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Simulation-Based Training In Brain Death Determination

Benjamin Macdougall

SIMULATION-BASED TRAINING IN BRAIN DEATH DETERMINATION

Benjamin J. MacDougall, Jennifer D. Robinson, Liana Kappus, Stephanie N. Sudikoff, David M. Greer. Department of Neurology, Yale University, School of Medicine, New Haven, CT.

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Benjamin J. MacDougall

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Abstract

Despite straightforward guidelines on brain death determination by the American Academy of Neurology (AAN), substantial practice variability exists internationally, between states, and among institutions. We created a simulation-based training course on proper determination based on the AAN practice parameters to address and assess knowledge and practice gaps at our institution. Our intervention consisted of a didactic course and a simulation exercise, and was bookended by before and after multiple-choice tests. The 40-minute didactic course, including a video demonstration, covered all aspects of the brain death examination. Simulation sessions utilized a SimMan 3G manikin, and involved a complete examination, including an apnea test. Possible confounders and signs incompatible with brain death were embedded throughout. Facilitators evaluated performance with a 26-point checklist based on the most recent AAN guidelines. One hundred eleven physicians from multiple specialties have participated in the didactic session, and 38 have completed the simulation. Pre-test scores were poor (41.4%), with attendings scoring higher than residents (46.6% vs. 40.4%, p=0.07), and neurologists and neurosurgeons significantly outperforming other specialists (53.9% vs. 38.9%, p=0.003). Post-test scores (73.3%) were notably higher than pre-test scores (45.4%). Participant feedback has been uniformly positive. Baseline knowledge of brain death determination among providers was low but improved greatly after the course. In conclusion, our intervention represents an effective model that can be replicated at other institutions to train clinicians in the determination of brain death according to evidence-based guidelines.

Acknowledgements

It has been known for some time that there is a concerning amount of variability in brain death determination protocols across the country. Efforts to ameliorate the situation have focused on expanding our toolkit for diagnosing brain death, but have largely ignored assessing and improving physician competence in using our current model of brain death determination—a model that we know works.

My mentor, David Greer, set out to determine how effective we were at practicing according to these well-established, proven guidelines. He correctly anticipated that that clinical competence in this examination – even at an institution like Yale – was unacceptably poor and needed to be addressed through a novel simulation-based training course. Dr. Greer understood the need to create a reliable, high-quality course, and conducted every single simulation himself—an arduous time commitment for any senior faculty member. He should be commended for this exceptional level of dedication.

I benefitted immensely from this project, and was given wonderful opportunities to interact with clinicians and learn more about this incredibly important topic. I owe Dr. Greer a resounding thank you for this experience. He is a true mentor in every sense of the word: responsive, encouraging, thoughtful, and incredibly supportive. His commitment to medical student and resident education is admirable, and with this project he continues to extend this commitment to his professional community.

I would also like to thank Jennifer Robinson for her help in facilitating the simulations, and Stephanie Sudikoff for her help in creating thoughtful and fair questions for the tests, as well as for her valuable input on the original manuscript.

Finally, I would like to thank Liana Kappus for her help in planning and constructing the simulation scenarios, and for her support throughout the simulation process.

All simulation expertise and resources for this project including, but not limited to simulation enhanced curricular construction, scenario design, simulator adaptation, and technical support, were provided by the SYN:APSE Center for Learning, Transformation and Innovation at Yale-New Haven Health System.

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Introduction

Historical Context

Prior to the mid-twentieth century, the concept of brain death did not exist. In fact, there was essentially no need to define death in precise terms, as respiratory and circulatory arrest inevitably led to loss of function of all organ systems. At this time, severe and irreversible brain injury inevitably led to respiratory arrest secondary to insufficient breathing drive and an inability to maintain patency of the upper airway, which would eventually trigger circulatory arrest—fulfilling the "cardiopulmonary" definition of death (1). In this way, loss of function of the brain and brainstem was inextricably linked to the loss of circulatory and respiratory function. However, in the 1950s, the introduction of endotracheal intubation to preserve respiratory function allowed for widespread use of mechanical ventilation in intensive care units (ICU) (1,2). Additionally, a decade earlier the first successful cardiac defibrillation was performed, which allowed for resuscitation of patients with severe – and previously irreversible – cardiopulmonary injury (3). This created a novel scenario: with the help of the mechanical ventilator, patients who had suffered catastrophic and irreversible brain injury could now be maintained with adequate cardiopulmonary function, and the death of the brain could temporarily be dissociated from respiratory and circulatory function. Thus, there emerged a need to define this state—both to provide finality for families and to preserve vital ICU resources.

The characterization of this novel neurologic state began with the French neurologists Mollaret and Goulon's 1959 article "Le Coma Dépassé." In it, they

described 23 cases of coma, the severity of which clinically surpassed anything described in the literature to that point. They provided the first comprehensive clinical and EEG description of "the irretrievable coma," and were also the first to distinguish it from other comatose states (4). The paper was initially overlooked outside of France, but it would eventually set the stage for further development and application of the concept of brain death (1).

In the United States, the pressure to develop criteria for the irreversible coma came from two groups: physicians working with critically ill patients, who wanted to better define when care was futile, and transplant surgeons, who recognized the possibilities created by a new pool of eligible, high quality organ donors. This push was not without controversy—many transplant surgeons did not feel comfortable harvesting organs from patients who had not fulfilled the cardiopulmonary definition of death, and some felt that this practice would cause the field of transplantation to fall into disrepute with the rest of the medical profession (1). Nonetheless, in 1968 the Ad Hoc Committee of Harvard Medical School, which included neurologists, a neurosurgeon, an ethicist, and an anesthesiologist convened, with the goal of "defin[ing] irreversible coma as a new definition for death" (5). They produced a set of guidelines titled "A Definition of Irreversible Coma."

These guidelines were largely accepted among members of the medical community, and prompted the development of similar criteria in the United Kingdom and other nations. However, the guidelines had not yet gained any traction within the legal community (1).

In 1981, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research published guidelines defining brain death as the irreversible cessation of all function of the entire brain, including the brainstem (6). The Uniform Determination of Death Act (UDDA)(7) is based directly on these seminal guidelines. The act forms the basis for brain death laws in the United States, and since it was drafted in 1981 has been adopted by all 50 states and the District of Columbia. The UDDA states: "An individual who has sustained either 1) irreversible cessation of circulatory and respiratory functions, or 2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead." While the UDDA provides a legal framework for brain death, it does not spell out the details of the exam that would allow clinicians to make that determination. Rather, it simply states that determination of death must be made "in accordance with acceptable medical standards."

In most US states, all physicians are legally permitted to determine brain death. Once a determination has been made, there will be no criminal liability resulting from removing life support measures, except in New Jersey and New York, where physicians must yield to religious objections.

Diagnosing Brain Death: A Review of the AAN Practice Parameters

Given the inherent ambiguity of the UDDA, the American Academy of Neurology (AAN) published practice parameters in 1995(8) and 2010(9) to guide clinicians in the determination of brain death. The AAN derived its approach from the requirements of the UDDA, and created a four-step protocol for providers,

specifying: 1) clinical prerequisites for beginning the determination process, 2) the appropriate neurological examination (including apnea testing), 3) ancillary testing (if needed), and 4) documentation in the medical record. Based on a literature review done as part of the 2010 practice parameters, the AAN concluded that there were no reports of recovery of neurological function after a determination made according to the 1995 AAN practice parameters. Each step of the brain death determination protocol will be reviewed here. All steps are taken from the 2010 AAN practice parameters, except where indicated.

Prerequisites

A number of prerequisites must be met before the clinical evaluation to ensure that the condition is irreversible. First, the cause of the coma must be established, and the cause must be irreversible. This step is important to ensure that there are no conditions that may be mimicking brain death. The presence of central nervous system-depressant drugs must be excluded: by plasma levels or calculation of clearance using five times the drug's half-life. There should be no recent administration of neuromuscular blocking agents. If the patient had been drinking alcohol, the guidelines suggest that the examination can proceed with a blood alcohol content less than the legal limit (0.08%). The guidelines also mandate that there be no severe electrolyte, acid base, or endocrine abnormalities, though they do not specify exact values. Prior to the clinical exam, the patient must also achieve normal or near normal core temperature (>36°C) and normal systolic blood pressure (≥100 mm Hg).

There are a number of clinical scenarios that may erroneously lead to the impression that brain death has occurred. These brain death mimics, which include Guillain-Barré syndrome, baclofen overdose, organophosphate intoxication, lidocaine toxicity, and delayed vecuronium clearance have been reported in the literature and can present with many examination findings consistent with brain death (10-13). However, the AAN guidelines specify that the cause must be irreversible in order for a determination to occur. As alluded to above, no published case of a brain death mimic has involved a complete examination according to the AAN practice parameters. Moreover, many of these cases had at least one documented finding that is inconsistent with brain death (9, 10).

Clinical Examination

Once the prerequisites have been fulfilled, the neurologic examination to determine brain death can take place. The goal of this examination is to determine if the patient meets the three cardinal criteria of brain death: coma, brainstem areflexia, and apnea. These findings, when present concomitantly in the absence of confounders, confirm irreversible cessation of function of the entire brain, including the brainstem. Hence, a patient with these findings is brain dead, and legally dead according to the UDDA.

Coma is defined as a state of unarousable unresponsiveness in which the patient lies with eyes closed and does not respond appropriately to stimuli, even with vigorous stimulation. Coma must be confirmed by ensuring the patient lacks evidence of responsiveness to auditory, motor, and sensory stimulation. This can be

done by yelling the patient's name, clapping loudly, and vigorously shaking the patient's body. Response to noxious stimuli can be tested by applying pressure to the nail beds, the temporomandibular joint, and the supraorbital ridge.

The required brainstem examination is thorough, and includes testing for the following reflexes: pupillary, oculocephalic, oculovestibular, corneal, pharyngeal, and tracheal. Prior to oculocephalic testing, integrity of the cervical spine must be ensured. The pharyngeal reflex can be tested by stimulation of the posterior pharynx with an object or suction device, and the tracheal reflex should be tested by providing 1 or 2 passes with a suction catheter at the level of the carina.

Apnea Testing

If the patient's neurologic exam has revealed complete brainstem areflexia, the clinician should proceed to the apnea test to assess for an absence of breathing drive as the presence of breathing drive suggests retained brainstem function. Before beginning the test, the patient should be preoxygenated for >10 minutes with 100% FiO_2 to a PaO_2 >200 mm Hg, and the $PaCO_2$ normalized to 35-45 mm Hg (assuming no known CO_2 retention). A baseline blood gas is drawn for reference. The patient is then disconnected from the ventilator, and oxygenation is preserved by delivering 100% O_2 at 6 L/min at the level of the carina with an insufflation catheter. For the next 8-10 minutes, the clinician must monitor closely for respiratory movements. If no such movements are observed during this time period, a repeat ABG is drawn and the patient is placed back on the ventilator. An increase in the arterial PCO_2 to ≥60 mm Hg (or ≥20 mm Hg over the baseline value) is

consistent with brain death as this confirms absence of breathing drive, an essential sign of definitive loss of brainstem function. If the patients oxygen saturation is <85% for >30 seconds, the test should be aborted. In these cases, the procedure can be repeated with CPAP increased to 10 cm H_2O and the 100% O_2 increased to 12L/min.

The apnea test is the most avoided part of the brain death examination (14). This is likely due to fear of complications, which have been reported to be as high as 21% (15). Other studies, however, show that serious complications are uncommon when the patient is adequately preoxygenated and carefully monitored during the test (16,17). Unfavorable pre-test conditions, such as acid-base abnormalities, electrolytes abnormalities, or arrhythmias significantly increase the risk of complications (17,18). Sedatives can depress the respiratory drive during the apnea test and lead to increased pre-test pCO_2 (19). A common difficulty that arises with apnea testing is the inability to predict how quickly pCO_2 will increase once the patient is disconnected from the ventilator (20). The AAN practice parameters recommend 8-10 minutes, which represents the average time for the pCO_2 to rise by 20 mm Hg. This formula, however, does not apply to all patients. If the pCO_2 rises more precipitously, acidosis may lead to hypotension and arrhythmias. Conversely, if the pCO_2 rises slowly, the apnea test will be inconclusive and repeat testing would be required. Alternative methods for monitoring pCO_2 rise, including end-tidal capnography, have led to better estimations of blood gas during the apneic period of the tests. Exogenous administration of CO_2 has also been shown to be a safe method, though this technique is not currently standard practice (21).

Ancillary Testing

If uncertainty exists about a part of the neurologic examination, or if the apnea test cannot be performed, it is acceptable to use one of many ancillary tests to confirm the diagnosis. These confirmatory tests are not mandatory in the United States and are only used during situations when uncertainty exists. In many countries, confirmatory tests are mandatory (22). Ancillary tests are employed to demonstrate loss of bioelectrical activity of the brain or to confirm cerebral circulatory arrest (10). These tests include cerebral angiography, transcranial Doppler ultrasonography (TCD), radionuclide scintigraphy, EEG, CT angiography (CTA), and MR angiography (MRA) (although the latter two are not validated nor recommended).

Cerebral angiography involves injection of contrast medium at high pressure into the aortic arch in order to allow entry into the anterior and posterior circulations. In brain death, no intracerebral filling via the carotid or vertebral arteries should be detected. TCD should show either reverberating flow or small peaks in early systole, and there should be bilateral and anterior/posterior insonation with the probe placed over the temporal bone. A finding of absence of flow is not reliable, as this could be a reflection of inadequate bone windows. Cerebral scintigraphy should show no radionuclide localization in the anterior cerebral artery, middle cerebral artery, or basilar artery territories. Only minimal tracer may be seen in the superior sagittal sinus, since some tracer may drain there from scalp blood vessels. CTA is not currently a preferred ancillary test for confirming brain death, given studies showing high false-negative rates (23) as well

as case reports of false-positives (24). EEG should confirm a lack of reactivity to intense somatosensory or audiovisual stimuli.

The use of ancillary testing to support brain death is not universally accepted. In recent years, there have been arguments by Wijdicks (22) and others against the use of ancillary tests as "confirmatory" tests. In a 2010 review, Wijdicks emphasized that brain death is a clinical state with no prototypical neuropathologic findings. If no such findings exist, then what are we testing for with ancillary tests? He also argued that these tests are costly, and false positives and negatives can (and often do) result in confusion and delays in the organ donation process. Nevertheless, many countries around the world continue to require these tests to be performed (25) and clinicians in the United States frequently elect to perform them (14).

The authors of the most recent AAN practice parameters caution against using ancillary tests in lieu of critical components of the neurologic exam. Indeed, deferring brain death determination is often the most prudent approach in these situations.

The Need

Variability of Guidelines

Despite the publication of AAN practice parameters for the determination of brain death, the ambiguity of the UDDA – originally intended to take into account future advancements in diagnostic techniques – allowed for significant variation in protocols for brain death determination among hospitals, between states, and internationally.

In 2008, Greer et al. (26) evaluated differences in brain death guidelines among leading U.S. hospitals, and found that many centers did not adhere to the AAN practice parameters with respect to the clinical examination, apnea testing and ancillary tests. Institutions varied widely with regard to who could perform brain death determination: a neurologist or neurosurgeon was required to be involved in only 42% of guidelines, and of these, only 35% required that an attending physician be involved. There was poor compliance with the prerequisites specified in the practice parameters, most notably in establishing a cause (63%), as well as in ensuring absence of sedatives and paralytics (55%), acid-base disorders (45%), and endocrine disorders (42%). Widely disparate minimum temperatures were mentioned, with 80% of guidelines specifying temperatures colder than the minimum recommended temperature. The prerequisite blood pressure to begin the examination was also variable, and 24% of guidelines did not specify a value. Only 55% of protocols specified using supplementary oxygen during the apnea test, and only 66% required that an ABG be drawn before the test.

A study by Wijdicks in 2002 (25) examined variability in brain death guidelines across 80 different countries and found that there is also considerable international variability in brain death criteria. Most striking was the omission of the apnea test in 41% of the surveyed countries. Countries also differed in the number of physicians required to declare brain death and the expertise of the examining physicians. A study by Citerio et al. in 2014 (27) confirmed the persistence of widely disparate brain death criteria among countries in Europe.

Variability of Practice

In 2013, Shappell et al. (14) reviewed the charts of all adult brain dead organ donors during 2011 from 68 hospitals in the Midwestern United States, and found that documentation of brain death determination was often deficient, and did not reflect strict adherence to the AAN practice parameters. There was documentation of abnormal sodium levels in two thirds of the subjects, and 15.5% had a core body temperature lower than 36°C. Testing of brainstem reflexes and response to noxious stimulation was documented completely in 45.1% of patients. Apnea testing was not completed in 20.8% of cases, and of these, 93.3% had ancillary testing consistent with brain death. Overall, 44.7% adhered strictly, 37.2% adhered loosely, and 18.1% received a designation of "incomplete." This study was the first to examine brain death determination in actual practice. The authors emphasized that the observed variability in documentation, while highly concerning and certainly unacceptable, does not necessarily reflect practice.

The study by Shappell et al. provided a valuable snapshot of the state of documentation of brain death determination. This is an important first step in ensuring proper practice in determining brain death; however, no study to date has directly evaluated the clinical competence of physicians determining brain death. It is well known that the neurologic examination requires special expertise. For example, the differentiation of spinally-mediated reflexes from retained motor responses associated with brain activity is difficult for any non-neurologist without special training. Similarly, the apnea test requires that the operator be adept in prevention and management of potential complications. If practice is consistent

with knowledge, the studies mentioned above suggest that there is a striking knowledge gap in this area—one that has yet to be assessed directly or addressed effectively. This deficiency of knowledge in such a clinically important, legally complicated, and emotionally charged area led us to develop a training course in brain death determination at our home institution.

Statement of Purpose

We created a two-part brain death determination training course – with both didactic and simulation sessions – in order to achieve the following goals. First, we wanted to determine baseline knowledge of brain death concepts among physicians at varying levels of training and across different specialties at Yale-New Haven Hospital. Second, we wanted to evaluate the clinical competence of these physicians in performing the brain death examination under varied circumstances. Finally, we sought to instruct physicians in the proper determination of brain death via a didactic lecture, video demonstration, and simulation exercise. A long-term aim of our work was to use the experience of running the course and refining our process within our home institution to create a replicable training course that could be implemented at institutions across the country.

Based on our own experience and studies that had emerged highlighting variability of practice, we hypothesized that baseline knowledge of brain death determination among providers would be low. However, we anticipated that knowledge of brain death concepts and clinical competence in performing the examination would increase dramatically following the training course.

Methods

Division of Responsibilities

Ben MacDougall: creation of the simulation scenario, script, and checklist; first assist for ~1/3 of the simulations; data collection and all statistical analysis; preparation of manuscript.

David Greer: creation of the simulation scenario; creation of multiple-choice test questions; primary facilitator for all simulations; data collection; preparation of manuscript.

Liana Kappus: creation of the simulation scenario; preparation of the simulation environment.

Jennifer Robinson: first assist in many of the simulations.

Stephanie Sudikoff: creation of multiple-choice test questions.

Objective

We implemented a simulation-based training course on brain death determination based on the AAN practice parameters to address and assess knowledge and practice gaps at our institution. The intervention consisted of a two-part training course: a didactic session and a scored simulation exercise, and was bookended by before and after multiple-choice tests to assess baseline and post-course knowledge.

Evaluation

Knowledge was assessed using 20-question, multiple-choice pre- and post-tests. The pre-test was given immediately before the didactic session to assess baseline knowledge, and the post-test was given immediately after the simulation to assess the course's efficacy in improving knowledge. The participants were not notified of the pre-test in advance since we sought an accurate assessment of baseline knowledge. Questions formulated by experts at our institution were based on the AAN practice parameters as well as common pitfalls described in the literature. The questions were categorized based on the type of knowledge required to test for specific areas of weakness. The categories were: general knowledge (4 on pre-test, 4 on post-test), clinical exam (4, 4), apnea test (4,4), ancillary testing (3,2), confounders (2,3), and prerequisites (3, 3).

Simulation performance was evaluated according to a 26-point checklist (figures 2,3) that closely mirrors the checklist provided in the AAN practice parameters. In addition to completion of a standard brain death examination, points were awarded for recognizing and responding to several embedded confounders and signs, and for ensuring that prerequisite requirements were met prior to the examination, as described below.

Didactic

The didactic session covered the following aspects of brain death determination: 1) historical context and definition, 2) clinical examination, 3) apnea testing, 4) ancillary testing, 5) confounders and 6) common pitfalls. David Greer, a

neurologist and brain death expert at our institution, gave all didactics. To illustrate the technical aspects of the examination, a proper brain death examination video was shown.

Simulation

We chose a simulation-based approach given its superiority over traditional medical education techniques in achieving specific clinical skills goals (28).

Preparation and Equipment

We utilized the SimMan 3G simulation manikin (SimMan 3G®, Laerdal Medical, Wappingers Falls, NY). This model was selected for its pupil reactivity and seizure functionalities, both used in our scenario. We adapted the manikin with an on-layed earpiece that allowed for injection of water into the ear canal to assess the oculovestibular reflex without compromising the electronics. The manikin was intubated with a 7.0 mm cuffed endotracheal tube with an in-line suction catheter in place. The monitor displayed heart rate, oxygen saturation, blood pressure, temperature, respiratory rate and end tidal CO_2.

We provided ice water and a 60 cc syringe with tubing to assess the oculovestibular reflex (OVR); cotton swabs for corneal reflex testing; a reflex hammer to assess deep tendon reflexes, plantar response, and responsiveness to noxious stimuli; a flashlight for pupillary assessment; and a suction catheter and oxygen tubing for the apnea test. The scenario was scripted and programmed using Laerdal SimMan 3G software and progressed based on the participant performing

critical actions and/or the facilitator offering cues to move forward within the simulation.

Staff

A simulation technician prepared the environment and controlled the simulator from a control room. The facilitator, a senior neurologist versed in brain death, conducted the session, including the orientation, simulation, and debriefing. We also invited nurses and mid-level providers from our neuro ICU to assist with the simulation and debriefing exercises. Facilitators were required to participate in an 8-hour faculty development course run by our institution's simulation center (SYN:APSE Center for Learning, Transformation and Innovation).

Orientation and Initial Prompt

Participants were read a scripted orientation to the simulator's capabilities and limitations, the environment and equipment, and the process and expectations for the session (figure 1). The facilitator provided a scenario of a 54-year-old man who suffered a prolonged cardiac arrest 48 hours earlier, not treated with therapeutic hypothermia. Vital signs, oxygen saturation, ventilator settings, as well as recent chest x-ray, head computed tomography results and arterial blood gas (ABG) values were provided. We immediately provided information ruling out several confounders, rather than having the participant seek this information independently, including the absence of paralytics, prior therapeutic hypothermia, sedating medications, cervical spine injury, hyperammonemia, or significant acid-

base, endocrine or electrolyte disorders. In practice, eliminating these confounders is obviously of critical importance. However, we eliminated them to save time so that the simulation could be spent practicing the technical aspects of the clinical exam and apnea test, which lent themselves more to simulation-based learning.

Participants were told to perform a complete brain death exam, including an apnea test. They were informed that the facilitator was to function as nurse and respiratory therapist, that time was adjusted for the purposes of the exercise (for example, the facilitator could state that 24 hours had passed since a change was requested, rather than having to wait for the effects of a change), and that the patient might not be brain dead on initial evaluation. They were asked to verbalize their examination and thought process.

The Clinical Exam

Participants were allowed to complete the examination in whatever order they preferred, although the apnea test was to be performed last. A checklist adapted from the most recent AAN guidelines was used to track and evaluate performance (figure 2). If a participant omitted a component of the clinical exam, we did not notify them until after the exercise was completed.

The manikin was fully covered with a sheet. The physician was expected to uncover the extremities (maintaining decency on the manikin) to facilitate observation of any movement in response to stimulation. There were three findings on the examination that prevented the initial declaration of brain death. The first was communicated in the initial prompt—the patient's temperature was 34°C,

requiring warming to achieve at least 36°C. The second was recognition that the patient was having a seizure, manifested by spontaneous vigorous clonic activity of the manikin one minute into the exercise. If the physician correctly recognized that a seizure is incompatible with a determination of brain death, we then instructed that that one day had passed without any further witnessed seizures. The last incompatible finding was a reactive pupil. If the examiner correctly chose to stop the examination, we would indicate that one day had passed with no further evidence of pupillary reactivity. Upon further examination, the pupil would no longer react. The remainder of the clinical examination was consistent with a clinical diagnosis of brain death. The expected components of a complete examination, along with their associated findings, are outlined in the script (figure 2).

With completion of the clinical examination, we provided an additional prompt: the urine bag was filling rapidly, implicating possible central diabetes insipidus. The correct response was to give intravenous fluids and/or DDAVP to correct hypovolemia. If the participant did not respond appropriately, we explained the correct response to ensure that they could move forward with apnea testing.

The Apnea Test

The script and evaluation checklist for the apnea test (figure 3) were also adapted from the AAN practice parameters. The facilitator began by reorienting the participant with the most recent ventilator settings, blood pressure and ABG values. The ABG reflected any changes in minute ventilation or FiO_2 the participant may have made earlier, such as pre-oxygenation or establishing normocarbia. The initial

ABG values were pH 7.54, pCO_2 30 mm Hg, and pO_2 110 mm Hg (henceforth abbreviated as pH/pCO_2/pO_2), with the ventilator set on assist control ventilation (respiratory rate 20/minute, tidal volume 750 mL, FiO_2 50%, PEEP 5 cm H_2O). The facilitator asked the participant if they wished to modify the ventilator settings before the apnea test. We listed three potential ABG values in the script based on these modifications (figure 1). If the participant chose to decrease the minute ventilation, the ABG would be 7.38/42/90, and if they also chose to increase the FiO_2 to 100% the ABG would be 7.38/42/270. The appropriate action was to decrease the minute ventilation via respiratory rate and/or tidal volume reduction, and to increase the FiO_2 to 100% for pre-oxygenation.

At the equivalent of three minutes into the apnea test, the participant was informed that the blood pressure was slightly lower (but still within an acceptable range); no action was warranted. At the equivalent of six minutes into the apnea test, the participant was notified that the patient's blood pressure had dropped to 98/50 mmHg. The correct response was *not* to terminate the exam, but rather to administer a vasopressor or fluid bolus, which results in correction of the blood pressure to an acceptable level. At the equivalent of ten minutes into the apnea test, the participant was notified that 10 minutes had passed and that the patient's pulse oximetry reading was 88%. This reading is within the acceptable range, and the correct response was to ask for an ABG and reconnect the ventilator. The final ABG result was 7.10/66/65, and the participant was expected to declare brain death.

Unlike during the clinical examination, the facilitator guided the participants through the apnea test if they were unsure of the next step to ensure that every

participant had the experience of conducting a full apnea test. Furthermore, in the context of a simulation exercise, anticipating and realistically simulating the results of an incorrectly conducted apnea test was tedious and of little educational value, since the results of an apnea test are only meaningful if conducted according to established guidelines. In addition, the physiological models that the simulator employs are not sophisticated enough to account for the heterogeneous constellations of disturbances that often occur in patients that have suffered severe neurological damage. For these reasons, we chose to only offer three possible ABG values based on the correct changes in the ventilator settings (i.e. decreasing minute ventilation, increasing FiO_2 to 100%, or both).

Debriefing

Following the simulation, the participant and facilitator debriefed. The structure of this session was based on the 3-phased approach prominent in simulation literature. This approach includes: 1) a description phase during which participants offer initial reactions and their understanding of the clinical facts of the case; 2) an analysis phase during which the facilitator and participant discussed performance gaps; and 3) a synthesis phase during which the facilitator and participant summarized key take home points to apply to clinical practice (29-31). The checklist was used during the analysis phase to provide specific feedback on performance. Participants also had the opportunity to return to the mannequin to practice challenging techniques. Subsequent to the debriefing, participants

completed an evaluation of the session and facilitator for quality improvement purposes. They then completed the 20-question post-test.

Statistical Analysis

Test and simulation scores between groups were compared using Student's *t*-test for continuous variables. Statistical significance was established at $p < 0.05$ (2-tailed). Comparisons were made between pre-course, post-course and simulation scores across different specialties and different levels of training. The Pearson product-moment correlation coefficient was calculated based on matched pre-test and simulation scores of all simulation participants.

Results

111 clinicians participated in the course (table 1), 38 of whom completed the simulation. Our highest participation rates came from neurology attendings (17/32 practicing faculty), trauma and surgical critical care attendings (10/11 practicing faculty), neurology residents (19/23 from PGY2-4), neurosurgery residents (9/14 from PGY1-7), and emergency medicine residents (13/38 from PGY2-4).

Participants scored an average of 43.1% (n=111) on the pre-course test. Overall, pre-test scores (figure 4) were higher among attendings (n= 51) than residents (n= 42), with scores of 49.0% vs. 40.4%, respectively (p= 0.008). There was also a positive trend among residents between post-graduate years (PGY) 1 and 4, with residents scoring incrementally higher in each successive year (figure 5). Residents in PGY5 and above, however, did not follow the same trend. Among physicians in neurology and neurosurgery, attendings scored significantly higher than residents (54.7% vs. 42.1%, p= 0.002). Attendings in neurology and neurosurgery scored significantly higher than those in other specialties (54.7% vs. 41.0%, p= 0.002). Similarly, residents in neurology and neurosurgery outperformed other residents, though the margin was not significant (42.1% vs. 37.1%, p= 0.24). Interestingly, pre-test scores among the 38 participants who have completed the entire course were significantly higher than the 52 who have had the opportunity to complete the simulation but have not yet done so (45.3% vs. 38.6%, p= 0.04).

Simulation performance (figure 6) was weakly correlated (r=0.30) with pre-test scores. The mean simulation score among all providers was 67.2% (n= 38). There were no significant differences in simulation performance based on specialty

or level of training. Attendings (n=21) scored higher than residents (n=15) on the 26-point evaluation (72.2% vs. 64.4%, p = 0.15), and physicians in neurology and neurosurgery scored higher than those in other fields (69.8% vs. 65.7%, p = 0.47). Common omissions (figure 7) included: uncovering the extremities during the clinical exam (79% omitted), uncovering the chest and abdomen during the apnea test (79% omitted), and testing for blinking to visual threat (76% omitted). Areas of strength (figure 8) included: testing the oculocephalic reflex (95% performed), decreasing the minute ventilation on the ventilator to achieve normocarbia prior to the apnea test (82% performed), detaching the ventilator and providing O_2 via suction catheter to begin the apnea test (84% performed), asking for a repeat ABG and the end of the apnea test (89% performed), and correctly declaring brain death (87% performed).

The simulation cohort's post-test scores were significantly higher than their pre-test scores (figure 9), improving from a mean of 45.4% to a mean of 73.3% ($p<0.001$). Participants improved significantly in all categories, with the exception of ancillary testing, where there was a non-significant decrease in scores.

On the post-course feedback form, participants gave the course an average rating of "excellent," and selected "strongly agree" in response to the statements "the course was realistic," "I was able to practice skills I often don't get to practice," and "I will apply what I learned to my job."

Discussion

Herein we describe a didactic and simulation-based intervention for caregivers to increase competence in clinical brain death determination. The necessity of this intervention was evidenced by participants scoring an average of 43.1% (n=111) on the pre-course test, and 67.2% (n= 38) on the simulation, which evaluated fundamental knowledge and clinical skills required to perform an accurate brain death examination. These results are even more striking considering that the majority of these physicians were specialists in fields in which the brain death examination features prominently. Overall, the success of our intervention is evidenced by a 27.9% (n=38) absolute improvement in mean score from pre-test to post-test, and by the uniformly positive feedback we received from our participants, who routinely emphasized the importance and utility of training in brain death determination.

Based on pre-course tests, attendings in neurology and neurosurgery are more familiar with brain death concepts and guidelines than specialists in other fields commonly involved in brain death determination. This finding is particularly important when considering that most brain death examinations are not performed by neurologists or neurosurgeons (14), and that many leading U.S. hospitals' guidelines do not require these specialists to perform the examination, or to be involved at any point during the process (26). Level of training also seems to play an important role: despite scoring higher than residents in other specialties, neurology and neurosurgery residents scored significantly lower than attending physicians in their field. This is not reflected in hospital policies: among the above-mentioned

hospitals that require a neurologist or neurosurgeon to perform the brain death examination, the majority do not specify that this must be an attending physician (26). Furthermore, in our study population, knowledge of brain death concepts among residents increased with each post-graduate year. The exception in our study was the PGY5+ cohort, which performed the poorest of all groups of residents. This could be explained by the relatively small sample size of 5 PGY5+ residents, and by the fact that the neurology program – which represents the highest-performing group of residents – ends at PGY4. This trend suggests that residents themselves cannot be viewed as a homogenous group in regard to clinical competence in brain death determination. Again, we are not aware of any directives in hospital policies that would suggest that this knowledge gap has been acknowledged. This is even more remarkable when considering that only the top 50 U.S. News and World Report-ranked institutions were included in the Greer et al. study. Presumably, these institutions have consistent access to attending neurologists and neurosurgeons who could perform all brain death determinations. It is reasonable to suggest that these physicians should be the preferred examiners in brain death cases at hospitals with adequate staff, at least until a time that other practitioners can be appropriately trained.

No group performed significantly better than another in the simulation exercise, and simulation scores were weakly correlated ($r=0.30$) with pre-test scores. This lack of correlation could be due to a number of factors. Firstly, the pre-test was administered without warning, which likely provided a truer assessment of baseline knowledge. Before the simulation, however, all participants benefited from

the didactic session and significant time for preparation, which served to mitigate this initial knowledge gap. It is also possible that physicians who did not have a background in neurology or neurosurgery spent more time preparing for the simulation, and that those with a neurology or neurosurgery background were overconfident in their abilities. Finally, our ability to evaluate higher-level technical and observational skills, such as differentiating spinally-mediated reflexes from cerebrally-mediated motor responses, was somewhat limited by the simulation mannequin's capabilities. It is possible that neurologists and neurosurgeons may have scored higher if evaluated while performing the examination on a potentially brain dead patient, where these skills can be more easily demonstrated and evaluated. This setting, however, is not conducive to training and evaluating a large group of physicians due to: 1) the paucity of brain death examinations occurring at our institution, and 2) the time required to coordinate such a session. We feel that the simulation mannequin allows trainees to benefit from an excellent hands-on experience without wasting time or institutional resources. An added benefit is that we were able to standardize all signs and neurological exam findings for every trainee to ensure uniformity across the study population. Additionally, for trainees who wish to return for repeat simulation sessions, we are able to vary the signs and findings to provide them with the broadest possible experience in a safe environment.

Barriers to successful implementation of this strategy on a large scale – including multi-departmental cooperation and participation – are daunting. But our experience speaks to the promise of our approach. Thus far, 111 clinicians have

participated in the course. This, as shown above, represents a significant proportion of the clinicians who could foreseeably be involved in a brain death determination at Yale-New Haven Hospital. Of these 111 participants, 38 have completed the simulation component. Promisingly, Dr. Greer was recently able to implement a similar simulation training course at a national conference (Neurocritical Care Society) for 20 trainees, utilizing 5 other brain death experts and 2 SimMan manikins.

A critical issue throughout the implementation of this training course was that the number of completed simulations lags behind the number of didactic attendees. This happened for several reasons. First, the didactic was usually scheduled during a lecture slot requiring attendance, including grand rounds, noon conference or special invited lectures to a specific group. However, simulation required participants to schedule 30-minute sessions. Furthermore, the prospect of being evaluated by a senior physician can be daunting, and it is possible that fear of criticism – especially among those unfamiliar with the brain death exam – may have led to avoidance of the simulation session, a point supported by significantly lower pre-test scores among those who did not sign up for the simulation. We have also been limited by our ability to provide enough time slots for participants. At 30 minutes per participant, it was unrealistic to train all 111 participants within a year. This problem could be overcome by involving more instructors in the training course. At our institution, a single physician administered the entire course, including didactics and simulations, in order to ensure uniformity across the study population. Implementing this course at other institutions would require much less

time and effort if additional instructors participate, opening up more simulation time slots and expediting the training process. Other institutions can also expect a much higher rate of simulation participation, since all of their trainees will have have ostensibly signed up for a simulation-based experience. Our study population was not aware of the course's existence prior to the pre-test and didactic component, which was administered without warning to accurately measure baseline knowledge. Thus, despite our best efforts to identify those most likely to be involved in a brain death determination, we surely gave the didactic to many physicians who felt that they would not gain much from our course.

In considering how to best implement our intervention at other sites, we should contextualize it within existing programs. At present, there are two emerging training courses in brain death determination. These courses, offered by the Cleveland Clinic and the University of Chicago, represent opposite ends of the spectrum in terms of rigor and generalizability.

The Cleveland Clinic course (32) is free, online, and intended for physicians, fellows, and residents. The course takes approximately 1 hour to complete and covers all aspects of brain death determination clearly and concisely. Each step of the cranial nerve examination is illustrated through videos, showing responses consistent/inconsistent with brain death. In addition to the examination, the course provides information on documenting brain death and tools for discussing brain death with families. An outline of the laws and accepted medical standards for each state is also provided. The benefit of this web-based approach is its potential for wide impact – the course can be administered at minimal cost, and it can reach

many institutions that would otherwise have little or no exposure to a contemporary brain death training course. A drawback is the lack of hands-on experience or feedback on clinical skills in the context of an evolving clinical scenario, which can only be gained through a simulation-based experience or on-the-job training.

On the opposite end of the spectrum is the University of Chicago Brain Death Simulation Workshop (33), which is a full day training course intended to provide participants with a comprehensive, simulation-based experience. The workshop is run yearly in Chicago and has 20 slots available for interested faculty, fellows, or residents in neurology, neurosurgery, critical care, trauma surgery, and emergency medicine. Simulation stations provide hands-on experience with the brain death exam, including proper management in the setting of a hemodynamic crisis or diabetes insipidus. The workshop also includes opportunities to discuss brain death with professional actor "families." Complementing these simulations are lectures and case studies emphasizing various brain death concepts. All activities are highly structured and staffed by expert faculty members who provide personalized feedback. The clear strength of this course lies in its comprehensiveness – it provides participants with unparalleled hands-on learning under the supervision of expert faculty. The limitations of this course are associated with its scale – only 20 physicians can be trained per year, at a cost of $500-1000 per physician. The impact of this workshop, therefore, relies on the ability of trained physicians to transmit the expertise they have gained to their home and surrounding institutions. We believe that participants who have completed this workshop are ideal candidates to become

"champions," and operate a smaller scale course – such as the one described herein– at their home institutions.

Our course lies between these two with regard to resource and learning intensity, as it combines a short, easily replicable didactic session with a hands-on learning experience in a manner that can be delivered to substantial numbers of participants at once. As outlined above, participants typically devote only about one and a half hours to the course, and derive a significant amount of benefit from their time investment. We strongly believe that our model provides the correct level of rigor to train a core nucleus of clinicians at any hospital.

However, limitations to widespread dissemination of our intervention include that it was implemented at a major teaching hospital with resources such as a staffed simulation center, which may limit applicability to other institutions. At Yale, we also had a neurointensivist who was fully dedicated to this project and the countless hours of lectures and simulation required to see it to completion. Our hope is that other institutions will recognize the need to improve upon clinician competence and standardization of brain death determination, and heed the "call to action" that has been echoed in our community so often in recent years. Partnerships with neighboring institutions for resource sharing will be essential in achieving this end.

Our immediate goal is to finish training all physicians involved in brain death determination at our institution. In doing so, we will work to further hone our intervention to ensure its optimal effectiveness. More broadly, we aim to train all interested physicians in our region, which includes Connecticut, New York, Rhode

Island, and Massachusetts. For physicians in the immediate area capable of driving to Yale-New Haven Hospital (YNHH), we will be able to schedule 30-minute simulation time slots on an individual basis. Our brain death experts could give the didactic session to a large group at their local hospital, or it could be arranged to take place at YNHH. Eventually, we may replace the didactic with a video lecture or online mini-course that participants could complete before arriving for their simulation. This would further enhance participant knowledge prior to the simulation, and would eliminate the need to coordinate the didactic sessions. For physicians travelling to YNHH from greater distances, we plan to hold multiple half-day sessions. These sessions will consist of a group didactic portion followed by multiple simultaneous simulation exercises led by several of our staff neurointensivists, who will be appropriately trained in brain death determination and simulation. At YNHH, we have 5 SimMan 3G simulators and 6 neurointensivists boarded in neurocritical care, which would allow for 5 simultaneous sessions.

Using this model, our aim is to train 75-100 physicians every 6 months, with the ultimately goal of training 300-400 physicians over the next two years. We are currently in the process of applying for an R18 grant to fund this exciting expansion of our training course.

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Brain Death Simulation

Initial prompt:

Doctor, the patient, Mr. Jones, is a 54-year-old man S/P prolonged cardiac arrest 48 hours ago. He has not received any paralytics, induced hypothermia, or sedating medications. His cervical spine has been cleared from injury. He has no significant acid-base, endocrine, electrolyte disorders or hyperammonemia. He is no longer overbreathing the set rate on the ventilator.

Vitals: BP 120/75 HR 80 Temp 34°C O_2 saturation 98%

Vent settings: Assist Control Ventilation RR 20 TV 750 FiO_2 50% PEEP 5

Most recent ABG: pH 7.54 pCO_2 30 pO_2 110

CXR: wnl

CT: diffuse cerebral edema severe enough to cause cerebral circulatory arrest and death

Doctor, you can do a complete brain death exam on this patient, including an apnea test. You may safely perform all aspects of the evaluation. If you need any additional information or equipment, please let me know. Please note that time is adjusted for the purposes of this examination: for example, if you change one parameter you may get a response in 2 seconds that represents 5 minutes or even one day. Please note that the patient may or may not be truly brain dead. I will function as a nurse and as a respiratory therapist. Please verbalize your examination as you perform it.

Note:

- If they choose to decrease the RR or TV now: *Doctor, the ABG is now 7.38/42/90*.

- If they also choose to increase FiO_2 to 100%: *Doctor, the ABG is now 7.38/42/270*.

- If no changes are made, ABG stays the same until apnea testing.

Fig. 1 Initial prompt, including vitals, oxygen saturation, ventilator settings, and a recent ABG. Three possible ABG values are listed here based on initial changes made in ventilator settings.

Interventions	Prompt
Prerequisites	
Use of bear hugger or other warming method ☐	If used: *Doctor, the temperature is now 37 °C*
Clinical Examination	
Uncovers extremities ☐	Approximately 1 minute into the evaluation, patient will spontaneously seize. ↓ (response should be to end examination) ↓ *Doctor, it has now been 1 day and the patient has not had any additional seizure-like movements.* ↓ (response should be to repeat examination, patient will now be unresponsive)
Stops examination following seizure ☐	
Provides auditory and tactile stimulation ☐	Loudly calling name, sternal rub, shaking, etc.
Tests blink to visual threat ☐	First time examiner tests pupillary function, one pupil will be reactive. ↓ (response should be to end examination) ↓ *Doctor, it has now been 1 day, and the patient appears to have lost the pupillary reflex; would you like to repeat the examination?* ↓ (response should be to repeat examination, pupils will now be non-reactive)
Tests reactivity of pupils: stops following reactive pupils (1st time) ☐	
pupils are non-reactive (2nd time) ☐	
No oculocephalic reflex ☐	
Positions HOB at 30° ☐	If they do cold water in one ear: *Doctor, it has been 5 minutes, do you want to go to the other side?* If they go to test the other side, can tell them not necessary.
Confirms patency of ear canals ☐	
No oculovestibular reflex in either ear ☐	
No grimace to noxious stimulation on the cranium ☐	Cranium locations for pain: supraorbital ridge, TMJ May also perform nasal tickle in addition to corneal reflex
No corneal reflex ☐	
No cough with ET tube stim of posterior pharynx ☐	
No cough with deep bronchial suctioning ☐	
No motor response to pain in all 4 extremities ☐	
Following clinical examination: *Doctor, the urine bag keeps filling rapidly, approximately 300-400 cc's per hour, and needs to be changed.*	
Gives fluid bolus, increases IVF rate, and/or gives DDAVP. ☐	

Fig. 2 Script and checklist for the clinical examination portion of the simulation.

Apnea Test		
Decreases minute ventilation	☐	Restate most recent vent settings, ABG, and BP. *Doctor, do you want to change the vent settings before we start the apnea test?* ↓ (response should be to decrease RR and/or TV and increase FiO_2 to 100% (if not already done earlier)) ↓ If changes are made: *Doctor, it has now been 30 minutes, and the ABG is 7.38/42/270. The BP is 110/70.* ↓ (response should be to detach ventilator and tape suction catheter attached to O_2 at 5-10L) ↓ If changes are made: *Doctor, it has now been 3 minutes and the blood pressure is 110/60* ↓ (response should be none) ↓ *Doctor, it has now been 6 minutes and the blood pressure is 98/50.* ↓ (response should be pressor +/- fluid bolus) If changes are made: *Doctor, the blood pressure is now 108/65* ↓ Regardless of response: *Doctor, it has now been 10 minutes and the pulse ox is 88%.* ↓ (response should be to ask for ABG, reconnect the ventilator) ↓ If they ask for ABG: *Doctor, the ABG is 7.10/66/65* ↓ (response should be to declare brain death)
Changes FiO_2 to 100%	☐	
Detaches ventilator, suction catheter placed at level of carina with O_2 at 5-10 liters	☐	
Uncovers chest/abdomen	☐	
Observes chest/abd wall movement, monitors vitals during apnea test	☐	
Responds with vasopressor +/- fluid bolus	☐	
Reconnects patient to the ventilator	☐	
ABG at the end of apnea test to see if threshold is met	☐	
Declares evaluation compatible with brain death	☐	

Fig. 3 Script and checklist for the apnea test portion of the examination.

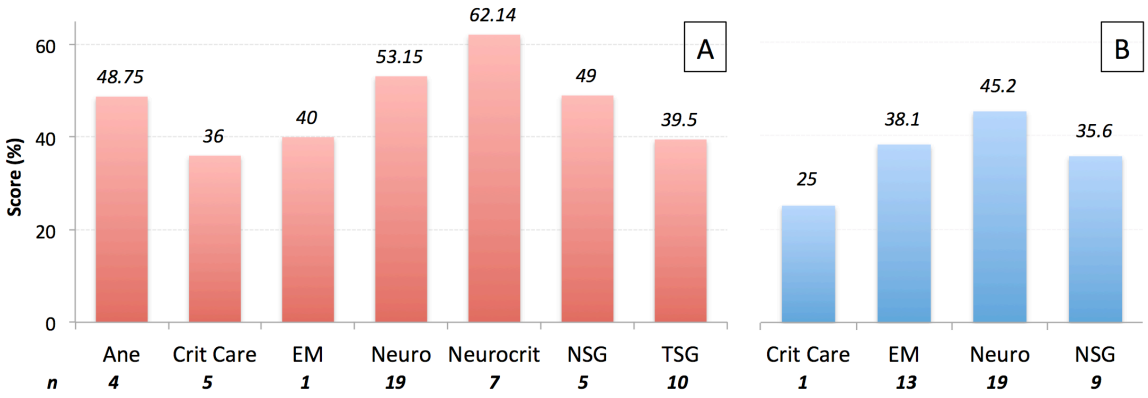

Fig. 4 Pre-test scores (%) among: A) attendings and B) residents, by specialty. Mean score among all providers on the pre-test was 43.1% (n=111). Ane, anesthesia; Crit Care, critical care; EM, emergency medicine; Neuro, neurology; Neurocrit, neurocritical care; NSG, neurosurgery; TSG, trauma surgery.

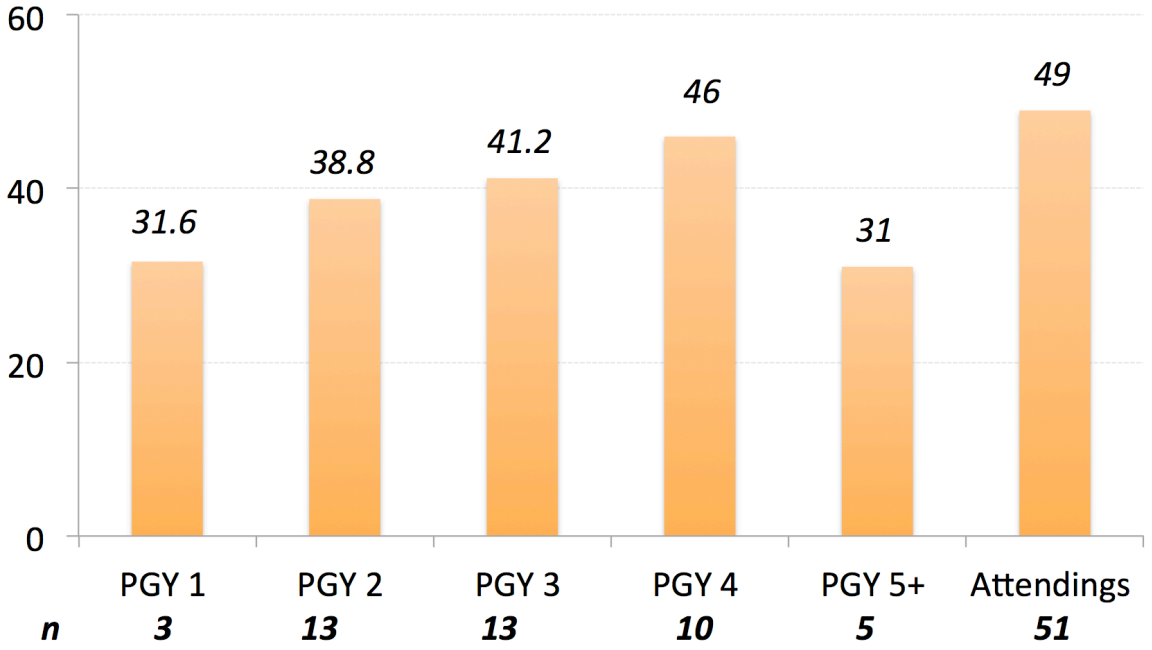

Fig. 5 Pre-test scores (%) by level of training. PGY, post-graduate year.

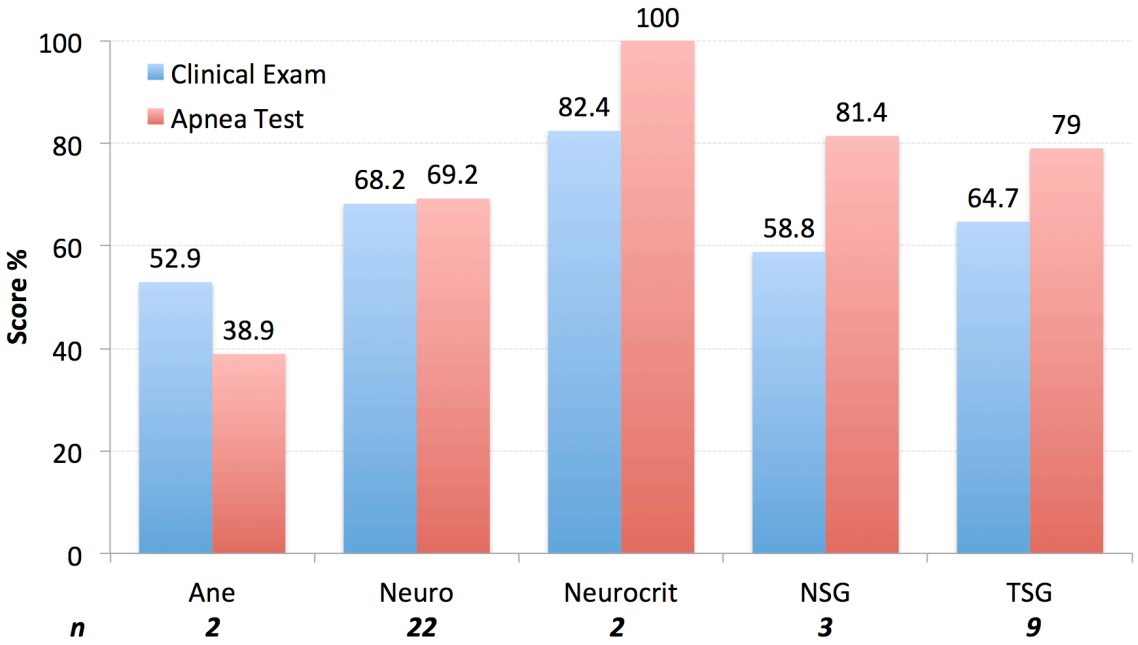

Fig. 6 Simulation scores (%) on the clinical exam and apnea test by specialty, including both residents and attendings. Mean simulation score among all participants was 67.2% (n=38). Ane, anesthesia; Neuro, neurology; Neurocrit, neurocritical care; NSG, neurosurgery; TSG, trauma surgery.

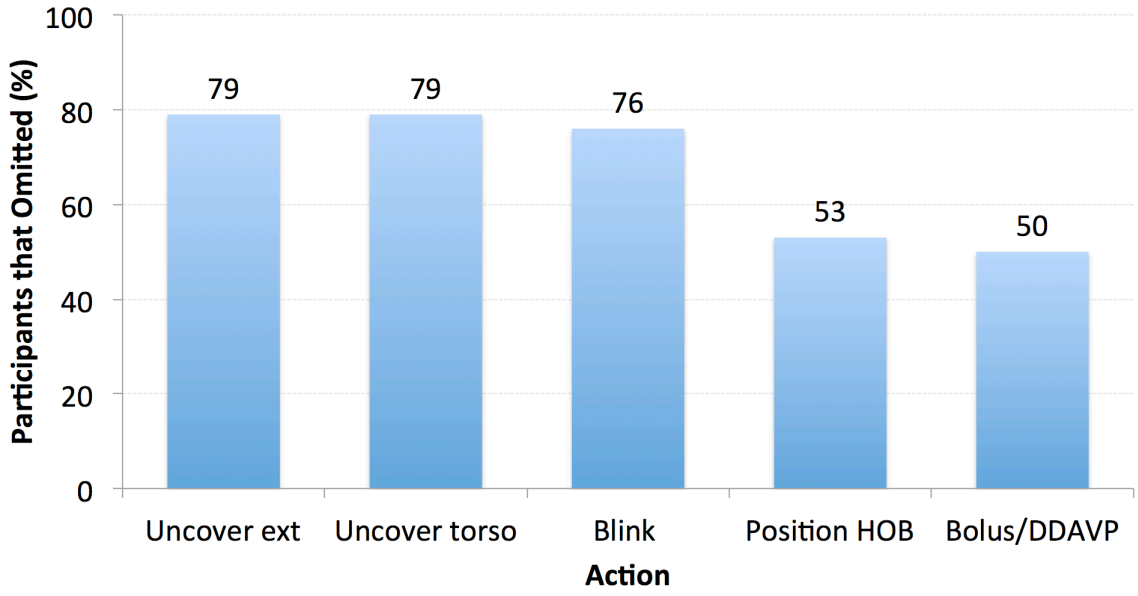

Fig. 7 Common omissions in the simulation exercise. Uncover ext: uncovers extremities during clinical exam; Uncover torso: uncovers torso during apnea test; Blink: tests blink to visual threat; Position HOB: positions head of bed at 30° for oculovestibular reflex testing; Bolus/DDAVP: provides fluid bolus or DDAVP to correct central diabetes insipidus.

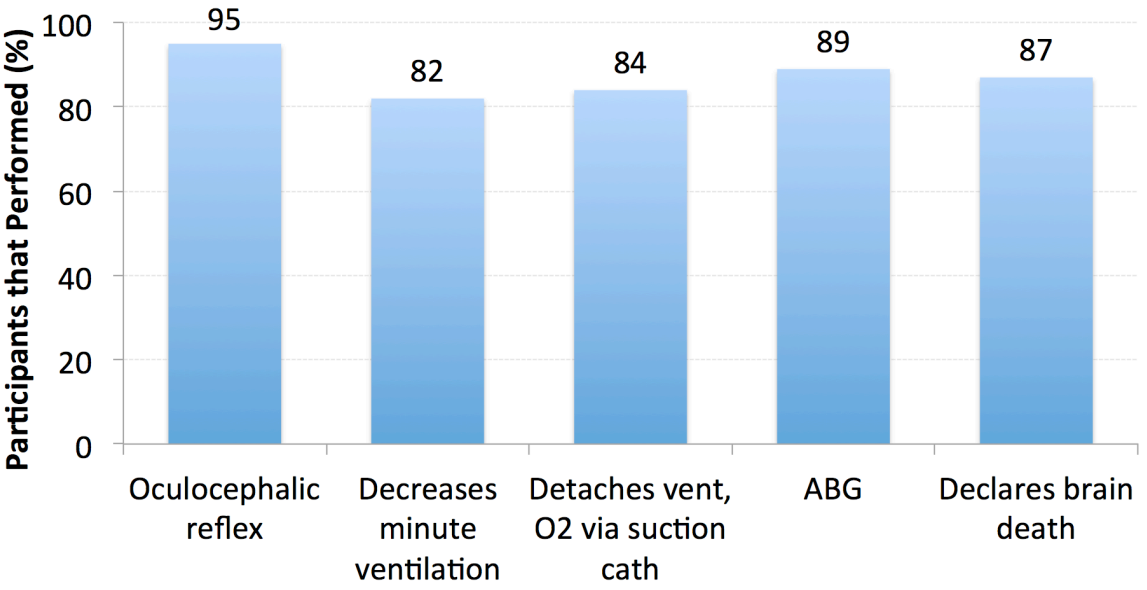

Fig. 8 Areas of strength in the simulation exercise. Oculocephalic reflex: tests oculocephalic reflex; decreases minute ventilation: action performed at beginning of apnea test to achieve eucapnea; detaches vent, O2 via suction cath: action performed at beginning of apnea test to start CO2 challenge; ABG: asks for ABG at the end of the apnea test; declares brain death: recognizes that ABG is consistent with diagnosis of brain death at end of apnea test.

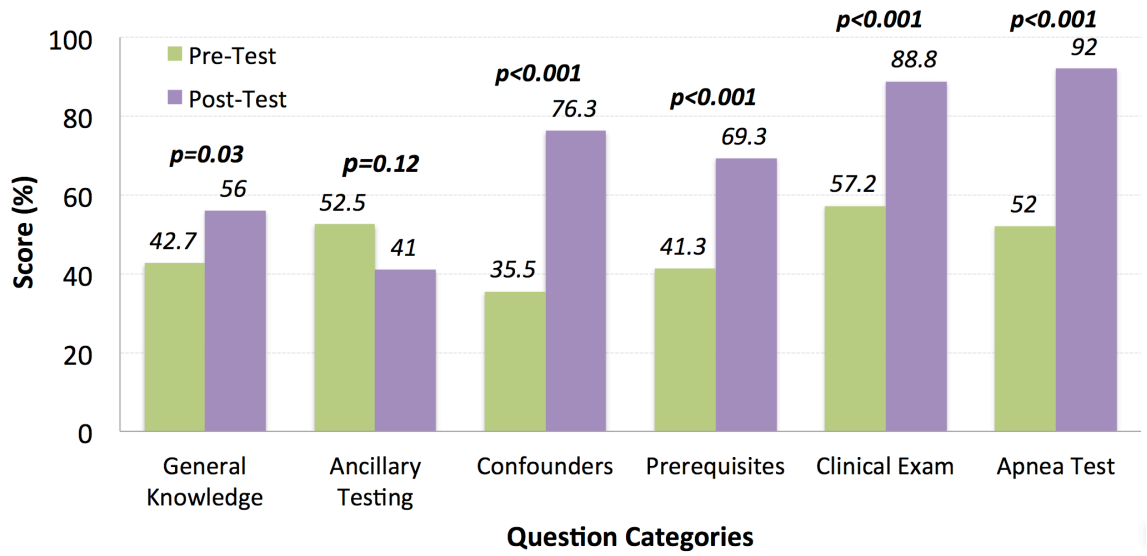

Fig. 9 Pre-Test and Post-Test scores among simulation participants, by question category. In this group, mean scores on the pre-test and post-test were 45.4% and 73.3%, respectively.

Table 1. Specialty and level of training of didactic and simulation participants.

Level of Training *Specialty*	**All Participants** (n = 111)	**Simulation Participants** (n = 38)
Attending	**51**	**21**
Anesthesia	*4*	2
Critical Care Medicine	*5*	0
Emergency Medicine	*1*	0
Neurocritical Care	*7*	2
Neurology	*19*	8
Neurosurgery	*5*	0
Trauma Surgery	*10*	9
Fellow	**2**	1
Critical Care Medicine	*1*	0
Neurology	*1*	1
Resident	**42**	**15**
Critical Care Medicine	*1*	0
Emergency Medicine	*13*	0
Neurology	*19*	12
Neurosurgery	*9*	3
Physician Assistant	**3**	**1**
Critical Care Medicine	*1*	0
Anesthesia	*1*	0
Neurology	*1*	1
Nurse	**8**	**0**
Critical Care	5	0
Other	3	0
Student (Medicine, PA)	**6**	**0**