this benefit was not evaluated quantitatively and was beyond the scope of the present study.

After the test's implementation for twelve months, a few barriers remained. Some staff still felt issues with CTP's interpretations and were unsure of the appropriate course of action when its results were inconsistent with those of CTA. Similarly, some critical care physicians expressed a continued familiarity with CTA and MRI rather than CTP. This, once again, may stem from unfamiliarity with CTP and thus, would be difficult to change in such a short period of time. It is important to note, however, that a study done by Briard et al attempted to assess the diagnostic accuracy of ancillary tests for NDD. They found that most ancillary imaging modalities lack sufficient evidence to make definitive claims about any tests' superiority over other tests [24] This once again reaffirms the need for more robust research and continued education about this topic, so as to increase familiarity and trust in newer test modalities and innovation.

Death can be a challenging concept, often laden with many cultural, religious, and spiritual connotations. In many cases, NDD may be difficult to grasp for family members of affected patients. The counterintuitive nature of brain death was noted in a study by Sarti et al, in which family members explained how they felt death was contradictory to how their loved one physically appeared [25]. A similar feeling of uncertainty in NDD decisions can be noted in our study, when a family member expressed that the process of NDD was confusing. Keeping the already sensitive nature of NDD in mind, multiple ancillary tests can be exceedingly perplexing for family members. This highlights the need for a reliable test with high specificity and sensitivity like CTP to minimize the uncertainty surrounding these decisions. Additionally, family members found witnessing the clinical assessments or ancillary tests of patients to help greatly with their understanding of NDD and with gaining closure [2]. This is consistent with what family members expressed in our study, noting that seeing the imaging tests may enhance their confidence in the ultimate determination. One of the family members also expressed their preference for direct communication with a doctor instead of a nurse, perhaps due to a general perception of doctors being of higher authority and therefore, better able to provide a sense of certitude regarding these results. Above all, family members expressed their desire for the uncertainty attached to NDD to be minimized.

Most important limitations of the study were being a single-center study and the sample size was limited. However, when conducting interviews regarding staff knowledge and experience, 100 percent of the population consisting of neuroradiologists at our center were included. It is also important to note that interviews about this subject may be difficult for family members of affected patients and should be handled with utmost sensitivity. It is not an easy conversation to have and thus, our sample size of family members comfortable and willing to be interviewed was limited. As a result, there may be some degree of selection bias as it may be plausible that only family members with relatively good experiences agreed to be a part of the study.

Conclusion

Our study demonstrates that efforts to standardize the use of CTP were successful with open discussions with neuroradiologists, critical care physicians and family members. Despite its novelty and some unfamiliarity for NDD, with continued education and training for its adopters, CTP appears to be well positioned as the gold standard ancillary test of choice when considering NDD in the future. The ambiguity surrounding the process of NDD proved to be disadvantageous for everyone involved. Family members deserved a consistent answer and any uncertainty in the process may only make their grieving process more difficult. Standardizing ancillary imaging tests for NDD is, therefore, necessary.

Take Home message

- Accurate Neurological determination of death (NDD), or brain death, is critical and ancillary imaging tests are being increasingly used in this process.
- Currently ancillary tests for NDD is not standardized but CT perfusion holds promise.
- Neuroradiologists are apprehensive about the use of results from ancillary imaging tests as they have limited clinical information at the time of image interpretation.
- Implementation of new ancillary imaging tests for NDD in any center needs open discussions with neuroradiologists, critical care physicians and family members.

Author Contributions: RT and BH put together the first draft and RT finalized the manuscript. RG oversaw the critical care aspect of the research. JS conceptualized and secured the grant and oversaw the whole research. All authors reviewed the final draft of the manuscript.

Funding: TRIC grant from NSHA.

Institutional Review Board Statement: Ethics approval was taken from the institutional ethics board

Informed Consent Statement: Consent to participate and publication was taken from the participants.

Data Availability Statement: Data and material are available for review on request

Acknowledgments: We are very thankful to Dr Robin Urquahrt for her help in design and conduct of the study. We also want to thank Vicky Sorhaindo and Brandie Stewart for their help and support throughout this study.

Conflicts of Interest: No competing interests.

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Appendix 1: Questionnaire

Questionnaire for physicians

We are interested in your knowledge of imaging tests for neurological determination of death (NDD).

1. Please list all of the imaging tests that can be used for NDD. Please also list the sensitivity and specificity of the tests, if you are aware of that information.

Name of test	Sensitivity	Specificity

2. Are you aware that CT perfusion is used as an ancillary imaging test for NDD? (circle one)

YES NO

3. Have you ever ordered CT perfusion for NDD? (circle one)

YES NO

4. If you circled YES for question 3, approximately how many times have you ordered CT perfusion for NDD? (select one)

- None
- At least once
- 1-5
- >5

Appendix 2: Focus Group Guide Physicians

Focus group guide – physicians

Introductory points

- First, I want to thank you for taking the time to speak with us today. Your participation in our study is greatly appreciated.

- Today, we will be talking about the ancillary imaging protocol of CT perfusion (CTP) for neurological determination of death (NDD). Specifically, we will ask you about:
  - our experience with ancillary imaging tests for NDD
  - What effects the imaging protocol has had for you
  - Your experience using CTP for NDD
  - How we can increase use of CTP in the future

Ground rules for session

- So, today you are here to take part in a focus group related to these issues. You are all experts in this area and your input is greatly appreciated.

- We are interested in all of your ideas. There are no right or wrong answers here. Some of you may disagree with us, or each other, and that's fine. We would like to hear as many points of view as possible. You can respond to each other, not just to me. You don't have to wait for me to call on you to speak.

- Even though you all come from a variety of healthcare settings, everyone's views on these issues are necessary to understand how CTP is being used for NDD.

- Please speak freely and honestly. Please introduce yourself when you say something. Only one person should speak at a time so that everyone has an opportunity to say something.

- You were given a consent form that you were asked to review and sign. The consent form contained information about the study and how the information you provide will be used. Let's go through it briefly.

- At this point, do you have any questions about the consent form or any of the information you received?

- Your participation in this focus group is entirely voluntary. You are free to withdraw your consent to participate at any time before, during, or after this focus group. You may also choose to not answer any of the questions.

- This session is being tape-recorded and the research assistant will be taking notes about the discussion. The reason for the tape-recording is that we want to make sure we remember everything you say today. However, your comments will remain confidential and will be used for research purposes only. Your names will not appear in any report or presentation related to this project. Is this OK with everyone?

- Do you have any questions before we begin?

Experience with CTP for NDD	
1. Some of you may be using CTP for NDD. a. For those who are using it: What are your experiences? (i.e., How easy it is to get done? Is it informative? Do you use it for decision making? Is there any resistance at any point when you order it? Do you still order other ancillary imaging tests for NDD?) 2. Some of you may not being using CTP for NDD. b. Have you ordered it? c. Why/why not?	
Implications and impacts	
3. Has the protocol of CTP for NDD reduced uncertainty about: a. What test to order? b. Diagnosis/prognosis?	
4. Has using CTP for NDD affected your interactions with family members? (e.g., made it easier/harder to explain prognosis) 5. Has using CTP for NDD affected your interactions with colleagues? (e.g., made it easier/harder to agree on ancillary test, made it easier/harder to agree on prognosis)	
Barriers and facilitators	
6. What aspects of the protocol have helped you use CTP for NDD? (e.g., that a protocol exists at all, technologists familiarity with the protocol, support from DI management, personal knowledge about the utility of the test, colleagues' familiarity with the test) 7. What aspects of the protocol have prevented you from using CTP for NDD? (e.g., change from old protocol, understanding of professional guidelines, technologists' lack of familiarity with protocol, personal knowledge/attitudes about the test, colleagues' knowledge/attitudes) 8. What types of changes would help you use CTP in the future?	
Closing	
9. Is there anything at all we have not talked about that you believe is important with respect to using CTP for NDD?	