

OPO 34451L Death Declaration SBAR, updated 10/4/16

**Situation:** During a routine OPO site survey, site surveyors noted irregularities in brain death pronouncement documentation retained for donor records.

Six donor records were missing one of the following elements: clinical exam showing absence of all brainstem reflexes, confirmatory test in lieu of aborted apnea tests (donor instability), or brain death pronouncement note signed by an attending physician.

Following the site surveyors' request, the OPO produced (after several hours and contact with donor hospitals) the needed documentation for three of these records. The lead surveyor asked for an immediate containment plan to prevent any brain death documentation irregularities from occurring. A containment plan was provided before the end of the survey.

The remaining three records were cited in the initial report sent to the OPO along with a request for additional information requested by the MPSC. The response deadline to provide the CAP and all requested information for this expedited review was September 27, 2016.

The OPO provided the Corrective Action Plan and response to the additional information request on September 27, 2016. Additional findings of concern are noted under Assessment.

**Background:** Initial three cases cited in this case are listed below.

**Case #1:** [REDACTED] admitted with massive subarachnoid hemorrhage. Arrived to ED in comatose state. Poor prognosis discussed with family, then declared dead at 4:16pm by a Nurse Practitioner, "Pt EEG consistent with brain death. 1616 T.O.D. Reviewed c Dr. XX."

*UNOS staff asked for the OPO to provide additional documentation including the definitive neurological exam by physician as well as the hospital's policy on brain death determination (who can determine death).*

The OPO was provided an additional clinical note (by NP) "History and Physical: ...The patient on arrival was comatose. Pupils were fixed and dilated at 5mm bilaterally, showed minimal gag reflex. No response to deep painful stimuli. CT scan of her head did show a diffuse subarachnoid hemorrhage, bilateral basal cisterns, ventricles were dilated, and there was entrapment of the temporal horn. Hospital Cause: External ventricular drain and ICP monitor were placed. Poor prognosis was discussed with the family. She did have an EEG, which was consistent with brain death and was declared dead at 4:16pm" The OPO also included a copy of the EEG report, which is "consistent with electrical silence of the cortex."

Hospital policy (provided by the OPO) requires MD signature for brain death pronouncement.

**Case #2:** 17 year old female, [REDACTED] brain death documentation in donor record includes only neurological exam (consistent w BD), note of a second physician being in agreement with exam.

*Site surveyors asked the OPO to provide apnea test or other confirmatory test documentation. OPO case notes indicate that the OPO requested an apnea test, but the test was aborted r/t patient instability. No confirmatory test in lieu of an apnea has been provided to date.*

Case #3: Donor [REDACTED] – only death documentation is MD note that reports “I discussed with a large family group the results of the Cerebral Blood Flow Study. The study showed ‘No intracerebral blood flow,’ confirming our suspicions of brain death. Will place the time of death as that of the cerebral Flow Study: 1030 AM today (9/11/2015).”

Surveyors asked the OPO to provide the neurological exam contributing to determination of death. The OPO provided additional clinical notes, but no neurological exam was included. (“No meaningful response”) To date, no clinical neurological exam consistent with brain death has been provided.

**Assessment:**

Please note the following items of interest and/or concern under the Additional Information Request:

Response #1 – updated brain death policy titled “FS B3 000 – Verification and Documentation of Brain Death” (09/05/2016), new policy does not include the initial neurological exam as part of the standard documentation.

Responses #5 and #8 – no information provided by OPO for these questions.

Response #6 – Lookback Audit

\*Several documentation issues of concern cited below: (Please note more serious cases in top section.)

Donor: [REDACTED] no standard apnea test performed, CBF performed on 10/27/15 – 13:24 study did not meet criteria for brain death.

Donor: [REDACTED] clinical exam not in DonorNet, clinical exam provided by OPO states “Pupils are minimally if at all responsive to light.” Apnea not completed, confirmatory test noted in BD note, but UTV – not in DonorNet.

Donor: [REDACTED] clinical exam not in DonorNet, clinical exam submitted by OPO states “Patient still had positive respirations.” Confirmatory test is verified in DonorNet.

Donor: [REDACTED] no documented clinical exam per OPO, BD note included reference to completed apnea test.

Donor: [REDACTED] no documented clinical exam per OPO, confirmatory test verified.

Donor: [REDACTED] no documented clinical exam per OPO, confirmatory test verified.

\*The following cases had incomplete documentation or were unable to verify (not in DonorNet):

Donor: [REDACTED] unable to verify (UTV) confirmatory test, not in DonorNet. (Otherwise ok.)

Donor: [REDACTED] UTV confirmatory test results, not found in DonorNet. (BD note ok.)

Donor: [REDACTED] no confirmatory test or apnea test completed.

Donor: [REDACTED] UTV submitted donor information, no BD documentation in DonorNet. (Otherwise looks ok.)

Donor: [REDACTED] no confirmatory test or apnea test completed.

Donor: [REDACTED] UTV - clinical exam and confirmatory test not in DonorNet. (Otherwise ok.)

Donor: [REDACTED] UTV - clinical exam, apnea (no post-apnea ABG in chart per OPO), and confirmatory test not in DonorNet. (Otherwise ok.)

Donor: [REDACTED] clinical exam present, UTV confirmatory test - not in DonorNet. (Otherwise ok.)

Donor: [REDACTED] UTV – clinical exam and confirmatory test not in DonorNet. (Otherwise ok.)

23 total cases listed in OPO's Lookback Audit review; 15 cases with discrepancies or unverifiable documentation.

I checked to see if the documentation discrepancies related to one hospital over the other, but these issues were evenly distributed between both donor hospitals.