Eshibit 17



FILED

DEC 2 3 2013

ву /

SUPERIOR COURT OF THE STATE OF CALIFORNIA IN AND FOR THE COUNTY OF ALAMEDA

ATASHA WINKFIELD, the Mother of Jahi Case No. RG13-707598 McMath, a minor TEMPORARY RESTRAINING ORDER FOLLOWING PETITION FOR EMERGENCY Petitioner, PROTECTIVE/RESTRAINING ORDER AUTHORIZING MEDICAL TREATMENT AND AUTHORIZING PETITIONER TO GIVE CONSENT TO MEDICAL CHILDREN'S HOSPITAL OAKLAND, Dr. Dayid Durand M.D. and DOES 1 through 100, TREATMENT; inclusive [Prob. Code §§ 3200 et seq., §§ 4600 et seq.] Respondents Date: December 23, 2013 Time: 9:00 am Dept: 31

The court held a continued hearing on the verified petition of Latasha Linkfield at 1:30 p.m. on December 23, 2013, in Department 31 the Honorable Evelio M. Grillo presiding.

IT IS ORDERED THAT:

2

3

4 5

6

7

8

9

10

11

12

13

14

15 16

17

18

19

20

21

22

23

24

25 26 The Temporary Restraining Order entered on December 22, 2013, is hereby extended to Monday December 30, 2013. This order precludes the Respondent from removing Petitioner from the ventilator or ending any of the current treatment and support provided by Respondentin essence, the Court orders the respondent to maintain the "status quo" of treatment and support.

This Temporary Restraining Order orders the following:

1

Respondent CHO, its agents, employees, servants and independent contractors are
ordered to continue to provide Jahi McMath with the treatment and support which is
currently being provided as per the current medications and physicians orders until
further order of the court.

2. The order is to remain effect until further order of the court.

Dated: December 23, 2013

Judge of the Superior Court

Exhibit18

1 Douglas C. Straus (Bar No. 96301) Brian W. Franklin (Bar No. 209784) 2 Noel M. Caughman (Bar No. 154309) dstraus@archernorris.com 3 ARCHER NORRIS A Professional Law Corporation 2033 North Main Street, Suite 800 Walnut Creek, California 94596-3759 5 Telephone: 925.930.6600 Facsimile: 925.930.6620 6 Attorneys for 7 CHILDREN'S HOSPITAL & RESEARCH CENTER AT OAKLAND 8 9 SUPERIOR COURT OF THE STATE OF CALIFORNIA COUNTY OF ALAMEDA 10 11 LATASHA WINKFIELD, the mother of Case No. RG 13-707598 12 Jahi McMath, a minor, OPPOSITION TO PETITION TO 13 Petitioner, APPOINT DR. PAUL A. BYRNE AS INDEPENDENT EXPERT AND REQUEST 14 TO LIFT DECEMBER 23, 2013 TEMPORARY RESTRAINING ORDER 15 CHILDREN'S HOSPITAL & RESEARCH CENTER AT OAKLAND, et Date: December 24, 2013 16 Time: 9:30 A.M. al. Dept: 31 17 Respondents.. 18 19 INTRODUCTION 20 This brief assumes that Dr. Paul Fisher's Independent Expert Report presented to the 21 Court December 24, 2013 will conclude that Jahi McMath is, unfortunately, brain dead as defined 22 by both California Health & Safety Code section 7180 and medically recognized criteria. Based 23 on that assumption, Respondent Children's Hospital & Research Center at Oakland (Children's) 24 25 respectfully suggests that: (1) the Temporary Restraining Order obligating Children's to provide 26 continuing care to Jahi McMath should be lifted because Dr. Fisher's independent evaluation of 27 Jahi McMath satisfies the requirements of Health & Safety Code section 7181; and (2) the request 28 TXDCS/1722652-1

MEMORANDUM OF POINTS AND AUTHORITIES

TXDCS/1722652-1

of Petitioner Latasha Winkfield to appoint Paul Byrne as a second independent expert should be denied because such an appointment is unnecessary and Dr. Byrne, who is neither a neurologist nor a California physician, is not qualified and has already taken a position on this matter..

LEGAL ANALYSIS

 The TRO Should Be Lifted As Health & Safety Code Sections 7180-81 and 1254.4 Have Been Satisfied and There is No Evidence of Diagnostic Error.

This Court is well aware that Jahi McMath is deceased according to California law if she has sustained "irreversible cessation of all functions of the entire brain, including the brain stem.".

California Health & Safety Code § 7180. Children's presented two declarations of attending physicians who both concluded that Jahi McMath was brain dead.

Health & Safety Code § 7181 requires independent confirmation of any determination of brain death by a second physician. Because the Court was concerned that both these physicians were affiliated with Children's, the Court appointed Dr. Paul Fisher as an independent expert.

Assuming Dr. Fisher concludes that Jahi McMath is dead, there can no longer be any controversy that the statutory criteria establishing brain death have been met.

Petitioner insists that, because she would have a legal right to dictate healthcare measures for her daughter if she were still alive, that her consent is also required before Jahi McMath can be disconnected from the ventilator now that she is deceased. There is simply no law that supports this contention. Petitioner relies exclusively on cases where the patient has ongoing brain activity and section 7180 is inapplicable. In *Bartling v. Superior Court* (1984) 163 Cal. App. 3d 186, the patient was attempting to pull out medical devices because he wished to end his life. In *Conservatorship of Valerie N.* (1985) 40 Cal.3d 143, the conservatee was a disabled adult with an IQ of 30. *In The Matter of Baby K* 832 F.Supp. 1022 (1993 D. Va.), which had nothing to do with California law, involved an infant who had brain stem function and, contrary to the

POINT AND AUTHORITIES

claim of Petitioner, brain death was not the central issue. *In re Wanglie*, No. PX-91-283 (Hennepin County, Minnesota), involved a woman in a persistent vegetative state (i.e., brain activity but unconscious). In *Conservatorship of Drabick* (1988) 200 Cal.App.3d 185, the Court of Appeal carefully explains that the conservatee is not dead because he can breath without a ventilator and his EEG "is not flat." 200 Cal.App.3d at 190.

Because Ms. McMath is dead, practically and legally, there is no course of medical treatment to continue or discontinue; there is nothing to which the family's consent is applicable. Cases cited by Petitioner, regarding the right to self-determination of treatment of a person living in a vegetative state, or on life support, are not applicable. To be blunt, Children's is currently merely preserving Ms. McMath's body from the natural post-mortem course of events. There is no legal, ethical or moral requirement that it continue to do so or that the family consent in the decision to stop doing so.

Petitioner cites no authority for the proposition that the patient's legal representatives have an automatic right to participate in the determination of brain death. Sections 7180-7181 are directly to the contrary. The California Legislature has decided that this is a *medical* determination. Health & Safety Code section 1254.4 recognizes that, after death has been declared, the hospital must provide a reasonable period of accommodation before discontinuation of cardiopulmonary support for the patient. That has, of course, been done here.

Dority v. Superior Court (1983) 145 Cal. App. 3d 273 is 100% consistent with the conclusion that the patient's representatives have no ongoing right to object to a medical determination of death under the facts here and that further court intervention is unwarranted in this case. Dority holds that the courts should be involved in second-guessing medical determinations of death only "upon a sufficient showing that it is reasonably probable that a mistake has been made in the diagnosis of brain death or where the diagnosis was not made in

TXDCS/1722652-1

accord with accepted medical standards." Emphasis added. 145 Cal. App. 3d at 281. The Dority decision goes on to confirm that medical devices should not be disconnected without consulting with the family and giving them time "until the initial shock of the diagnosis dissipates.\(^{1}\)" Ibid. Children's has, of course, done this.

Nothing in *Dority* suggests that the trial court is automatically required to function as final arbiter any time the family objects to the determination of brain death. Rather, *Dority* holds that judicial intervention is appropriate only after proof is offered that it is "reasonably probable" that a mistake has been made or that the diagnosis deviated from accepted medical standards.

Petitioner has offered not a scintilla of evidence of any diagnostic error or deviation from accepted medical standards in the determination of brain death. Children's has fully complied with sections 7180, 7181 and 1254.4 The temporary restraining order requiring continuing care of the body of Jahi McMath should be lifted.

Appointment of Another Expert is Unnecessary and Petitioner's Proposed Appointee is Neither Qualified Nor Impartial.

The Court has appointed Dr. Paul Fisher of the Stanford University and Lucile Packard Children's Hospital (Children's Stanford) to serve as an independent expert in this matter. Dr. Fisher has conducted a brain death evaluation of Jahi McMath. Assuming Dr. Fisher has confirmed brain death, the criteria of sections 7180 and 7181 have been satisfied. Absent some proof of a reasonable probability of error—and there is no such evidence—further expert examination of Jahi McMath is unwarranted.

Moreover, respectfully, Dr. Paul A. Byrne is not qualified. Fundamentally, he is not licensed in California. He is simply not allowed to examine patients in the State of California. Indeed, Children's would likely be in violation of licensing and credentialing standards if it were

TXDCS/1722652-1

¹ The Dority decision pre-dated section 1254.4.

to allow such an unlicensed professional to examine one of its patients.

In addition, Dr. Byrne is not a neurologist. He is not trained to read EEGs and he has shown no expertise in performing brain death examinations on teenagers. Indeed, Dr. Byrne has shown no knowledge or experience with the California statutory scheme governing brain death.

Finally, Dr. Byrne is not impartial as he has already published on the internet his opinions regarding Jahi McMath. See "Jahi Is Not Truly Dead," December 24, 2013, by Paul A. Byrne, renewamerica.com, in which Dr. Byrne, without examining Ms. McMath, concludes "And for Jahi, they just want to kill her, yes change the living Jahi into a cadaver."

CONCLUSION

For the foregoing reasons, Respondent respectfully requests that the Court deny

Petitioner's request to appoint Dr. Byrne and that the Court lift the Temporary Restraining Order.

Dated: December 24, 2013

ARCHER NORRIS

By Douglas C. Straus Attorneys for CHILDREN'S HOSPITAL & RESEARCH CENTER AT OAKLAND

TXDCS/1722652-1

POINT AND AUTHORITIES

² Dr. Byrne's lack of objectivity and his rush to asn erroneous judgment here are unsurprising. Internet search also revealed Dr. Byrne has authored a paper titled "Brain Death Is Not Death" (see TruthAboutOrganDonation.com) and similar papers—always presented or published in religious rather than academic scientific publications. Dr. Byrne is a crusader with an ideology-based bias, not a neutral expert physician.

Exhibit 19

Court Exhibit 1

Children's Hospital Oakland

747 Fifty Second Street • Oakland, CA 94609 • (510) 428-3000

TREATMENT AND PROGRESS RECORD

MR & 059459

MCMTM, JAHI
10/24/00
FISHER PINCE PICJ

LING WE & LICE
DATE TIME NEUROLING CONSULTATION NOTE
12/23/3 1845 ASKED BY COUNSEL FOR PATIENT AND CHO TO PERSONAL
WORKS BUT DOWN DOWN IN BRIEF, 13 12-40M-000
roune sle musiciony, amondo of notarente L choure
MRAST, AND THEN CATASTRIPHIC BRAND WIVEY. PATIENT HIS ALREST
MO 2 BUILD DOTHY EXAMINATIONS, ONE BY A NEVERLEUMST, ONE BY
A OZIDEAL CARE MO.
PROMOVERY, 12/11 HEND CT - SMIKINGLY DEVENCED DESCRIPT
MENGHAT BRAND, WITH PRIMITAGE OF VESSES.
12/11 EEG - ELECTROCENEMIN SILVAKE.
TOOM, EEL - ELECTROCOMENT SILONE, POULDE BY HISTER.
MOIONICUOE COMMANDE RUNG FUNDE STREET - NO
BURO KOW ID BAND.
MODERNIES AT MOSET-
ARTIFICUL TEMS
VASUMES ()
NO SEDATIVES ARE EARLIST TOM
URS 144 110 7.45 30 71 -35
4.6 25
ON MY DOM!
VS - T 36.5, 170-71, BP 96-107/56-62, 0, SAT95-987.
and Machinian vot, M SHIPTIMENT REPARTING CHART
CUR - NO RESPIRATIONY VARIABLITY NO MUNITUR.
NEUROLEO OL -
MONTAL STATUS - NO EXE OPOLICE, NO HOLDHOUT, NO VOCAUZAMIN
CRAMINA NERVES - RUMON PALE, PUPILS 5 MM ON ARGUNIC,
NO OCCUPACIONAL MATER, NO OCCUPATIBULA REPORT (NO
65740 (8/00)

12/23/13 1845 REPORTE TO CAMPRICE), NO REPORTE TO FROM MIND, NO CAMPAR.

REPORT TO TOUCH OR AR, NO GATE.

MOTOR - FLACOR TONE THROUGHOUT. NO MOVEMENT.

REPORTS - NO REST TONOW REPORT, NO BASINSHI SILD, MO

NTINOMIC - & REPORTAT, NO CHOINE VAMMILIM, NO SPINGCILLAND REFLEX.

ATTEN TEST PENIST, WITH VO-T OFF, 100 7. 02 STMMT 1538 7.309 49 126 -1.4 END 1547 7.198 73.3 143.4 0.4

SMAKE REFLEXES.

THAT IS, PATION FAILD AND TEST

OVERTIL, UNFORTUNATE CIRCUMSTANCE IN 13-YEAR-BUD WITH KNIMM,

IRREDORS IRVE BRUND INJURY AND NOW COMPLETE ASSOCIE OF

CEREGIAN RIPOTROND AND COMPLETE ASSOCIE OF BRUNDSTEN KNIGHOUD,

CHILD HERTS ALL CANTERIA FOR BRUND DETTH, BY PROFESSIONAL

SOCIETIES AND STATE OF CALIBRANA. MORRIND, AMOUNT TESTS

EED SHOWS NO ELECTRICA BAND ACTIVITY, AND BLOWN FLOW STON SHOW

NO CONSERAN BLOWD ROW. BY HY INDUSTRIANT EXAM, CALO BAND

12/23/13 AT 1845.

REDACTED REDACTED

Raul fisher Ms CALIE 684211

OFFICE (650) 721-5889

		100	ANNESSEE	a least take	120 2 3000
HEODARI	HEFAR	REPRESAN	ACADEM	ALC: N	THE RES
ACCUSED VALUE	100000	4.5		2011/11/19 19 19 19 19 19 19 19 19 19 19 19 19 1	10.46.20

		Н	CHITH,	JAHI DI	B 10/24/00
	for Documentation of Brain Death				2 10/21/10
12 23 13 1845	Brain Death Exam	plaatice for Infants	and Children		ML 059459
12/25/13 1813	Two physicians must perform indeg	e adeal examinations	echarated pl sheet	fled intervals.	1. ACQUEG
•	Age of Parient Learn to where 17 wrete perturbant upo and to to	Flore can may be perf		Autom 24 hours	1 to Ostari
	30 days old	borth OR following carding populations or other save	putmenty ne busin injury	because mailtary sauly	
Pleix see				(section 4) is consistent with brain death (E.A.) least 12 leasts OR	J
	3) days to 15 years old	I first exact only be yes! following configurations:	agued 24 frame	Lateral Material Co.	
011111		other severe brain injury	A temerimon as	because avoillary andy	
full handwritten				(section 4) is consistent with heater desets	.}
1011 185163411114	Sertico I. PREADQUISTTES for brain death run	eduction said appear test			
note. DO	A. IRREVERSIBLE AND UPDATIFIABLE Cause Translic brin injury 4 Age at boon injury	Known sortabolic district	Other (Specify)		1
note. M	· · · · · · · · · · · · · · · · · · ·		world die all the second	Examination Two	1
HP .	B. Correction of contributing factors that our intercembration	State and out acrossite.			-
1,5	a. Cour Book Trap is over 95° F 135° C. b. System: blood pressure or MAP in acceptab	the manue (Symmetry BIP nes	West No.		-
	less than 2 wented deviations below age a	pperspecial school based on	1		1
	Substitutionalgrate ding offices excluded on a	contributing factor	Syra It No		1
	d Metabolic lengiculus excluded as a consti c Neuromorphi blochade excluded as a cons	buring fregyr	See Ithi		
					1
	If Al.1. prorequisites are marked THIS, then provide conforming cardible surjections. Section 2. Physical Researcheston (Pienas check)	Applied may not been to	Faunitation (for	Exemination Two	
	NOTE: SPINAL CORD REPLEXES ARE ACCO	PTABLE	Date Sure	the lef files:	4
	 Floraid tops, pullent unrepressive to deep g Papile are pridocelling or fully delayed and i 	ight critexes are slocut	No.	4 Yes 11 No.	
	 Corneal, nough, sag refferer are abused 		Yes ille		
	Sucting and reasing referen are absent (in d. Octoberatibula referen are absent		Vice Like	1 Yes (1)19	
	e Spontaneous requires of ellips while on me in the (sponty) element of the	has an even manufact and the manifests	menti tranciali Lici	And the same of the same	1
	Ancillary study (1250 or redocusticle CTH) was the	elegate Ecopouning to gocolea	est brein death Section	Eastelantien Two	-
	Section 3. APNEA Test		Data/ Best 44 8	E o Patri Time.	
	No spouraneous respiratory elforts were observed de	mpite Shall PaCO, > 60 mm	Person Pachie	Appea duration:	
	Hig and a ≥ 20 seen Hig lucreano above baseline. (Has No appointment a respectorly efforts were observed do	mple faul PeCO; 2 60 mm	Podruted De 13	3 Proper Party	
	hig and a 2 20 mm life increase above baselines, of my	disting (an)			
			ne bereig death, i Section	de Date/Litre:	-
	Section 4. ANCILLARY resitors in required when causes be completed; (2) if there is uncertainty about	t the armits of the nemojody	c exemination; or (3) If	fa .	İ
	reduction effect may be present.	taxaa aanadaa daa aantad t	NAMES OF THE PERSONS ASSESSED.	relogic .	
	conclusion is required. Components of the next	LONGING CAN CARDINATED TO LA	n be performed calely		
	thought in completed in close providing to the An- Electrocates balance of Electrocate to	CORNEY HAVE	.,	Darre No	-
	Cerebral Blood Flew CBF) study regard documen	is no cemberó perfusion		Was No	
	Seetles S. Panetures Equators One	-1 - 17]
	Leculty that my examination is one latert with pear	ation of fusitions of the brain	n med healtstarm, Coydin	inglishy cases to Bellew	1
	(Printed Heart)	(Siptiture)			
	(Syn.hilly)	(Pages Whiterough)	the mi	MANY (1) (1) (MAN)	
	Exchange Two		nel and Interestable con	sation of function of the toru	. 1
	and becomes. The patient is the large expendent at Date/Time of death	With the County of Stand	No. wo. bit animary per		
	Detailing of death			lada law	ا
	(Prince Nume) NEUROLEVIT	1 Kumany y	111 12/	23/13 /841	
	(Syrvinky)	(Countilisemen)	(Pala jert	W#22222 Cline1	
	Charles and the second				1

Paul July Mo FISHOR, Paul Graham UR CA G84211 OFFICE (GSR) 721-5889

e735

Exhibit 20

Court Exhibit 2

T.F.	BLE 1 Summary Recommendations for the Diagnosis of Brain Death in Neonates, Infants, and Children		
, ia	BLE 1 Summary Recommendations for the Diagnosis of Grain Death in Reconstes, Interes, and Uniteres Recommendation	Evidence	Recommendation
	oppugning-padditigti	Score	Score
1.	Determination of brain depth in neonates, infants and children relies on a clinical diagnosis that is based on the absence of	High	Strong
	neurologic function with a known irreversible cause of coma. Coma and aprea must coexist to diagnose brain death. This		
	diagnosis should be made by physicians who have evaluated the history and completed the neurologic examinations.		
	Prereguisites for initiating a brain death evaluation 1. Bypotension, bypothermia, and metabolic disturbances that could affect the neurological examination must be	High	Strong
	corrected prior to examination for brain death	-	
-	 Sedatives, analysists, neuromuscular blockers, and anticonvulsant agents should be discontinued for a reasonable time 	Moderate	Strong
	period based on alimination half-life of the pharmacologic agent to ensure they do not affect the neurologic examination.		
	Knowledge of the tutal amount of each agent (mg/kg) administered since hospital admission may provide useful information concerning the risk of continued medication effects. Blood or plasma levels to confirm high or		
	supratherapeutic levels of anticonvulsants with sedative effects that are not present should be obtained (if available)		
	and repeated as needed or until the levels are in the low to mid therapoutic range.		
	The diagnosis of brain death based on neurologic examination alone should not be made if supratherapeutic or high	Moderate	Strong
	therapeutic levels of addative agents are present. When levels are in the low or in the mid-therapeutic range, medication		
	effects sufficient to affect the results of the neurologic examination are unlikely. If uncortainty remains, an ancillary		
	study should be performed. Assessment of neurologic function may be unreliable immediately following cardiopulmonary resuscitation or other.	Moderate	Strong
	severe agute brain injuries and evaluation for beain death should be deferred for 24 to 48 hours or longer if there are		-
	concerns or inconsistencies in the examination		
3.	Number of examinations, examiners and observation periods 1. Two examinations including apnea tosting with each examination separator by on observation period are required.	Moderate	Strong
i	 I we examinations including aprice testing with each examination separation by or conservation period are required. The examinations should be performed by different attending physicians involved in the card of the child. The aprica test may 	LOW	Strong
	be performed by the same physician, preferably the attending physician who is maneging ventilator care of the child		-
	Recommended observation periods	Maderate	Strong
	 (1) 24 hours for reconstex (57 weeks gestation to term infants 30 days of age) (2) 12 hours for infants and children (>> 30 days to 16 years). 	Wilderate	arrong
	The first examination determines the child has met neurologic examination criteria for brain cleath. The second	Moderate	Strong
	examination, performed by a different attending physician, confirms that the child has fulfilled criteria for brain death.		
-	Assessment of neurologic function may be unreliable immediately following cardiopulmonary resuscitation or other	Moderate	Strong
	severe ocute brain injuries and evaluation for brain death should be deferred for 24 to 48 hours or longer if there are		
4	concerns or inconsistencies in the examination. Appea testing		
-	Appea texting must be performed safely and requires documentation of an arterial Path, 20 mm Hg above the baseline	Moderate	Strong
	Pace, and ≥ 60 mm Hg with no respiratory effort during the testing period to support the diagnosis of brain death.		
	Some intents and children with chronic respiratory disease or insufficiency may only be responsive to supranormal		
	Page, levels in this instance, the Page, level should increase to ≥ 20 mm Hg above the baseline Page, level . If the opnes test cannot be performed due to a medical contraindication or cannot be completed because of	Moderate	Strong
	hemodynamic instability, desaturation to < 85%, or an inability to reach a Pacs, of 60 mm Hg or greater, an untillary		
	study should be performed		
5.	Ancillary studies Ancillary studies (EEG and radionuclide CBF) are not required to establish brain death unless the clinical examination or	Moderate	Strong
i	3 Ancillary studies (ELB and rapionucline CBF) are not required to establish prain death unless the climical examination of agree test cannot be completed.	Minnerate	Strong
	Ancillary studies are not a substitute for the neurologic examination.	Moderate	Strong
1	2. For all age groups, ancillary studies can be used to assist the clinician in making the diagnosts of brain death to reduce	Moderate	Strong
	the observation period or when (i) components of the examination or apnea testing cannot be completed safely due to		
	the underlying medical condition of the patient; (ii) if there is uncertainty about the results of the neurologic examination; or (iii) if a medication effect may interfere with evaluation of the patient. If the ancillary study supports the		
	diagnosis, the accord examination and aprece testing can then be performed. When an ancillary study is used to reduce		
	the observation period, all aspects of the examination and appea testing should be completed and dutumented		
	5 When en ancillary study is used because there are inherent examination limitations (ie. i to iii), then components of the	High	Strong
	examination done initially should be completed and documented.	Moderate	Strong
-	If the ancillary study is equivocal or if there is concern about the validity of the ancillary study, the patient cannot be pronounced dead. The patient should continue to be observed until brain death can be declared on clinical examination.	August me	511, 511,
	criteria and appea testing, or a follow-up ancillary study can be performed to assist with the determination of brain		
	death. A waiting period of 24 hours is recommended before further clinical reevaluation or repeat ancillary study is		
	performed. Supportive patient care should continue during this time period.		
6.	Declaration of death Ocean is declared after confirmation and completion of the second clinical examination and upnea test.	High -	Strong
	 Wear applicant studies, are used, documentation of components from the second clinical examination that can be 	High	Strong
	completed must remain consistent with brain death. All aspects of the clinical examination, including the upnea fest, or		
	applification attention must be appropriately decumented.	High	Strong
	a. The clinical exemination should be corried out by experienced clinicians who are familiar with intents and children, and	1 of Bri	anong
	heve specific training in neurocritical care		

FROM THE AMERICAN ACADEMY OF PEDIATRICS
Downloaded from pediatrics aappublications org at Stanford Univ Med Cir on December 22, 2013

The "evaluation score" is based on the strength of the evidence evaluation at the time of publication.

The "recommendation score" is the strength of the recommendations based on available evidence at the time of publication. Scoring guidelines are listed in Table 2.

Exhibit 21

Court Exhibit 3

PEDIATRICS

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Guidelines for the Determination of Brain Death in Infants and Children: An Update of the 1987 Task Force Recommendations

Thomas A. Nakagawa, Stephen Ashwal, Mudit Mathur, Mohan Mysore and the Society of Critical Care Medicine, Section on Critical Care and Section on Neurology of the American Academy of Pediatrics, and the Child Neurology Society Pediatrics 2011;128;e720; originally published online August 28, 2011;

DOI: 10.1542/peds.2011-1511

The online version of this article, along with updated information and services, is located on the World Wide Web at: http://pediatrics.aappublications.org/content/128/3/e720.full.html

PEDIATRICS is the official journal of the American Academy of Pediatrics. A monthly publication, it has been published continuously since 1948. PEDIATRICS is owned, published, and trademarked by the American Academy of Pediatrics, 141 Northwest Point Boulevard, Elk Grove Village, Illinois, 60007. Copyright © 2011 by the American Academy of Pediatrics. All rights reserved. Print ISSN: 0031-4005. Online ISSN: 1098-4275.



Downloaded from pediatrics.aappublications.org at Stanford Univ Med Ctr on December 22, 2013

Guidance for the Clinician in Rendering Pediatric Care

Clinical Report—Guidelines for the Determination of Brain Death in Infants and Children: An Update of the 1987 Task Force Recommendations

abstract



OBJECTIVE: To review and revise the 1987 pediatric brain death guidelines. **METHODS:** Relevant literature was reviewed. Recommendations were developed using the GRADE system.

CONCLUSIONS AND RECOMMENDATIONS: (1) Determination of brain death in term newborns, infants and children is a clinical diagnosis based on the absence of neurologic function with a known irreversible cause of coma. Because of insufficient data in the literature, recommendations for preterm infants less than 37 weeks gestational age are not included in this guideline.

- (2) Hypotension, hypothermia, and metabolic disturbances should be treated and corrected and medications that can interfere with the neurologic examination and apnea testing should be discontinued allowing for adequate clearance before proceeding with these evaluations.
- (3) Two examinations including apnea testing with each examination separated by an observation period are required. Examinations should be performed by different attending physicians. Apnea testing may be performed by the same physician. An observation period of 24 hours for term newborns (37 weeks gestational age) to 30 days of age, and 12 hours for infants and chi (> 30 days to 18 years) is recommended. The first examination determines the child has met the accepted neurologic examination criteria for brain death. The second examination confirms brain death based on an unchanged and irreversible condition. Assessment of neurologic function following cardiopulmonary resuscitation or other severe acute brain injuries should be deferred for 24 hours or longer if there are concerns or inconsistencies in the examination.
- (4) Apnea testing to support the diagnosis of brain death must be performed safely and requires documentation of an arterial Paco₂ 20 mm Hg above the baseline and ≥ 60 mm Hg with no respiratory effort during the testing period. If the apnea test cannot be safely completed, an ancillary study should be performed.
- (5) Ancillary studies (electroencephalogram and radionuclide cerebral blood flow) are not required to establish brain death and are not a substitute for the neurologic examination. Ancillary studies may be us d to assist the clinician in making the diagnosis of brain death (i) when components of the examination or apnea testing cannot be completed safely due to the underlying medical condition of the patient; (ii) if there is uncertainty about the results of the neurologic examination; (iii) if a medication effect may be present; or (iv) to reduce the inter-examination observation period. When ancillary studies are used, a second clinical examination and apnea test should be performed and components that can be completed must remain consistent with brain death. In this instance the observation interval may be shortened and the second neurologic examination and apnea test (or all components that are able to be completed safely) can be performed at any time thereafter.

(6) Death is declared when the above criteria are fulfilled. Pediatrics 2011;128: e720–e740 Thomas A. Nakagawa, MD, Stephen Ashwal, MD, Mudit Mathur, MD, Mohan Mysore, MD, and THE SOCIETY OF CRITICAL CARE MEDICINE, SECTION ON CRITICAL CARE AND SECTION ON NEUROLOGY OF THE AMERICAN ACADEMY OF PEDIATRICS, AND THE CHILD NEUROLOGY SOCIETY

KEY WORDS

apnea testing, brain death, cerebral blood flow, children, electroencephalography, infants, reonates, pediatrics

ABBREVIATIONS

EEG-electroencephalogram

CBF—cerebral blood flow CT—computed tomography

MRI--magnetic resonance imaging

ETT-endotracheal tube

CPAP—continuous positive airway pressure

ICP-intracranial pressure

ECS-electrocerebral silence

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

www.pediatrics.org/cgi/doi/10.1542/peds.2011-1511

doi:10.1542/peds.2011-1511

All plinical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275)

Copyright © 2011 by the American Academy of Pediatrics, the Society for Critical Care Medicine, and the Child Neurology Society

INTRODUCTION

In 1987, guidelines for the determination of brain death in children were published by a multi-society task force.1.2 These consensus based guidelines were developed because existing guidelines from the President's Commission failed to adequately address criteria to determine brain death in pediatric patients. They emphasized the importance of the history and clinical examination in determining the etiology of coma so that correctable or reversible conditions were eliminated. Additionally, age-related observation periods and the need for specific neurodiagnostic tests were recommended for children younger than 1 year of age. In children older than 1 year, it was recommended that the diagnosis of brain death could be made solely on a clinical basis and laboratory studies were optional. Little guidance was provided to determine brain death in neonates less than 7 days of age because of limited clinical experience and lack of sufficient data.

These guidelines generally have been accepted and used to guide clinical practice; however they have not been reviewed nor revised since originally published. Several inherent weaknesses have been recognized including: (1) limited clinical information at the time of publication; (2) uncertainty concerning the sensitivity and specificity of ancillary testing; (3) biological rationale for the use of age-based criteria; and (4) little direction as to whether, when and how the diagnosis of brain death could be made in neonates. Despite national and legal acceptance of the concept of brain death, these limitations have resulted in the lack of a standardized approach to determining brain death in children.3-9 These issues are not unique to infants and children 10 nor limited to the United States. The American Academy of Neurology published guidelines to determine brain death in adults in 1995 which have been revised in 2010.^{11,12} Additionally, guidelines to determine brain death in adults and children have been published in Canada.¹³

The Society of Critical Care Medicine (SCCM) and the Section on Critical Care and Section on Neurology of the American Academy of Pediatrics (AAP), in conjunction with the Child Neurology Society (CNS), formed a multidisciplinary committee of medical and surgical subspecialists under the auspices of the American College of Critical Care Medicine (ACCM) to review and revise the 1987 guidelines. Its purpose was to review the neonatal and pediatric literature from 1987, including any prior relevant literature. and update recommendations regarding appropriate examination criteria and use of ancillary testing to diagnose brain death in neonates, infants and children. The committee was also charged with developing a checklist to provide guidance and standardization to document brain death. Uniformity in the determination of brain death should allow physicians to pronounce brain death in pediatric patients in a more precise and orderly manner and ensure that all components of the examination are performed and appropriately documented.

Tables 1-3 of this publication contain the committee's updated recommendations, the GRADE classification system, and clinical and neurologic examination criteria for brain death. Appendices 1-7 provide additional information concerning the diagnosis of brain death in children. Appendix 1 (check list) and Appendix 2 (pharmacological data for the time interval to testing after medication discontinuation) provide additional resources to aid the clinician in diagnosing brain death. Appendix 3 summarizes data regarding apnea testing. Appendices 4-6 provide data on the diagnostic

yield of ancillary testing, specifically electroencephalography (EEG), and radionuclide cerebral blood flow (CBF) studies. Appendix 7 compares the 1987 guideline's criteria to the revised recommendations. Appendix 8 provides an algorithm for the determination of brain death in infants and children.

This update affirms the definition of death as stated in the 1987 pediatric guidelines. This definition had been established by multiple organizations including the American Medical Association, the American Bar Association, the National Conference of Commissioners on Uniform State Laws, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research and the American Academy of Neurology as follows: "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 brainstem, is dead. A determination of death must be made in accordance with accepted medical standards."1

METHODS

A multidisciplinary committee composed of physicians and nurses with expertise in pediatrics, pediatric critical care, neonatology, pediatric neurology and neurosurgery, nuclear medicine, and neuroradiology was formed by the SCCM and the AAP to update the guidelines for the diagnosis of pediatric brain death. The committee was divided into three working groups, each charged with reviewing the literature on brain death in neonates, infants and children for the following specific areas: (1) examination criteria and observation periods; (2) ancillary testing; and (3) declaration of death by medical personnel including legal and ethical implications.

A Medline search of relevant literature published from January 1987 to June

TABLE 1: Summary Recommendations for the Diagnosis of Brain Death in Neonates, Infants, and Children Recommendation Evidence Recommendation Score Score 1. Determination of brain death in recorates, infants and children relies on a clinical diagnosis that is based on the absence of High Strong neurologic function with a known irreversible cause of coma. Coma and apnea must coexist to diagnose brain death, This diagnosis should be made by physicians who have evaluated the history and completed the neurologic examinations 2. Prerequisites for initiating a brain death evaluation Hypotension, hypothermia, and metabolic disturbances that could affect the neurological examination must be High Strone corrected prior to examination for brain death. b Sedatives, analgesics, neuromuscular blockers, and anticonvulsant agents should be discontinued for a reasonable time Moderate Strong period based on elimination half-life of the pharmacologic agent to ensure they do not affect the neurologic examination. Knowledge of the total amount of each agent (mg/kg) administered since hospital admission may provide useful information concerning the risk of continued medication effects. Blood or plasma levels to confirm high or supratherapeutic levels of anticonvulsants with sedative effects that are not present should be obtained (if available) and repeated as needed or until the levels are in the low to mid therapeutic range. The diagnosis of brain death based on neurologic examination alone should not be made if supratherapeutic or high Moderate Strong therapeutic levels of sedative agents are present. When levels are in the low or in the mid-therapeutic range, medication effects sufficient to affect the results of the neurologic examination are unlikely. If uncertainty remains, an ancillary study should be performed. Assessment of neurologic function may be unreliable immediately following cardiopulmonary resuscitation or other Moderate Strong severe acute brain injuries and evaluation for brain death should be deferred for 24 to 48 hours or longer if there are concerns or inconsistencies in the examination 3. Number of examinations, examiners and observation periods Two examinations including agnea testing with each examination separated by an observation period are required. Moderate Strong b. The examinations should be performed by different attending physicians involved in the care of the child. The apnea test may Low Strong be performed by the same physician, preferably the attending physician who is managing ventilator care of the child. c. Recommended observation periods (1) 24 hours for regnates (37 weeks gestation to term infants 30 days of age) Moderate Strong (2) 12 hours for infants and children (> 30 days to 18 years). d. The first examination determines the child has met neurologic examination criteria for brein death. The second Moderate Strong examination, performed by a different attending physician, confirms that the child has fulfilled criteria for brain death. Assessment of neurologic function may be unreliable immediately following cardiopulmonary resuscitation or other Moderate Strong sovere acute brain injuries and evaluation for brain death should be deferred for 24 to 48 hours or longer if there are concerns or inconsistencies in the examination 4. Apnea testing Apnea testing must be performed safely and requires documentation of an arterial Paco, 20 mm Hg above the baseline Moderate Strong Pace, and ≥ 60 mm Hg with no respiratory effort during the testing period to support the diagnosis of brain death. Some infants and children with chronic respiratory disease or insufficiency may only be responsive to supranormal Paco, levels. In this instance, the Paco, level should increase to ≥ 20 mm Hg above the baseline Paco, level. b. If the apnea test cannot be performed due to a medical contraindication or cannot be completed because of Moderate Strong hemodynamic instability, desaturation to < 85%, or an inability to reach a Pace, of 60 mm Hg or greater, an ancillary study should be performed 5. Ancillary studies a. Ancillary studies (EEG and radionuclide CBF) are not required to establish brain death unless the clinical examination or Moderate Strong apnea test cannot be completed b. Ancillary studies are not a substitute for the neurologic examination. Moderate Strong c. For all age groups, ancillary studies can be used to assist the clinician in making the diagnosis of brain death to reduce Moderate Strong the observation period or when (i) components of the examination or apnea testing cannot be completed safely due to the underlying medical condition of the patient; (ii) if there is uncertainty about the results of the neurologic examination; or (iii) if a medication effect may interfere with evaluation of the patient. If the ancillary study supports the diagnosis, the second examination and apnea testing can then be performed. When an ancillary study is used to reduce the observation period, all aspects of the examination and apnea testing should be completed and documented, d. When an ancillary study is used because there are inherent examination limitations (ie, i to iii), then components of the High Strong examination done initially should be completed and documented. e. If the ancillary study is equivocal or if there is concern about the validity of the ancillary study, the patient cannot be Moderate Strong pronounced dead. The patient should continue to be observed until brain death can be declared on clinical examination criteria and apnea testing, or a follow-up ancillary study can be performed to assist with the determination of brain death. A waiting period of 24 hours is recommended before further clinical reevaluation or repeat ancillary study is performed. Supportive patient care should continue during this time period. 6. Declaration of death Death is declared after confirmation and completion of the second clinical examination and agnes test Strong b. When ancillary studies are used, documentation of components from the second clinical examination that can be High Strong completed must remain consistent with brain death. All aspects of the clinical examination, including the apnea test, or ancillary studies must be appropriately documented. c. The clinical examination should be carried out by experienced clinicians who are familiar with infants and children, and Strong

have specific training in neurocritical care.

e722

The "evaluation score" is based on the strength of the evidence available at the time of publication.

The "recommendation score" is the strength of the recommendations based on available evidence at the time of publication. Scoring guidelines are listed in Table 2.

FROM THE AMERICAN ACADEMY OF PEDIATRICS

TABLE 2 Grading of Recommendations Assessment, Development and Evaluation (GRADE) System 4-4

Classification of evidence
 Grade
 A. High

B. Moderate

C. Low

0. Very low

 Recommendations. The strength of a recommendation reflects the extent to which we can be confident that desirable effects of an intervention outweigh undesirable effects.

Strong

Weak

No specific recommendations

Further research is very unlikely to change our confidence in the estimate of effect Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate

Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate

Any estimate of effect is very uncertain

When the desirable effects of an intervention clearly outweight he undesirable effects, or clearly do not.

(a) For patients—most people in your situation would want the recommended course of action and only a small proportion would not

(b) For clinicians—most patients should receive the recommended course of action

(c) For policy makers—the recommendation can be adopted as a policy in most situations Evidence suggests that desirable and undesirable effects are closely balanced or the quality of evidence is low.

 (a) For patients—most people in your situation would want the recommended course of action, but many would not

(b) For clinicians—you should recognize that different choices will be appropriate for different patients and you must help each patient to arrive at a management decision consistent with his or her values and preferences.

(c) For policy makers—policy making will require substantial debate and involvement of many stakeholders

The advantages and disadvantages of the recommendations are equivalent or where there is insufficient evidence on which to formulate a recommendation

2008 was conducted. Key words included: brain death, neurologic death, neonatal, pediatric, cerebral blood flow, electroencephalography, apnea test, and irreversible coma with the subheading, "children." Additional articles cited in the post 1987 literature that were published prior to 1987 were also reviewed if they contained data relevant to this guideline. Abstracts and articles were independently reviewed and summarized by at least two individuals on each committee. Data were summarized into five categories: clinical examination, apnea testing, observation periods, ancillary tests, and other considerations.

Methodological issues regarding analysis of evidence warrant further discussion as they directly affected the decision of how information and recommendations about brain death are presented. No randomized control trials examining different strategies re-

garding the diagnosis of brain death exist. Standard evidence-based approaches for guidelines used by many organizations attempting to link the "strength of the evidence" to the "strength of the recommendations" therefore cannot be used in this instance. There is, however, considerable experiential consensus within observational studies in the pediatric population. Grading of Recommendations Assessment, Development and Evaluation (GRADE), a recently developed standardized methodological consensus-based approach, allows panels to evaluate the evidence and opinions and make recommendations.14-17 GRADE uses 5 domains to judge the balance between the desirable and undesirable effect of an intervention. Strong recommendations are made when there is confidence that the desirable effects of adherence to a recommendation outweigh the unde-

sirable effects. Weak recommendations indicate that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, but the panel is less confident. No specific recommendations are made when the advantages and disadvantages of alternative courses of action are equivalent or where there is insufficient evidence on which to formulate a recommendation. 15,18 Table 2 outlines the GRADE methodology used in formulating recommendations for this guideline. Each committee member assigned a GRADE score for (i) the strength of evidence linked to a specific recommendation and (ii) indicated (a) "yes," (b) "no" or (c) "uncertain" for each of the six recommendations listed at the end of this report. By a priori consensus, the committee decided that a "strong" recommendation could only be made if greater than 80% of the committee members voted "yes"

TABLE 3 Neurologic Examination Components to Assess for Brain Death in Neonates, Infants and Children* Including Agnes Testing

Reversible conditions or conditions that can interfere with the neurologic examination must be excluded prior to brain death testing. See text for discussion

1. Coma. The patient must exhibit complete loss of consciousness, vocalization and volitional activity.

- Patients must lack all evidence of responsiveness. Eye opening or eye movement to noxious stimuli is absent.
- Noxious stimuli should not produce a motor response other than spinally mediated reflexes. The clinical differentiation of spinal responses from retained motor responses associated with brain activity requires expertise.

2. Loss of all brain stem reflexes including:

Midposition or fully dilated pupils which do not respond to light.

Absence of pupillary response to a bright light is documented in both eyes. Usually the pupils are fixed in a midsize or dilated position (4–9 mm). When uncertainty exists, a magnifying glass should be used.

Absence of movement of bulbar musculature including facial and oropharyngeal muscles.

Deep pressure on the condyles at the level of the temporomandibular joints and deep pressure at the supraorbital ridge should produce no grimacing or facial muscle movement.

Absent gag, cough, sucking, and rooting reflex

The pharyngeal or gag reflex is tested after stimulation of the posterior pharynx with a tongue blade or suction device. The tracheal reflex is most reliably tested by examining the cough response to tracheal suctioning. The catheter should be inserted into the trachea and advanced to the level of the carina followed by 1 or 2 suctioning passes.

Absent corneal reflexes

Absent conneal reflex is demonstrated by touching the connea with a piece of tissue paper, a cotton swab, or squirts of water. No eyelid movement should be seen. Care should be taken not to damage the connea during testing.

Absent oculovestibular reflexes

The oculovestibular reflex is tested by irrigating each ear with ice water (caloric testing) after the patency of the external auditory canal is confirmed. The head is elevated to 30 degrees. Each external auditory canal is irrigated (1 ear at a time) with ~ 10 to 50 mL of ice water. Movement of the eyes should be absent during 1 minute of observation. Both sides are tested, with an interval of several minutes.

- Apnea. The patient must have the complete absence of documented respiratory effort (if feasible) by formal apnea testing demonstrating a Paco₂ ≥ 60 mm Hg and ≥ 20 mm Hg increase above baseline.
 - Normalization of the pH and Pace₂, measured by arterial blood gas analysis, maintenance of core temperature > 35°C, normalization of blood pressure
 appropriate for the age of the child, and correcting for factors that could affect respiratory effort are a prerequisite to testing.
 - The patient should be preoxygenated using 100% oxygen for 5-10 minutes prior to initiating this test.
 - Intermittent mandatory mechanical ventilation should be discontinued once the patient is well oxygenated and a normal Paco, has been achieved.
 - The patient's heart rate, blood pressure, and oxygen saturation should be continuously monitored while observing for spontaneous respiratory effort throughout the entire procedure.
 - Follow up blood gases should be obtained to monitor the rise in Pace, while the patient remains disconnected from mechanical ventilation.
 - If no respiratory effort is observed from the initiation of the apnoaltest to the time the measured Pace₂ ≥ 60 mm Hg and ≥ 20 mm Hg above the baseline level, the apnealtest is consistent with brain death.
 - The patient should be placed back on mechanical ventilator support and medical management should continue until the second neurologic examination and apnea test confirming brain death is completed.
 - If oxygen saturations fall below 85%, hemodynamic instability limits completion of apnea testing, or a Paco₂ level of ≥ 80 mm Hg cannot be achieved, the
 infant or child should be placed back on ventilator support with appropriate treatment to restore normal oxygen saturations, normocarbia, and
 hemodynamic parameters. Another attempt to test for apnea may be performed at a later time or an ancillary study may be pursued to assist with
 determination of brain death.
 - · Evidence of any respiratory effort is inconsistent with brain death and the apnea test should be terminated.
- 4. Flaccid tone and absence of spontaneous or induced movements, excluding spinal cord events such as reflex withdrawal or spinal myocionus.
 - The patient's extremities should be examined to evaluate tone by passive range of motion assuming that there are no limitations to performing such an
 examination (eg. previous trauma, etc) and the patient observed for any spontaneous or induced movements.
 - If abnormal movements are present, clinical assessment to determine whether or not these are spinal cord reflexes should be done.

for a recommendation and that a "weak" recommendation was made if greater than 60% but less than 80% voted "yes." "No recommendation" was made if less than 60% of the committee voted "yes" for a specific recommendation. Table 1 summarizes GRADE recommendations and evidence scores.

The committee believes these revised diagnostic guidelines, summarized in Table 1 and a standardized checklist

form (Appendix 1), will assist physicians in determining and documenting brain death in children. This should ensure broader acceptance and utilization of such uniform criteria. The committee recognizes that medical judgment of involved pediatric specialists will direct the appropriate course for the medical evaluation and diagnosis of brain death. The committee also recognizes that no national brain

death law exists. State statutes and policy may restrict determination of brain death in certain circumstances. Physicians should become familiar with laws and policies in their respective institution. The committee also recognizes that variability exists for the age designation of pediatric trauma patients. In some states, the age of the pediatric trauma patient is defined as less than 14 years of age.

Criteria adapted from 2010 American Academy of Neurology criteria for brain death determination in adulta (Wijdicks et al, 2010)

Trauma and intensive care practitioners are encouraged to follow state/ local regulations governing the specified age of pediatric trauma patients. The committee believes these guidelines to be an important step in protecting the health and safety of all infants and children. These revised guidelines and accompanying checklist are intended to provide a framework to promote standardization of the neurologic examination and use of ancillary studies based on the evidence available to the committee at the time of publication.

TERM NEWBORNS (37 WEEKS GESTATIONAL AGE) TO CHILDREN 18 YEARS OF AGE

Definition of Brain Death and Components of the Clinical Examination (Recommendation 1, Table 1 and Table 3)

Brain death is a clinical diagnosis based on the absence of neurologic function with a known diagnosis that has resulted in irreversible coma. Coma and apnea must coexist to diagnose brain death. A complete neurologic examination that includes the elements outlined in Table 3 is mandatory to determine brain death with all components appropriately documented.

Prerequisites for Initiating a Clinical Brain Death Evaluation (Recommendations 2a-d, Table 1)

Determination of brain death by neurologic examination should be performed in the setting of normal ageappropriate physiologic parameters. Factors potentially influencing the neurologic examination that must be corrected before examination and apnea testing include: (1) shock or persistent hypotension based on normal systolic or mean arterial blood pressure values for the patient's age. Systolic blood pressure or MAP should be in an ac-

ceptable range (systolic BP not less than 2 standard deviations below age appropriate norm) based on age; (2) hypothermia; (3) severe metabolic disturbances capable of causing a potentially reversible coma including electrolyte/glucose abnormalities; (4) recent administration of neuromuscular blocking agents; and (5) drug intoxications including but not limited to barbiturates, opioids, sedative and anesthetic agents, antiepileptic agents. and alcohols. Placement of an indwelling arterial catheter is recommended to ensure that blood pressure remains within a normal range during the process of diagnosing brain death and to accurately measure Paco, levels during apnea testing.

Hypothermia is used with increasing frequency as an adjunctive therapy for individuals with acute brain injury. 19-22 Hypothermia has also been used following cardiac arrest to protect the brain because it reduces cerebral metabolic activity.23-28 The clinician caring for critically ill infants and children should be aware of the potential impact of therapeutic modalities such as hypothermia on the diagnosis of brain death. Hypothermia is known to depress central nervous system function27-29 and may lead to a false diagnosis of brain death. Hypothermia may alter metabolism and clearance of medications that can interfere with brain death testing. Efforts to adequately rewarm before performing any neurologic examination and maintain temperature during the observation period are essential. The 1987 guidelines stated that the patient must not be significantly hypothermic however no definition was provided.1 It is reasonable that the core body temperature at the time of brain death examination be as close to normal to reproduce normal physiologic conditions. A core body temperature of >35°C (95°F) should be achieved and maintained during examination and testing to determine death. This temperature is consistent with current adult guidelines and is relatively easy to achieve and maintain in children. 11,13

Severe metabolic disturbances can cause reversible coma and interfere with the clinical evaluation to determine brain death. Reversible conditions such as severe electrolyte imbalances, hyper or hyponatremia, hyper or hypoglycemia, severe pH disturbances, severe hepatic or renal dysfunction or inborn errors of metabolism may cause coma in a neonate or child,28,29 These conditions should be identified and treated before evaluation for brain death, especially in situations where the clinical history does not provide a reasonable explanation for the neurologic status of the child.

Drug intoxications including barbiturates, opioids, sedatives, intravenous and inhalation anesthetics, antiepileptic agents, and alcohols can cause severe central nervous system depression and may alter the clinical examination to the point where they can mimic brain death.28.29 Testing for these drugs should be performed if there is concern regarding recent ingestion or administration. When available, specific serum levels of medications with sedative properties or side effects should be obtained and documented to be in a low to mid therapeutic range before neurologic examination for brain death testing, Longer acting or continuous infusion of sedative agents can also interfere with the neurologic evaluation. These medications should be discontinued. Adequate clearance (based on the age of the child, presence of organ dysfunction, total amount of medication administered, elimination half-life of the drug and any active metabolites) should be allowed before the neurologic examination. In some instances this may require waiting several half-

lives and rechecking serum levels of the medication before conducting the brain death examination. If neuromuscular blocking agents have been used, they should be stopped and adequate clearance of these agents confirmed by use of a nerve stimulator with documentation of neuromuscular junction activity and twitch response. Other unusual causes of coma such as neurotoxins, and chemical exposure (ie, organophosphates, and carbamates) should be considered in rare cases where an etiology for coma has not been established. Recommendations of time intervals before brain death evaluation for many of the commonly used medications administered to critically ill neonates and children are listed in Appendix 2.

Clinical criteria for determining brain death may not be present on admission and may evolve during hospitalization. Assessment of neurologic function may be unreliable immediately following resuscitation after cardiopulmonary arrest30-33 or other acute brain injuries and serial neurologic examinations are necessary to establish or refute the diagnosis of brain death. Additionally, initial stabilization may take several hours during which time correcting metabolic disturbances and identifying and treating reversible conditions that may imitate brain death can be accomplished. It is reasonable to defer neurologic examination to determine brain death for 24 hours or longer if dictated by clinical judgment of the treating physician in such circumstances. If there are concerns about the validity of the examination (eg. flaccid tone or absent movements in a patient with high spinal cord injury or severe neuromuscular disease) or if specific examination components cannot be performed due to medical contraindications (eg. apnea testing in patients with significant lung injury, hemodynamic instability,

or high spinal cord injury), or if examination findings are inconsistent, continued observation and postponing further neurologic examinations until these issues are resolved is warranted to avoid improperly diagnosing brain death. An ancillary study can be pursued to assist with the diagnosis of brain death in situations where certain examination components cannot be completed.

Neuroimaging with either computed tomography (CT) or magnetic resonance imaging (MRI) should demonstrate evidence of an acute central nervous system injury consistent with the profound loss of brain function. It is recognized that early after acute brain injury, imaging findings may not demonstrate significant injury. In such situations, repeat studies are helpful in documenting that an acute severe brain injury has occurred. CT and MRI are not considered ancillary studies and should not be relied on to make the determination of brain death.

Number of Examinations, Examiners and Observation Periods (Recommendations 3a-e, Table 1)

Number of Examinations and Examiners

The 1987 guidelines recommended observation periods between brain death examinations based on age and the results of neurodiagnostic testing.1 Two examinations and EEG's separated by at least 48 hours were recommended for infants 7 days to 2 months. Two examinations and EEG's separated by at least 24 hours were recommended for children 2 months to 1 year. A repeat EEG was not necessary if a cerebral radionuclide scan or cerebral angiography demonstrated no flow or visualization of the cerebral arteries. For children older than 1 year, an observation period of 12 hours was recommended and ancillary testing was not

required when an irreversible cause existed. The observation period in this age group could be decreased if there was documentation of electrocerebral silence (ECS) or absent cerebral blood flow (CBF). The general consensus was the younger the child, the longer the waiting period unless ancillary studies supported the clinical diagnosis of brain death and if so, the observation period could be shortened.

The current committee supports the 1987 guideline recommending performance of two examinations separated by an observation period. The committee recommends that these examinations be performed by different attending physicians involved in the care of the child. Children being evaluated for brain death may be cared for and evaluated by multiple medical and surgical specialists. The committee recommends that the best interests of the child and family are served if at least two different attending physicians participate in diagnosing brain death to ensure that (i) the diagnosis is based on currently established criteria, (ii) there are no conflicts of interest in establishing the diagnosis and (iii) there is consensus by at least two physicians involved in the care of the child that brain death criteria are met. The committee also believes that because the apnea test is an objective test, it may be performed by the same physician, preferably the attending physician who is managing ventilator care of the

Duration of Observation Periods

A literature review of 171 children diagnosed as brain dead found that 47% had ventilator support withdrawn an average of 1.7 days after the diagnosis of brain death was made. Seventy-nine children (46%) in whom support was continued after declaration of brain death suffered a cardiac arrest an average of 22.7 days later. The re-

maining children died by an unknown mechanism (5%), or made an incomplete (1%) or complete recovery (0.5%). Review of the children who survived indicates they did not fulfill brain death criteria by accepted medical standards. The age range of the children in this study included preterm and term neonates and older infants and children up to 18 years of age. These data and the reports of more recent studies35,38 suggest that there is likely no biological justification for using different durations of observation to diagnose brain death in infants greater than one month of age, in fact, there are no reports of children recovering neurologic function after meeting adult brain death criteria based on neurologic examination findings.37 Although some authors have reported apparent reversibility of brain death, further review of these cases reveals these children would not have fulfilled brain death criteria by currently accepted US medical standards.38

Based on the above data, currently available literature and clinical experience, the committee recommends the observation period between examinations should be 24 hours for neonates (37 weeks up to 30 days), and 12 hours for infants and children (> 30 days to 18 years). The first examination determines the child has met neurologic examination criteria for brain death. The second examination confirms brain death based on an unchanged and irreversible condition. Timing of the first clinical brain death examination, reduction of the observation period, and use of ancillary studies are discussed in separate sections of this guideline.

Apnea Testing (Recommendations 4a,b, Table 1)

Apnea testing should be performed with each neurologic examination to determine brain death in all patients unless a medical contraindication exists. Contraindications may include conditions that invalidate the apnea test (such as high cervical spine injury) or raise safety concerns for the patient (high oxygen requirement or ventilator settings). If apnea testing cannot be completed safely, an ancillary study should be performed to assist with the determination of brain death.

The normal physiologic threshold for apnea (minimum carbon dioxide tension at which respiration begins) in children has been assumed to be the same as in adults with reports demonstrating that Paco, levels in the normal range (24-38 mm Hg) may be adequate to stimulate ventilatory effort in children with residual brainstem function.39 Although expert opinion has suggested a range of Paco, levels from 44 to 60 mm Hg for apnea testing in adults, the general consensus in infants and children has been to use 60 mm Hg as a threshold.40-42 Appendix 3 summarizes data from 4 studies (3 being prospective) on 106 apnea tests in 76 children 2 months old to 17 years with suspected brain death.39-42 73 of 76 children had no spontaneous ventilatory effort. In 3 of these studies mean Paco, values were 59.5 ± 10.2, 68.1 ± 17.7, and 63.9 ± 21.5 mm Hg; in the fourth study, mean Paco2 values were not reported, only the range (ie, 60-116 mm Hg).39-42 Three children exhibited spontaneous respiratory effort with measured Paco, levels < 40 mm Hg.30.42 Serial measurements of Paco, were done in most studies and 15 minutes was the usual end point of testing although patients may have had apnea for longer periods. The maximum rate of Paco2 increase usually occurred within 5 minutes. Sixty five children had no ventilatory effort during the apnea test. After completion of apnea testing, support was withdrawn in all of these patients. Patient outcome was not reported for one study although these 9 children all had absent brainstem reflexes for a period of > 72 hours.⁴¹ In one study 4/9 patients had phenobarbital levels that were interpreted as not affecting the results of apnea testing.⁴¹

There are three case reports discussing irregular breaths or minimal respiratory effort with a Pco₂ > 60 mm Hg in children who otherwise met criteria for brain death. 43-45 Two children died, one after meeting all criteria for brain death including a second apnea test. The remaining child survived and was supported in a chronic care facility with a tracheostomy, chronic mechanical ventilation and a gastrostomy tube. One other report describes a 3-month-old who met all criteria for brain death including 2 apnea tests with serial Pco,'s of 69.3 mm Hg and 62.1 mm Hg respectively. This infant was declared dead on hospital day 5. This infant developed irregular spontaneous respirations at a rate of two to three breaths per minute 38 days later which continued while receiving mechanical ventilator support until death on day 71.46 Review of this case and others remind us to be cautious in applying brain death criteria in young infants. However, these cases should not be considered to represent reversible deficits or failure of current brain death criteria.47

Technique for Apnea Testing

Apnea testing in term newborns, infants, and children is conducted similar to adults. Normalization of the pH and Paco₂, measured by arterial blood gas analysis, maintenance of core temperature > 35°C, normalization of blood pressure appropriate for the age of the child, and correcting for factors that could affect respiratory effort are a prerequisite to testing. The patient must be preoxygenated using 100% oxygen for 5–10 minutes before initiating this test. Intermittent manda-

ì

tory mechanical ventilation should be discontinued once the patient is well oxygenated and a normal Pace, has been achieved. The patient can then be changed to a T piece attached to the endotracheal tube (ETT), or a selfinflating bag valve system such as a Mapleson circuit connected to the ETT. Tracheal insufflation of oxygen using a catheter inserted through the ETT has also been used, however caution is warranted to ensure adequate gas excursion and to prevent barotrauma. High gas flow rates with tracheal insufflation may also promote CO, washout preventing adequate Pace, rise during apnea testing. Continuous positive airway pressure (CPAP) ventilation has been used during apnea testing. Many current ventilators automatically change from a CPAP mode to mandatory ventilation and deliver a breath when apnea is detected. It is also important to note that spontaneous ventilation has been falsely reported to occur while patients were maintained on CPAP despite having the trigger sensitivity of the mechanical ventilator reduced to minimum levels.48 Physician(s) performing apnea testing should continuously monitor the patient's heart rate, blood pressure, and oxygen saturation while observing for spontaneous respiratory effort throughout the entire procedure. Paco, measured by blood gas analysis, should be allowed to rise to ≥ 20 mm Hg above the baseline Paco₂ level and ≥ 60 mm Hg. If no respiratory effort is observed from the initiation of the apnea test to the time the measured Pace, ≥ 60 mm Hg and ≥ 20 mm Hg above the baseline level, the apnea test is consistent with brain death. The patient should be placed back on mechanical ventilator support and medical management should continue until the second neurologic examination and apnea test confirming brain death is completed. If oxygen saturations fall below 85%, hemodynamic in-

stability limits completion of apnea testing, or a Paco₂ level of ≥ 60 mm Hg cannot be achieved, the infant or child should be placed back on ventilator support with appropriate treatment to restore normal oxygen saturations, normocarbia, and hemodynamic parameters. In this instance, another attempt to test for apnea may be performed at a later time or an ancillary study may be pursued to assist with determination of brain death. Evidence of any respiratory effort that is inconsistent with brain death and the apnea test should be terminated and the patient placed back on ventilatory support.

Ancillary Studies (Recommendations 5a-e, Table 1)

The committee recommends that ancillary studies are not required to establish brain death and should not be viewed as a substitute for the neurologic examination. Ancillary studies may be used to assist the clinician in making the diagnosis of brain death (i) when components of the examination or apnea testing cannot be completed safely due to the underlying medical condition of the patient; (ii) if there is uncertainty about the results of the neurologic examination; (iii) if a medication effect may be present; or (iv) to reduce the inter-examination observation period. The term "ancillary study" is preferred to "confirmatory study" since these tests assist the clinician in making the clinical diagnosis of brain death. Ancillary studies may also be helpful for social reasons allowing family members to better comprehend the diagnosis of brain death.

Four-vessel cerebral angiography is the gold standard for determining absence of CBF. This test can be difficult to perform in infants and small children, may not be readily available at all institutions, and requires moving the patient to the angiography suite poten-

tially increasing risk of exacerbating hemodynamic and respiratory instability during transport of a critically ill child outside of the intensive care unit. Electroencephalographic documentation of electrocerebral silence (ECS) and use of radionuclide CBF determinations to document the absence of CBF remain the most widely used methods to support the clinical diagnosis of brain death in infants and children. Radionuclide CBF testing must be performed in accordance with guidelines established by the Society of Nuclear Medicine and the American College of Radiology. 48,50 EEG testing must be performed in accordance with standards established by the American Electroencephalographic Society.51 Interpretation of ancillary studies requires the expertise of appropriately trained and qualified individuals who understand the limitations of these studies to avoid any potential misinterpretation.

Similar to the neurologic examination, hemodynamic and temperature parameters should be normalized before obtaining EEG or CBF studies. Pharmacologic agents that could affect the results of testing should be discontinued (Appendix 2) and levels determined as clinically indicated. Low to mid therapeutic levels of barbiturates should not preclude the use of EEG testing. Evidence suggests that radionuclide CBF study can be used in patients with high dose barbiturate therapy to demonstrate absence of CBF. 52.55

Diagnostic Yield of the EEG in Suspected Brain Dead Children

Appendix 4 summarizes EEG data from 12 studies in 485 suspected brain dead children in all age groups. 34,54-65 The data show that 76% of all children who were evaluated with EEG for brain death on the first EEG had ECS. Multiple EEGs increased the yield to 89%. For those children who had ECS on their

first EEG, 64/66 patients (97%) had ECS on a follow-up EEG. The first exception was a neonate who had a phenobarbital level of 30 µg/mL when the first EEG was performed.65 The second exception was a 5 year old head trauma patient who was receiving pentobarbital and pancuronium at the time of the initial EEG.⁶² This patient also had a CBF study performed demonstrating flow. In retrospect, these two patients would not have met currently accepted standards for brain death based on pharmacologic interference with EEG testing. Additionally, of those patients with EEG activity on the first EEG, 55% had a subsequent EEG that showed ECS. The remaining 45% either had persistent EEG activity or additional EEGs were not performed. All died (spontaneously or by withdrawal of support). Only one patient survived from this entire group of 485 patients. a neonate with an elevated phenobarbital level whose first EEG showed photic response and survived severely neurologically impaired.

Diagnostic Yield of Radionuclide CBF Studies in Suspected Brain Dead Children

Appendix 5 summarizes CBF data from 12 studies in 681 suspected brain dead children in all age groups. 36,54,55,57,38,60,63,64-68 Different but well standardized and conventional radionuclide cerebral angiography methods were used. Absent CBF was found in 86% of children who were clinically brain dead and the yield did not significantly change if more than one CBF study was done (89%). Appendix 5 also summarizes follow-up data on children whose subsequent CBF study showed no flow. 24/26 patients (92%) had no flow on follow-up CBF studies when the first study showed absent flow. The two exceptions where flow developed later were newborns. The first newborn had minimal flow on the second study and ventilator support was discontinued. The

other newborn developed flow on the second study and had some spontaneous respirations and activity. A phenobarbital level two days after the second CBF study with minimal flow was 8 μ g/mL.^{SS}

In those patients with preserved CBF on the first CBF study, 26% (9/34) had a second CBF study that showed no flow. The remaining 74% either had preserved flow or no further CBF studies were done and all but one patient died (either spontaneously or by withdrawal of support). Only one patient survived with severe neurologic impairment from this entire group of patients—the same neonate as noted previously with no CBF on the first study but presence of CBF on the second study.

Diagnostic Yield of the Initial EEG Versus Radionuclide CBF Studies in Brain Dead Children

Appendix 6 summarizes the comparative diagnostic yield of EEG versus CBF determinations in children who had both studies done as part of the initial brain death evaluation. Data from the 12 studies cited in Appendices 4 and 5 were stratified by 3 age groups: (i) all children (n=149); (ii) newborns (< 1 month of age, n=30); and (iii) children age > 1 month to 18 years (n=119). 36.54–36.58–88

The data in Appendices 4 and 5 show that the yield from the initial CBF studies was higher (86%) than from the initial EEG (76%) but no differences were present for any CBF study (89%) vs any EEG study (89%). In contrast the data in Appendix 6 for all children show that when both studies are initially performed, the diagnostic yield is the same (70% had ECS; and 70% showed absent CBF). The diagnostic yield for children greater than 1 month of age was similar for both tests (EEG with ECS, 78%; no CBF, 71%). For newborns, EEG with ECS was less sensitive (40%)

than absence of CBF (63%) when confirming the diagnosis of brain death but even in the CBF group the yield was low.

In summary, both of these ancillary studies remain accepted tests to assist with determination of brain death in infants and children. The data suggest that EEG and CBF studies are of similar confirmatory value. Radionuclide CBF techniques are increasingly being used in many institutions replacing EEG as an ancillary study to assist with the determination of brain death in infants and children.5.59 Other ancillary studies such as the Transcranial Doppler study and newer tests such as CT angiography, CT perfusion using arterial spin labeling, nasopharyngeal somatosensory evoked potential studies, MRI-MR angiography, and perfusion MRI imaging have not been studied sufficiently nor validated in infants and children and cannot be recommended as ancillary studies to assist with the determination of brain death in children at this time.

Repeating Ancillary Studies

If the EEG study shows electrical activity or the CBF study shows evidence of flow or cellular uptake, the patient cannot be pronounced dead at that time. The patient should continue to be observed and medically treated until brain death can be declared solely on clinical examination criteria and apnea testing based on recommended observation periods, or a follow-up ancillary study can be performed to assist and is consistent with the determination of brain death, or withdrawal of life-sustaining medical therapies is made irrespective of meeting criteria for brain death. A waiting period of 24 hours is recommended before further ancillary testing, using a radionuclide CBF study, is performed allowing adequate clearance of Tc-99m.4959 While no evidence exists for a recommended

waiting period between EEG studies, a waiting period of 24 hours is reasonable and recommended before repeating this ancillary study.

Shortening the Observation Period

If an ancillary study, used in conjunction with the first neurologic examination, supports the diagnosis of brain death, the inter-examination observation interval can be shortened and the second neurologic examination and apneatest (or all components that can be completed safely) can be performed and documented at any time thereafter for children of all ages.

SPECIAL CONSIDERATIONS FOR TERM NEWBORNS (37 WEEKS GESTATION) TO 30 DAYS OF AGE (RECOMMENDATIONS 1-5, TABLE 1)

Preterm and term neonates younger than 7 days of age were excluded from the 1987 Task Force guidelines. The ability to diagnose brain death in newborns is still viewed with some uncertainty primarily due to the small number of brain-dead neonates reported in the literature54,65,70 and whether there are intrinsic biological differences in neonatal brain metabolism, blood flow and response to injury. The newborn has patent sutures and an open fontanelle resulting in less dramatic increases in intracranial pressure (ICP) after acute brain injury when compared with older patients. The cascade of events associated with increased ICP and reduced cerebral perfusion ultimately leading to herniation are less likely to occur in the neonate.

Clinical Examination

Limited data are available regarding the clinical examination for brain death in preterm and term infants. 70 lt has been recognized that examination of the preterm infant less than 37 weeks gestation to determine if they meet brain death criteria may be difficult because of the possibility that

some of the brainstem reflexes may not be completely developed and that it is also difficult to assess the level of consciousness in a critically ill, sedated and intubated neonate. Because of insufficient data in the literature. recommendations for preterm infants less than 37 weeks gestational age were not included in this guideline. However, as discussed in the following section on observation periods, the available data suggest that recovery of neurologic function is unlikely when a term newborn is diagnosed with brain death. Based on review of the literature, the task force supports that brain death can be diagnosed in term newborns (37 weeks gestation) and older, provided the physician is aware of the limitations of the clinical examination and ancillary studies in this age group. It is important to carefully and repeatedly examine term newborns, with particular attention to examination of brainstem reflexes and apnea testing. As with older children, assessment of neurologic function in the term newborn may be unreliable immediately following an acute catastrophic neurologic injury or cardiopulmonary arrest. A period of 24 hours or longer is recommended before evaluating the term newborn for brain death.

Apnea Testing

Neonatal studies reviewing Paco₂ thresholds for apnea are limited. However, data from 35 neonates who were ultimately determined to be brain dead revealed a mean Paco, of 65 mm Hg suggesting that the threshold of 60 mm Hg is also valid in the newborn.35 Apnea testing in the term newborn may be complicated by the following: (1) Treatment with 100% oxygen may inhibit the potential recovery of respiratory effort.71.72 (2) Profound bradycardia may precede hypercarbia and limit this test in neonates. A thorough neurologic examination must be performed in conjunction with the apnea test to make the determination of death in any patient. If the apnea test cannot be completed as previously described, the examination and apnea test can be attempted at a later time, or an ancillary study may be performed to assist with determination of death. Ancillary studies in newborns are less sensitive than in older children. There are no reported cases of any neonate who developed respiratory effort after meeting brain death criteria.

Observation Periods in Term Newborns

There is some experience concerning the duration of observation periods in neonates being evaluated for brain death. A review of 87 newborns revealed that the duration of coma from insult to brain death was 37 hours and the duration of time from the initial neurologic examination being indicative of brain death to final confirmation was 75 hours. The overall average duration of brain death in these neonates was about 95 hours or almost 4 days.37 53 neonates less than 7 days of age donating organs for transplantation had a total duration of brain death including time to transplantation that averaged 2.8 days; for neonates 1-3 weeks of age, the duration of brain death was approximately 5.2 days.37 None of these patients recovered any neurologic function. These data suggest that once the diagnosis of brain death is made in newborns, recovery is unlikely. Based on data extracted from available literature and clinical experience the committee recommends the observation period between examinations should be 24 hours for term newborns (37 weeks) to 30 days of age.

Ancillary Studies

Ancillary studies performed in the newborn < 30 days of age are limited. As summarized in Appendix 6, ancillary studies in this age group are less sensitive in detecting the pres-

ence/absence of brain electrical activity or cerebral blood flow than in older children. Of the two studies, detecting absence of CBF (63%) was more sensitive than demonstration of ECS (40%) in confirming the diagnosis of brain death, however even in the CBF study group the sensitivity was low.⁷⁰

EEG activity is of low voltage in newborns raising concerns about a greater chance of having reversible ECS in this age group. In a retrospective review of 40 newborns with ECS, 9/10 with ECS on the initial EEG showed ECS on repeated studies.70 The remaining patient had a phenobarbital level of 30 µg/mL at the time of the initial EEG, probably accounting for the initial ECS. Several other cases have been reported with initial ECS but careful review found that the patients were not clinically brain dead. Based on available data it is likely that if the initial EEG shows ECS (assuming an absence of correctable conditions) in a newborn who meets all clinical criteria for brain death, then it is an accurate and reliable predictor of brain death and repeat EEG studies are not indicated.

CBF in viable newborns can be extremely low because of the decreased level of brain metabolic activity. So However earlier studies using stable xenon computed tomography measurements of CBF have shown that the level of CBF in brain dead children is much lower than that seen in viable newborns. 74.74

The available data suggest that ancillary studies in newborns are less sensitive than in older children. This can pose an important clinical dilemma in this age group where clinicians may have a "greater level of uncertainty about performing a valid neurologic examination. There is a greater need to have more reliable and accurate ancillary studies in this age group. Awareness of this limitation would suggest that longer periods of observation and repeated neurologic examinations are

needed before making the diagnosis of brain death and also that as in older infants and children, the diagnosis should be made clinically and based on repeated examinations rather than relying exclusively on ancillary studies.

DECLARATION OF DEATH (FOR ALL AGE GROUPS) (RECOMMENDATIONS 6a-c, TABLE

1 AND APPENDIX 8 ALGORITHM)

Death is declared after the second neurologic examination and apnea test confirms an unchanged and irreversible condition. An algorithm (Appendix 8) provides recommendations for the process of diagnosing brain death in children. When ancillary studies are used, documentation of components from the second clinical examination that can be completed, including a second apnea test, must remain consistent with brain death. All aspects of the clinical examination, including the apnea test, or ancillary studies must be appropriately documented. A checklist outlining essential examination and testing components is provided in Appendix 1. This checklist also provides standardized documentation to determine brain death.

ADDITIONAL CONSIDERATIONS (FOR ALL AGE GROUPS)

In today's modern pediatric and neonatal intensive care units, critical care practitioners and other physicians with expertise in neurologic injury are routinely called on to declare death in infants and children. Because the implications of diagnosing brain death are of great consequence, examination should be conducted by experienced clinicians who are familiar with neonates, infants and children and have specific training in neurocritical care. These physicians must be competent to perform the clinical examination and interpret results from ancillary studies. Qualified clinicians include: pediatric intensivists and neonatolo-

gists, pediatric neurologists and neurosurgeons, pediatric trauma surgeons, and pediatric anesthesiologists with critical care training. Adult specialists should have appropriate neurologic and critical care training to diagnose brain death when caring for the pediatric patient from birth to 18 years of age. Residents and fellows should be encouraged to learn how to properly perform brain death testing by observing and participating in the clinical examination and testing process performed by experienced attending physicians. It is recommended that both neurologic examinations be performed and documented by an attending physician who is qualified and competent to perform the brain death examination.

These revised pediatric brain death diagnostic guidelines are intended to provide an updated framework in an effort to promote standardization of the neurologic examination and use of ancillary studies. A standardized checklist (Appendix 1) will help to ensure that all components of the examination, and ancillary studies if needed, are completed and documented appropriately. Pediatric specialists should be invited to participate in the development of institutional guidelines to ensure that the brain death examination is conducted consistently each time the diagnosis is being considered, A comparison of the 1987 pediatric brain death guidelines and 2011 update for neonatal and pediatric brain death guidelines are listed in Appendix 7.

Diagnosing brain death must never be rushed or take priority over the needs of the patient or the family. Physicians are obligated to provide support and guidance for families as they face difficult end-of-life decisions and attempt to understand what has happened to their child. It is the responsibility of the physician to guide and direct families during the treatment of their child. Communication with families must be clear and concise using simple termi-

nology so that parents and family members understand that their child has died. Permitting families to be present during the brain death examination. apnea testing and performance of ancillary studies can assist families in understanding that their child has died. The family must understand that once brain death has been declared, their child meets legal criteria for death. Families may otherwise become confused or angry if discussions regarding withdrawal of support or medical therapies are entertained after declaration of death. It should be made clear that once death has occurred, continuation of medical therapies, including ventilator support, is no longer an option unless organ donation is planned. Appropriate emotional support for the family should be provided including adequate time to grieve with their child after death has occurred. Consultation or referral to the medical examiner or coroner may be required by state law in certain situations when death occurs.

FUTURE DIRECTIONS

Development of a national database to track infants and children who are diagnosed as brain dead should be strongly considered. Information compiled from this database would increase our knowledge about brain death, especially in neonates.

- Studies comparing traditional ancillary studies to newer methods to assess CBF and neurophysiologic function should be pursued. Further information about ancillary studies, waiting periods, and research regarding validity of newer ancillary studies is needed for future recommendations to assist with determination of brain death in children.
- Cerebral protective therapies such as hypothermia may after the natural progression of brain death and their impact should be reviewed as more information becomes avail-

able. The clinician caring for critically ill infants and children should be aware of the potential impact of new therapeutic modalities on the diagnosis of brain death.

- 3. While each institution and state may have specific guidelines for the determination of brain death in infants and children, we should work with national medical societies to achieve a uniform approach to declaring death that can be incorporated in all hospital policies. This will help eliminate confusion among medical personnel thereby fostering further trust from the community of patients and families that we serve.
- Additional information or studies are required to determine if a single neurologic examination is sufficient for neonates, infants, and children to determine brain death as currently recommended for adults over 18 years of age.^{12,76}

ENDORSEMENTS AND APPROVALS

This document has been reviewed and endorsed by the following societies:

American Academy of Pediatrics

Sub sections:

Section on Critical Care

Section on Neurology

American Association of Critical Care Nurses

Child Neurology Society

National Association of Pediatric Nurse Practitioners

Society of Critical Care Medicine

Society for Pediatric Anesthesia

Society of Pediatric Neuronadiology

World Federation of Pediatric Intensive and Critical Care Societies

American Academy of Neurology affirms the value of this manuscript.

The following societies have had the opportunity to review and comment on this document

American Academy of Pediatrics Sub sections:

Committee on Bioethics

Committee on Child Abuse and Neglect

Committee on Federal Government Affairs

Committee on Fetus and Newborn

Committee on Hospital Care

Committee on Medical Liability and Risk Management

Committee on Pediatric Emergency Medicine

Committee on Practice and Ambulatory Medicine

Committee on State Government Affairs

Council on Children With Disabilities

Section on Anesthesiology and Pain Medicine

Section on Bioethics

Section on Child Abuse and Neglect

Section on Critical Care

Section on Emergency Medicine

Section on Hospital Medicine

Section on Neurology

Section on Perinatal Pediatrics

Section on Neurological Surgery

Section on Pediatric Surgery

The Pediatric Section of the American Association of Neurosurgeons and the Congress of Neurologic Surgeons have been provided the opportunity to review this document

ACKNOWLEDGMENTS

SCCM staff support:

Laura Kolinski. SCCM. Mount Prospect, III

Lynn Retford. SCCM. Mount Prospect, III

SCCM Board of Regents:

M. Michele Moss, MD, FCCM

Tim Yeh, MD, FCCM

SCCM Facilitator:

Lorry Frankel, MD, FCCM

Roman Jaeschke, MD, for his direction in the GRADE evaluation process.

REFERENCES

- American Academy of Pediatrics, Task Force on Brain Death in Children. Report of Special Task Force: guidelines for determination of brain death in children. Pediatrics. 1987:80(2):298–300
- Guidelines for determination of brain death in children. Pediatr Neurol. 1987;3(4):242-243
- Chang MY, McBride LA, Ferguson MA. Variability in brain death declaration practices in pediatric head trauma patients. *Pediatr Neurosurg.* 2003;39(1):7–9
- Mejia RE, Pollack MM. Variability in brain death determination practices in children. JAMA. 1995;274(7):550–553
- Mathur M, Petersen L, Stadtler M, et al. Variability in pediatric brain death determination and documentation in southern California. Pediatrics. 2008;121(5):968–993
- 6 Hornby K, Shemic SD, Teitelbaum J, Doig C. Variability in hospital-based brain death guidelines in Canada. Can J Anaesth. 2006; 53(6):613—619
- Joffe AR, Anton N. Brain death: understanding of the conceptual basis by pediatric intensivists in Canada. Arch Pediatr Adolesc Med. 2006;160(7):747-752
- Lynch J, Eldadah MK. Brain-death criteria currently used by pediatric intensivists. Clin Pediatr (Phila). 1992;31(8):457–460
- Harrison AM, Botkin JR. Can pediatricians define and apply the concept of brain death? Pediatrics. 1999;103(6). Available at: www. pediatrics.org/cgi/content/full/103/6/e82
- Greer DM, Varelas PN, Haque S, Wijdicks EFM. Variability of brain death determination guidelines in leading US neurologic institutions. *Neurology*. 2008;70(4):284–289
- Practice parameters for determining brain death in adults. Neurology. 1995;45(5): 1012–1014
- Wijdicks EFM, Varelas PN, Greer DM. Determining brain death in adults: 2009 guideline update. Neurology. 2010;74(23):1911–1918
- Shemie SD, Doig C, Dickens B, et al, Pediatric Reference Group; Neonatal Reference Group. Severe brain injury to neurological determination of death: Canadian forum recommendations, CMAJ. 2006;174(6):51–13
- Atkins D. Best D. Briss PA, et al; GRADE Working Group. Grading quality of evidence and strength of recommendations. BMJ. 2004; 328(7454):1490–1494
- Guyatt GH, Oxman AD, Kunz R, et al. Rating quality of evidence and strength of recommendations. GRADE: going from evidence to recommendations. BMJ. 2006;336(7652):1049~1051
- 16 Jaeschke R. Guyatt GH, Dellinger P, et al: GRADE Working Group. Use of GRADE grid to

- reach decisions on clinical practice guidelines when consensus is elusive. *BMJ*, 2008; 337:a744
- Guyatt GH, Oxman AD, Vist GE, et al; GRADE Working Group. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ. 2008; 336(7650):924-926.
- Grade Working Group. Home page. Available at: www.gradeworkinggroup.org. Accessed September 19, 2009
- Hutchison JS, Ward RE, Lacroix J, et al. Hypothermia therapy after traumatic brain injury in children. Il Engl J Med. 2008;358(23): 2447–2456
- Biswas AK, Bruce DA, Sklar FH, et al. Treatment of acute traumatic brain injury in children with moderate hypothermia improves intracranial hyportension. *Crit Care Med*. 2002;30(12):2742–2751
- Adelson PD, Ragheb J, Kanez P, et al. Phase II clinical trial of moderate hypothermia after traumatic brain injury in children. Neurosurgery. 2005;58(4):740-754
- Azzopardi DV, Strohm B, Edwards AD, et al; TOBY Study Group. Moderate hypothermia to treat perinatal asphyxial encephalopathy. II Engl J Med. 2009;361(14):1349–1358
- Hutchison JS, Doherty DR, Orlowski JP, Kissoon N. Hypothermia therapy for cardiac arrest in pediatric patients. *Pediatr Clin North Am.* 2008;55(3):529–544
- Kochanek PM, Fink EL, Bell JM, Bayir H, Clark RSB. Therapeutic hypothermia: applications in pediatric cardiac arrest. J Neurotrauma. 2009;26(3):421–427
- Doherty DR, Parshuram CS, Gaboury I, et al. Hypothermia after pediatric cardiac arrest. Circulation, 2009;119(11):1492–1500
- Hoehn T, Hansmann G, Buhrer C, et al. Therapeutic hypothermia in neonates: review of current clinical data, ILCOR recommendations and suggestions for implementation in neonatal intensive care units. Resuscitation. 2008;78(1):7–12
- Danzi DF, Pozos RS. Accidental hypothermia N Engl J Med. 1994;331(26):1756-1760
- Abend NS, Kessler SK, Helfaer MA, Licht DJ. I: evaluation of the comatose child. In: Nichols DGRogers Textbook of Pediatric Intensive Care. 4th ed. Philadelphia, PA: Lippincott, Wilkiams & Wilkins; 2008.846—861
- Michelson DJJ, Ashwal S. Evaluation of coma. In: Wheeler DS, Wong HR, Shanley TPPediatric Critical Care Medicine: Basic Science and Clinical Evidence. London, United Kingdom: Springer-Verlag; 2007: 224-934

- Booth CM, Boone RH, Tomlinson G, Detsky AS. Is this patient dead, vegetative, or severely neurologically impaired? Assessing outcome for comatose survivors of cardiac arrest. JAMA. 2004;291(7):879~879
- Haque IV, Udassi JP, Zaritsky AL. Outcome following cardiopulmonary arrest. Pediatr Clin North Am. 2008;55(4):969-987
- Mandel R, Marinot A, Delepoulte F. Prediction of outcome after hypoxic-ischemic encephalopathy: a prospective clinical and electrophysiologic study. J Pediatr. 2002;141(1:45–50)
- Carter BS, Butt W. A prospective study of outcome predictors after severe brain injury in children. Intensive Care Med. 2005;31(5):840–845
- Ashwal S, Schneider S. Brain death in children: part I. Pediatr Neurol. 1987;3(1):5–11
- Ashwal S. Brain death in the newborn, current perspectives. Clin Perinatol. 1997; 24(4):859-882
- Parker BL, Frewen TC, Levin SD, et al. Declaring pediatric brain death: current practice in a Canadian pediatric critical care unit. CMAJ, 1995:153(7):909–918
- Ashwal S. Clinical diagnosis and confirmatory testing of brain death in children. In: Wijdick EBrain Death. Philadelphia, PA: Lippincott, William & Wilkins; 2001:91–114
- Joffe AR, Kolski H, Duff J, deCaen AR. A 10 month old with reversible findings of brein death. *Pediatr Neural*. 2009;41(5):378–382
- Riviello JJ, Sapin JI, Brown LW, et al. Hypoxemia and hemodynamic changes during the hypercarbia stimulation test. *Pediatr Neu*rol. 1988;4(4):213–218
- Outwater KM, Rockoff MA. Apnea testing to confirm brain death in children. Crit Care Med. 1984;12(4):357–358
- Rowland TW, Donnelly JH, Jackson AH. Apnea documentation for determination of brain death in children. *Pediatrics*. 1984; 74(4):505–508
- Paret G, Barzilay Z. Apnea testing in suspected brain dead children: physiological and mathematical modeling. *Intensive Care Med.* 1995;21(3):247–252
- Vardis R, Pollack MM. Altered apnea threshold in a pediatric patient with suspected brain death. Crit Care Med. 1998;26(11):1917—1919
- Brilli RJ, Biges D. Threshold in a child with suspected brain death. J Child Neurol. 1995; 10(3):245–246
- Haun SE, Tobias JD, Deshpande JK. Apnoea testing in the determination of brain death: is it reliable? Clin Intensive Care. 1991;2(3):182–184.
- Okamoto K, Sugimoto T. Return of spontaneous respiration in an infant who fulfilled

- current criteria to determine brain death. Pediatrics, 1995;96(3 pt 1):518-520
- Fishman MA. Validity of brain death criteria in infants. Pediatrics. 1995;96(3 pt 1):513–515
- Wijdicks E. Confirmatory testing of brain death in adults: In: Wijdicks E, ed. Brain Death. Philadelphia, PA: Lippincott, William & Wilkins; 2001;61–90
- Donohoe KJ, Frey KA, Gerbaudo VH, et al. Procedure guideline for brain death scintigraphy. J Nucl Med. 2003;44(5):846–851
- ACR Practice Guideline for the performance of single photon emission computed tomography (SPECT) brain perfusion and brain death studies. ACR Practice Guidelines and Technical Standards 2007 Res21 2007 823—828
- American Electroencephalographic Society.
 Guideline three: minimum technical standards for EEG recording in suspected cerebral death. J Clin Neurophysiol. 1994;11(1):10–13
- LaMancusa J, Cooper R, Vieth R, Wright F. The effects of the falling therapeutic and subtherapeutic barbiturate blood levels on electrogerebral silence in clinically brain-dead children. Clin Electroencephalogr. 1991;22(2):112–117
- López-Navidad A, Caballero F, Domingo P, et al. Early diagnosis of brain death in patients treated with central nervous system depressant drugs. Transplantation. 2000; 70(1):131–135
- Ashwal S. Brain death in early infancy. J Heart Lung Transplant. 1993;12(6 pt 2):S176–S178
- Drake B, Ashwal S, Schneider S. Determination of cerebral death in the pediatric intensive care unit. Pediatrics. 1986;78(1):107–112
- Alvarez LA, Moshe SL, Belman AL, et al. EEG and brain death determination in children. Neurology. 1988;38(2):227–230
- Ashwal S, Schneider S. Brain death in children: part II. Pediatr Neurol. 1987;3(2) 69–77
- Ashwal S, Smith AJ, Torres F, et al. Radionuclide bolus angiography: a technique for verification of brain death in infants and children. J Pediatr. 1977;91(5):722–727
- Coker SB, Dillehay GL, Radionuclide cerebral imaging for confirmation of brain death in children the significance of dural sinus activity. *Pediatr Neurol* 1986;2(1):43–46
- Ruiz-GarciA Genzalez-Astiazaran M. Collado-Corona A, A et al. M.Brain death in children: clinical, neurophysiological and radioisotopic angiography findings in 125 patients. Childs Nerv Syst. 2000; 16(1):40-45
- Ruiz-López MJ, Martinez de Azagra A, Serrano A, Casado-Flores J. Brain death and evoked potentials in pediatric patients. Crit Care Med. 1999;27(2):412–416
- 62. Holzman BH, Curless RG, Sfakianskis GN, et

c734

- al Radionuclide cerebral perfusion scintigraphy in determination of brain death in children. *Neurology*, 1983;33(8):1027–1031
- Furgiuele TL, Frank LM, Riegle C, et al. Prediction of cerebral death by cranial sector scan. Crit Care Med. 1984;12(1):1–3
- Okuyaz C, Gucuyener K, Karabacak NI, et al. To:99m-HMPAD SPECT in the diagnosis of brain death in children. *Pediatr Int.* 2004; 46(6):711–714
- Ashwal S, Schneider S. Brain death in the newborn. Pediatrics. 1989;84(3):429–437
- Shimizu N, Shemie S, Miyasaka E, et al. Preliminary report: use of clinical criteria for the determination of pediatric brain death and confirmation by radionuclide cerebral blood flow. Masui. 2000;49(10):1126–1132
- Ahmann PA, Carrigan TA, Carlton D, et al. Brain death in children: characteristic common carotid arterial velocity patterns measured with pulsed Doppler ultrasound. J Pediatr. 1987;110(5):723–728
- Schwartz JA, Baxter J, Brill DR. Diagnosis of brain death in children by radionuclide cerebral imaging. *Pediatrics*. 1984;73(1):14–18
- Conrad GR, Sinha P. Scintigraphy as a confirmatory test of brain death. Semin Nucl Med. 2003;33(4):312–323
- Ashwal S. Brain death in the newborn. Clin Perinatal. 1989:16(2):501–518
- Saugstad OD, Rootwelt T, Aalen O. Resuscitation of asphysiated newborn infants with room air or oxygen: an international controlled trial: the Resair 2 study. *Pediatrics*. 1998;102(1). Available at: www.pediatrics.org/cgi/content/full/102/1/e1
- Hutchison AA. Recovery from hypopnea in preterm lambs: effects of breathing air or oxygen. Pediatr Pulmonol 1987;3(5):317–323
- Ashwal S, Schneider S, Thompson J. Xenon computed tomography cerebral blood flow in determination of brain death in children. *Ann Neurol.* 1989;25(6):539-546
- Altman DI, Powers WJ, Perlman JM, et al. Cerebral blood flow requirement for brain viability in newborn infants is lower than adults. *Ann Neurol*. 1988;24(2):218–226
- Choi EK, Fredland V, Zachodni C, et al. Brain death revisited: the case for a national standard. J Law Med Fthics. 2008;36(4):824–836
- Lustbader D, O'Hara D, Wijdicks EF, et al. Second brain death examination may negatively affect organ donation. Neurology. 2011;76(2):119–124
- Burtin P, Jacqz-Aigrain E, Girard P, et al. Population pharmacokinetics of midazolam in neonates. Clin Pharmacol Ther. 1994,56(6 pt 1):615–625

- de Wildt SN, Kearns GL, Hop WC, et al. Pharmacokinetics and metabolism of intravenous midazolam in preterm infants. Clin Pharmacol Ther. 2001;70(6):525–531
- Taketomo CK, Hodding JH, Kraus DM: Pediatric Dosage Handbook 16th Ed. Hudson, Ohio: Lexi-Comp., 2009
- de Wildt SN, de Hoog M, Vinks AA, van der Giesen E, van den Anker JN. Population pharmacokinetics and metabolism of midazolam in pediatric intensive care patients. Crit Cara Med 2003;31(7):1952–1958
- Czaja AS, Zimmerman JJ. The use of dexmedetomidine in critically ill children. Pediatr Crit Care Med. 2009;10(3):381–386
- Diaz SM, Rodarte A, Foley J, Capparelli EV. Pharmookinetics of dexmedetomidine in postsurgical pediatric intensive care unit patients: preliminary study. Pediatr Crit Care Med. 2007;8(5):419-424
- Potts AL, Andreson BJ, Warman GR, et al. Demedetomidine pharmacokinetics in pediatric intensive care: a pooled analysis. Poediatr Anaesth. 2009;19(11):1119-1129
- Gherpelli JL, Cruz AM, Tsanaclis LM, et al. Phenobarbital in newborns with neonatal seizures: a study of plasma levels after intravenous administration. *Brain Dev.* 1993; 15(4):258–262
- Touw DJ, Graafland O, Cranendonk A, et al. Clinical pharmacokinetics of phenobarbital in neonates. Eur. J Pharm Sci. 2000;12(2):111–116
- Morselli PL, Principi N, Tognoni G, et al. Diazepam elimination in premature and full term infants, and children. J Perinot Med. 1973;1(2):133–141
- Peinemann R, Daltrup T. Severe and prolonged sedation in five neonates due to persistence of active diazepam metabolites. Eur J Pediatr. 2001;160(6):378–381
- McDermott CA, Kowalczyk AL, Schnitzler ER, et al. Pharmacokinetics of Iorazepam in critically ill neonates with seizures. J Pediatr. 1992;120(3):479–483
- Saarenmaa E, Neuvonen PJ, Rosenberg P, Fellman V. Morphine clearance and effects in newborn infants in relation to gestational age. Clin Pharmacol Ther. 2000;88(2):160–166
- Chay PC, Duffy BJ, Walker JS. Pharmacokinetic-pharmacodynamic relationships of morphine in neonates. Clin Pharmacol Ther. 1992;51(3):334-342
- Róka A, Melinda KT, Vásárhelyi B, Machay T, Azzopardi D, Szabó M. Elevated morphine concentrations in neonates treated with morphine and prolonged hypothermia for hypoxic ischemic encephalopathy. *Pediat*rics. 2008;121(4). Available at: www. pediatrics.org/ogi/content/full/121/4/e844

APPENDIX 1 Check List for Documentation of Brain Death

Brain Death Exam Two physicians must perform indep	mination for Infants			led into	le		
Age of Patient	Timing of first exam	separated t	y speca			eval	
Term newhorn 37 works gestational age and up to				der-exam. Interval At least 24 hours			
30 days old	binh OH following caudio				literval shortesed		
	resocitation or other severe brain injury because (section with beautiful and the severe brain injury)			because	aucillary	study	
					ion 4) is consistent		
N. C.				rain death			
31 days in 18 years old					leart 12 hours OR		
	other severe brain injury				terval shortened		
	other severe brain injury				use ancillary study ion 4) is consistent		
				with brei		truent	
Section 1. PREREQUISITES for brain death oca-	minution and appealed			WITH DAM	n ecan		
A. IRREVERSIBLE AND IDENTIFIABLE CHIS	e of Coma (Please check)						
13 Treomatic brain injury Anoxic brain injury	Known metabolic disorder	Other (Spe	cify)				
B. Correction of contributing factors that can into	erfere with the neurologic	Examinatio	a Oue	Equ	aninatio	n Two	
examination							
a. Core Body Temp is over 95° F (35° C)		C Yes	FI No	FY		○ No	
 Systolic blood pressure or MAP in acceptable 	ie range (Systelie BP not	1º Yes	(i) No	CY	es.	∴ No	
less than 2 standard deviations below age ap	propriete mem) based on						
agu .							
 Sodutive/unalgesic drug effect excluded as a 	contributing factor	∏ Yes	G No	CY		□ No	
d. Metabolic intoxication excluded as a contrib		D Yes	∏ No	CY		7. No	
 Neuromiscular blinckade excluded as a com- iff ALL proregaristes are marked YES, their proceed 		I) Yex	I! No	E Y	6s	G No	
confounding variable was present.		n anderson In	. decome	a desired	and of	4	
Section 2. Physical Examination (Please check)	Authority wedy was mereste	Examination			minatio		
NOTE: SPINAL CORD REFLEXES ARE ACCE	PTABLE	Date/ time:			/ Time:		
a. Placeid tone, patient enresponsive to deep p	ainful stimuli	O Yes	O No	CY	**	C No	
b. Popils are midposition or fully dilated and la	chi reflexes are absent	O Yes	II No	CY		U No	
c. Corneal, cough, gag reflexes are absent	201111111111111111111111111111111111111	O Yes	C No	I C Y		□ No	
Socking and reasing reflexes are absent (in a	econates and infants)	☐ Yes	El No	10.00		E No	
d. Oculovestibular reflexes are obsent		Yes	FI No	1. 7	es	Nu	
 Spontaneous respiratory effort while on med 		ill Yes	(1 No	1.30	05	: No	
	e exam could not be performe						
Ancidley study (EEG or radiomechide CBP) was the	refure parformed to discusses						
Section 3. APNEA Test		Examination	n One		minetio	e Two	
No contract of the contract of		Date/Time			/ Time	Minneson -	
No spontaneous respiratory efforts were observed dea		Pretost PaCC			retest PaCO;:		
Hg and a ≥ 20 mm Hg increase above baseline. (Exemination Ose) No operations respiratory efforts were observed despite final PaCO₂ ≥ 60 mm			Apnes duration:		Aprea duration:		
Hg and n ≥ 20 mm Hg increase above beacline. (Exer		Posttess PaC	Postless PaCO ₂ :			Postlest PaCO _c	
Aprea lest is contraindicated or could not be perform		1 canala r ac	77	11000	THE REAL PROPERTY.	O'L STREET	
Ascillary study (EEG or radioeuclide CBF) was there		brain death. (Section 4)				
Section 4. ANCILLARY testing is required when ((i) any components of the ex-	amination ur a	pneu testi		ate/lim	e:	
cannot be completed; (2) if there is uncertainty about	the results of the neurologic	e saminetion, o	or (3) if a				
medication effect may be present.				- 1 -			
Ancillary testing can be performed to reduce the is				ogic			
examination is required. Components of the neuro		be performed	l safety	- 1			
should be completed in close proximity to the ancil Electroencephalogram (EEC) report documents ele					Yes !	1 No	
Cerebral Blood Flow(CBF) study report documents						1 No	
Section 5. Signatures	in ceresia perinstan			-+-	100	1:902	
Examiner One							
I certify that my examination is consistent with cessar	ion of function of the brain a	nd brainstein.	Confines	ыгу сава	i to falle	W.	
(Protest Name)	(Signature)						
(Specialty)	(Pager WLicense #)	r Do	we mmAld	Verent	(Time)		
Examiner Two							
I certify that my examination: and/or ancillary test	report L'confirms unchanged	and irreversit	de cessario	on of fue	time of	he brain	
and beainstein. The potient is doctared brain dead at th							
Dute/Time of death:							
(Printed Name)	(Signature)				-		
(Specialty)	(Pager MI iceme #)	- in	ate imm/kkl	Monage	(Time)		
Cohomondo	Configuration at		end Hittie OC	277777	(Lane)		

APPENDIX 2 Medications Administered to Critically III Pediatric Patients and Recommendations for Time Interval to Testing After Discontinuation

Medication	Infants/Children	Neonates
	Elimination W life	Elimination % life
Intravenous induction, anesthetic, and		
sedative agents		
Thiopental	Adults: 3-11.5 hours (shorter ½ life in children)	
Ketamine	2.5 hours	
Etomidate	2.6-3.5 hours	
Midazolam	2.9-4.5 hours	4-12 hours**-to
Propofol	2-8 minutes, Terminal ½ life 200 minutes (range 300-700 minutes)	
Dexmedetomidine	Terminal ½ life 83–159 minutes™	Infants have faster clearance*1.93
Antiepileptic drugs		
Phenobarbital	Infants: 20-133 hours*	45-500 hours*79.34.85
	Children: 37-73 hours*	
Pentobarbital	25 hours*	
Phenytoin	11~55 hours*	63-88 hours*
Diazepam	1 month-2 years: 40-50 hours	50-95 hours******
	2 years-12 years: 15-21 hours	
	12-16 years: 18-20 hours	
Lorazepam	infants: 40.2 hours (range 18-73 hours)	40 hours**
	Children: 10.5 hours (range 6-17 hours)	
Clonszepam	22-33 hours	
Valproic Acid	Children > 2 months: 7-13 hours*	10-67 hours*
	Children 2-14 years: Mean 9 hours; range 3.5-20 hours	
Levetiracetam	Children 4-12 years: 5 hours	
ntravenous narcotics		
Morphine sulfate	infants 1-3 months: 6.2 hours (5-10 hours)	7.6 hours (range 4.5-13.3 hours) Page.
	6 months-2.5 years: 2.9 hours (1.4-7.8 hours)	
	Children: 1-2 hours	
Meperidine	Infants < 3 months: 8.2-10.7 hours (range 4.9-31.7 hours)	23 hours (range 12-39 hours)
	Infants 3-18 months: 2.3 hours	•
	Children 5-8 years: 3 hours	
Fentanyl	5 months-4.5 years: 2.4 hours (mean) 0.5-14 years: 21 hours (range 11-36 hours for long term infusions)	1-15 hours
Sufentanil	Children 2-8 years: 97 ± 42 minutes	382-1162 minutes
duscle relaxants		
Succinylcholine	510 minutes	
	Prolonged duration of action in patients with pseudocholinesterase deficiency or mutation	
Pancuronium	110 minutes	
Vecuronium	41 minutes	65 minutes
Atracurium	17 minutes	20 minutes
Rocuronium	3-12 months: 1.3 ± 0.5 hours	
	1 to < 5 years: 1.1 ± 0.7 hours	
	3 to < 8 years: 0.8 ± 0.3 hours	
	Adults: 1.4-2.4 hours	

Modified from Ashwal and Schneider, 97

Metabolism of pharmacologic agents may be affected by organ dysfunction and hypothermia.

FROM THE AMERICAN ACADEMY OF PEDIATRICS

Downloaded from pediatrics.aappublications.org at Stanford Univ Med Ctr on December 22, 2013

Physicians should be aware of total amounts of administered medication that can affect drug metabolism and levels.

*Elimination ½ life does not guarantee therapeutic drug levels for longer acting medications or medications with active metabolitos. Drug levels should be obtained to ensure that levels are in a low to mid therapeuble range prior to neurologic examination to determine brain death. In some instances this may require waiting several half-lives and rechecking serum levels of the medication before conducting the brain death examination.

APPENDIX 3 Apnea Testing in Pediatric Brain Death

Author	n_	Age Range	Paco ₇	Comments		
Rowland (1984)**	9 children, 16 apnea tests performed	4 months-13 years	Range 60-116 mm Hg after 15 minutes of apnea	No sportaneous respiratory effort noted in any patient during testing. Phenobarbital levels of 10,11.6,18,25 mg/dt, were measured in 4 patien		
Outwater & Rockoff (1984)**	10 children	10 months-13 years	Mean 59.5 ± 10.2 mm Hg after 5 minutes of apnea	No spontaneous respiratory effort noted in any patient during testing or after support was withdrawn		
Riviello (1988) ³⁹	19 children	2 months-15 years	Mean 63.9 ± 21.5 mm Hg	2 children with Pco ₂ levels of 24 mm Hg and 38 mm Hg had spontaneous respirations during the apnea test. All other children had no spontaneous respiratory effort noted after support was withdrawn.		
Paret (1995)*2	38 children, 61 apnea tests performed	2 months-17 years	Mean 88.07 ± 17.86 after 5 minutes Mean 81.8 ± 20.2 after 10 minutes Mean 86.88 ± 25.6 after 15 minutes	1 child had spontaneous respiratory effort with a Paco ₂ of 49 mm Hg. This patient was retested 24 hours later and had no respiratory effort.		

APPENDIX 4 EEG in Pediatric Brain Death: Diagnostic Yield From First Versus Any Study

Study	Total # Pts in Study	% Patients With ECS on EEG#1	% Patients With ECS on Any EEG	% Pts With ECS on f/u EEG When First EEG Had ECS	% Pt With ECS on Later EEGs When First EEG Had Activity
Ruiz-Garcia et al, 2000 (60)	125	72% (88/122)	91% (111/122)	NA .	68% (23/34)
Drake et al. 1986 ^{to}	61	70% (33/47)	91% (43/47)	100% (17/17)	71% (10/14)
Parker et al, 1995%	60	100% (9/9)	100% (9/9)	NA.	NA
Alvarez et al, 1988**	52	100% (52/52)	100% (52/52)	100% (28/28)	NA
Ashwal, 199354	52	85% (28/33)	85% (28/33)	100% (3/3)	0% (0/1)
Ruiz-Lopez et al, 1999**	51	48% (14/29)	72% (21/29)	NA.	47% (7/15)
Ashwal & Schneider, 1989 ⁸⁵	18	50% (9/18)	78% (14/18)	88% (7/8)	56% (5/9)
Holzman et al, 1983 ⁶²	18	61% (11/18)	67% (12/18)	67% (2/3)	14% (1/7)
Ashwal et ai, 1977®	15	67% (10/15)	73% (11/15)	100% (2/2)	20% (1/5)
Coker et al, 198699	14	100% (11/11)	100% (11/11)	100% (5/5)	. NA
Furgiuele et al, 1984 ⁶⁵	11	100% (10/10)	100% (10/10)	NA	NA.
Okuyaz et al, 2004**	8	100% (8/8)	100% (8/8)	NA	NA.
Total	485	76% (283/372)	89% (330/372)	97% (64/66)	55% (47/85)

EEG Electrocncephalogram. ECS Electrocerebral silence.

APPENDIX 5 CBF in Pediatric Brain Death: Diagnostic Yield From First Versus Any Study

Study	Total # of Pts in Study	CBF#1: % Patients With Absent CBF*	% Patients With Absent CBF on Any Study**	% Pts With No CBF on f/u Study When First Study Had Shown No CBF	% Pt With No CBF on Later Study When First Study Had CBF Present
Shimizu et al, 2000 ⁶⁶	228	100% (27/27)	100% (27/27)	NA	NA
Ruiz-Garcia et al, 2000™	125	92% (83/90)	92% (83/90)	NA.	NA.
Drake et al, 1986 ³⁵	61	68% (32/47)	81% (38/47)	100% (17/17)	40% (6/15)
Parker et al, 1995 ²⁶	60	87% (26/30)	87% (26/30)	NA.	NA.
Coker et al. 1986se	55	100% (55/55)	100% (55/55)	NA	NA.
Ashwat, 199354	52	86% (19/22)	86% (19/22)	NA	NA
Ahmann et al, 1987 ⁶⁷	32	83% (6/8)	83% (6/6)	NA	NΛ
Ashwal &Schneider, 1989 ^{ts}	18	65% (11/17)	65% (11/17)	71% (5/7)	0% (0/3)
Holzman et al, 1983 ^{sp}	18	39% (7/18)	44% (8/18)	109% (2/2)	9% (1/11)
Ashwal et al, 197758	15	100% (11/11)	100% (11/11)	NA	NA NA
Schwartz et al. 198466	9	100% (9/9)	100% (9/9)	NA NA	NA
Okuyaz et al, 2004 ⁶⁴	8	75% (6/8)	100% (8/8)	NA.	100% (2/2)
Total	681	86% (292/340)	89% (301/340)	92% (24/26)	26% (9/34)

[&]quot;# pts with no CBF on first study/# pts with first CBF study.

" # pts with no CBF on any study/# pts with any CBF.

CBF Cerebral blood flow.

APPENDEX 6 EEG and CBF Diagnostic Screening Yield by Age Groups

	ECS	EEG+	Total	Diagnostic Screening Yield
All children (n = 149)*				
No CBF	86	18	104	% pt with ECS = 70%
CBF *	19	26	45	% pts with no CBF = 70%
Total	105	44	149	
Just newborns (< 1 month of age; $n = 30$)**				
No CBF	8	11	19	% pt with ECS = 40%
CBF*	4	7	11	% pts with no CBF == 63%
Total	12	18	30	
Children (> 1 month of age; n = 119)***				
No C8F	78	7	85	% pt with ECS = 78%
CBF+	15	19	34	% pts with no CBF = 71%
Total	93	26	119	

^{*} Data extracted from references cited in Appendix 4,5.

APPENDIX 7 Comparison of 1987 Pediatric Brain Death Guidelines and the Updated Guideline for Determination of Brain Death in Infants and Children

	1987	Updated Guidelines
Waiting period before initial brain death examination	Not specified	24 hours following cardiopulmonary resuscitation or severe acute brain injury is suggested if there are concerns about the neurologic examination or if dictated by clinical judgment
Clinical examination	Required	Required
Core body temperature	Not specified	> 35°C (95°F)
Number of examinations	Two exams	Two exams, irrespective of ancillary study results
	2nd examination not necessary in 2 months-1 year age group if initial examination, EEG and concomitant CBF consistent with brain death	(if ancillary testing is being done in lieu of initial examination elements that cannot be safely performed, the components of the second examination that can be done must be completed)
Number of examiners	Not specified	Two (Different attending physicians must perform the first and second exam)
Observation interval between neurologic examinations	Age dependent	Age Dependent
	 7 days-2 months: 48 hours 	 Term newborn (37 weeks gestation) to 30 days of age: 24 hours
	 2 months—1 year: 24 hours >1 year: 12 hours (24 hrs if HIE) 	• 31 days-18 years: 12 hours
Reduction of observation period between exams	Permitted only for > 1 year age group if EEG or CBF consistent with brain death	Permitted for both age groups if EEG or CBF consistent with brain death
Apnea testing	Required, number of tests ambiguous	Two apnea tests required unless clinically contraindicated
Final Pco, threshold for apnea testing	Not specified	≥60 mm Hg and ≥20 mm Hg above the baseline Paco ₂
Ancillary study recommended	 Age dependent 7 days—2 months: 2 EEGs separated by 48 hrs 	Not required except in cases where the clinical examination and apnea test cannot be completed
	 2 months—1 year: 2 EEG's separated by 24 hours. CBF can replace the need for 2nd EEG 	 Term newborn (37 weeks gestation) to 30 days of age: EEG or CBF are less sensitive in this age group. CBF may be preferred.
	 > I year: No testing required 	 >30 days—18 years: EEG and CBF have equal sensitivity
Time of death	Not specified	Time of the second examination and apnea test (or completion of ancillary study and the components of the second examination that can be safely completed)

EEG Electroencephalogram.

e738

[&]quot; Data extracted from references cited in Ashwal S.*

[&]quot;" Data represent the differences between "All children" and "just newborns" groups.

ECS Electrocerebral silence.

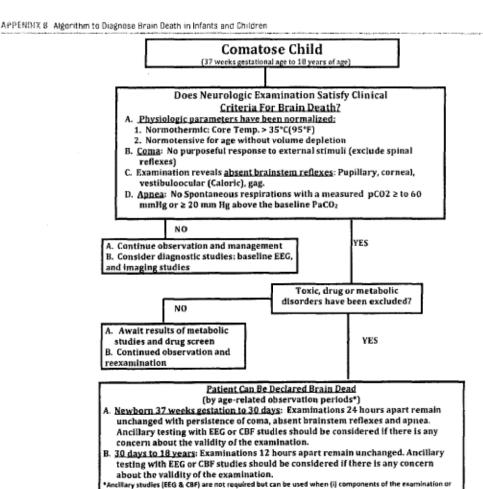
CBF Cerebral blood flow

EEG* Activity on EEG.

CBF ' Cerebral blood flow present.

CBF Cerebral blood flow.

HIE Hypoxic ischemic encephalopathy.



apnea testing cannot be safely completed; (ii) there is uncertainty about the examination; (iii) if a medication effect may interfere with evaluation or (iv) to reduce the observation period.

APPENDIX 9 Taskforce Organization

Sub-Committee Chairs

Brain death examination criteria and testing intervals: Mudit Mathur, MD, FAAP, Mohan Mysone, MD, FAAP, FCCM, Thomas A, Nakagawa, MD, FAAP, FCCM, Ancillary testing: Stephen Ashwal, MD, FAAP

Declaration of death, legal, and ethical implications: Jacqueline A. Williams-Phillips, MD, FCCM

Taskforce Committee Members

Stephen Ashwal, MD. Professor of Pediatrics. Department of Pediatrics, Chief, Division of Child Neurology. Loma Linda University School of Medicine. Loma Linda CA.

Derek Bruce, MD Professor of Neurosurgery and Pediatrics. Children's National Medical Center, Washington, DC

Edward E. Conway Jr MD, MS, FCCM. Professor of Pediatrics. Beth Israel Medical Center, Hartsdale, NY

Susan E Duthie, MD Pediatric Critical Care. Rady Children's Hospital-San Diego, San Diego, CA

Shannon Hamrick, MD Assistant Professor of Pediatrics. Emory University, Children's Healthcare of Atlanta. Atlanta GA

Rick Harrison, MD Professor of Pediatrics. David Geffen School of Medicine UCLA. Medical Director Mattel Children's Hospital UCLA. Los Angeles, CA. Andrea M. Kline, RN, MS, FCCM Nurse Practitioner. Riley Hospital for Children. Indianapolis, IN

Daniel J. Lebevitz, MD Associate Professor of Pediatrics, Cleveland Clinic Lenner College of Medicine, Cleveland Clinic Children's Hospital, Cleveland, OH Maureen A. Madden, MSN, PCCNP, FCCM Assistant Professor of Pediatrics, Robert Wood Johnson Medical School, Pediatric Critical Care Nurse Practitioner. Bristol-Myers Squibb Children's Hospital, New Brunswick, NJ

Mudit Mathur, MD, FAAP Associate Professor of Pediatrics. Division of Pediatric Critical Care. Loma Linda University School of Medicine. Loma Linda, CA Vicki L. Montgomery, MD, FCCM Professor of Pediatrics, University of Louisville. Chief, Division of Pediatric Critical Care Medicine. Medical Director. Patient Safety Officer. Norton Healthcare Kosair Children's Hospital. Louisville, KY

Mohan R. Mysore, MD, FAAP, FCCM Professor of Pediatrics, University of Nebraska College of Medicine. Director Pediatric Critical Care. Children's Hospital and Medical Center, Omaha, NE

Thomas A. Nakagawa, MD, FAAP, FCCM Professor Anesthesiology and Pediatrics. Wake Forest University School of Medicine Director, Pediatric Critical Care.

Brenner Children's Hospital at Wake Forest University Baptist Medical Center. Winston-Salem, NC

Jetfrey M. Periman, MBChB, FAAP, Professor of Pediatrics. Weill Cornell Medical College. New York, NY

Nancy Rollins, MD Professor of Pediatrics and Radiology. Children's Medical Center. Southwestern University, Dallas, Yexas

Nancy Rollins, MD Professor of Pediatrics and Radiology, Children's Medical Jenter, Southwestern of Sam D. Shemie, MD, FAAP, Professor of Pediatrics. Montreal Children's Hospital, Montreal, Canada

Amit Vohra, MD FAAP Assistant Professor of Pediatrics, Wright State University, Pediatric Critical Care, Children's Medical Center Dayton, OH.

Jacqueline A. Williams-Phillips, MD, FAAP, FCCM Associate Professor of Pediatrics. UMDNJ-Robert Wood Johnson Medical School, Director, Pediatric Intensive

Care Unit. Bristol-Myers Squibb Children's Hospital. New Brunswick, NJ

Guidelines for the Determination of Brain Death in Infants and Children: An Update of the 1987 Task Force Recommendations

Thomas A. Nakagawa, Stephen Ashwal, Mudit Mathur, Mohan Mysore and the Society of Critical Care Medicine, Section on Critical Care and Section on Neurology of the American Academy of Pediatrics, and the Child Neurology Society Pediatrics 2011;128;e720; originally published online August 28, 2011; DOI: 10.1542/peds.2011-1511

	ХИ: 10 1542/реок.2011-1511
Updated Information & Services	including high resolution figures, can be found at: http://pediatrics.aappublications.org/content/128/3/e720.full.h tml
References	This article cites 81 articles, 24 of which can be accessed free at: http://pediatrics.aappublications.org/content/128/3/c720.full.html//ref-list-1
Citations	This article has been cited by 1 HighWire-hosted articles: http://pediatrics.aappublications.org/content/128/3/e720.full.h tml#related-urls
Post-Publication Peer Reviews (P ³ Rs)	7 P ³ Rs have been posted to this article http://pediatrics.aappublications.org/cgi/eletters/128/3/e720
Subspecialty Collections	This article, along with others on similar topics, appears in the following collection(s): Section on Critical Care http://pediatrics.aappublications.org/egi/collection/section_on_critical_care Neurology http://pediatrics.aappublications.org/egi/collection/neurology_sub
Permissions & Licensing	Information about reproducing this article in parts (figures, tables) or in its entirety can be found online at: http://pediatrics.aappublications.org/site/misc/Permissions.xht ml
Reprints	Information about ordering reprints can be found online: http://pediatrics.aappublications.org/site/misc/reprints.xhtml

PEDIATRICS is the official journal of the American Academy of Pediatrics. A monthly publication, it has been published continuously since 1948. PEDIATRICS is owned, published, and trademarked by the American Academy of Pediatrics, 141 Northwest Point Boulevard, Elk Grove Village, Illinois, 60007. Copyright © 2011 by the American Academy of Pediatrics. All rights reserved. Print ISSN: 0031-4005. Online ISSN: 1098-4275.



Edubit 20

Court Exhibit 4

pediatrics.aappublications.org

Published online August 28, 2011, doi: 10.1542/peds.2011-1511 Pediatrics September 1, 2011 vol. 128 no. 3 e720-e740 doi: 10.1542/peds.2011-1511

From the American Academy of Pediatrics

Guidelines for the Determination of Brain Death in Infants and Children: An Update of the 1987 Task Force Recommendations

TABLE 3

Neurologic Examination Components to Assess for Brain Death in Neonates, Infants and Children* Including Apnea Testing

Reversible conditions or conditions that can interfere with the neurologic examination must be excluded prior to brain death testing.

See text for discussion

- Coma. The patient must exhibit complete loss of consciousness, vocalization and volitional activity.
 - Patients must lack all evidence of responsiveness. Eye opening or eye movement to noxious stimuli is absent.
 - Noxious stimuli should not produce a motor response other than spinally mediated reflexes. The clinical differentiation of spinal responses from retained motor responses associated with brain activity requires expertise.
- 2. Loss of all brain stem reflexes including:

Midposition or fully dilated pupils which do not respond to light.

Absence of pupillary response to a bright light is documented in both eyes. Usually the pupils are fixed in a midsize or dilated position (4–9 mm). When uncertainty exists, a magnifying glass should be used.

Absence of movement of bulbar musculature including facial and oropharyngeal muscles.

Deep pressure on the condyles at the level of the temporomandibular joints and deep pressure at the supraorbital ridge should produce no grimacing or facial muscle movement.

Absent gag, cough, sucking, and rooting reflex

The pharyngeal or gag reflex is tested after stimulation of the posterior pharynx with a tongue blade or suction device. The tracheal reflex is most reliably tested by examining the cough response to tracheal suctioning. The catheter should be inserted into the trachea and advanced to the level of the carina followed by 1 or 2 suctioning passes.

Absent corneal reflexes

Absent corneal reflex is demonstrated by touching the cornea with a piece of tissue paper, a cotton swab, or squirts of water. No eyelid movement should be seen. Care should be taken not to damage the cornea during testing.

Absent oculovestibular reflexes

The oculovestibular reflex is tested by irrigating each ear with ice water (caloric testing) after the patiency of the external auditory canal is confirmed. The head is elevated to 30 degrees. Each external auditory canal is irrigated (1 ear at a time) with $\sim \! 10$ to 50 mt. of ice water. Movement of the eyes should be absent during 1 minute of observation. Both sides are tested, with an interval of several minutes.

- Apnea. The patient must have the complete absence of documented respiratory effort (if feasible) by formal apnea testing demonstrating a Paco₂ ≥ 60 mm Hg and ≥ 20 mm Hg increase above baseline.
 - Normalization of the pH and Paco₂, measured by arterial blood gas analysis, maintenance of core temperature > 35°C, normalization of blood pressure appropriate for the age of the child, and correcting for factors that could affect respiratory effort are a prerequisite to testing.
 - The patient should be preoxygenated using 100% oxygen for 5
 -10 minutes prior to initiating this test.
 - Intermittent mandatory mechanical ventilation should be discontinued once the patient is well oxygenated and a normal Paco₂ has been achieved.
 - The patient's heart rate, blood pressure, and oxygen saturation should be continuously monitored while observing for spontaneous respiratory effort throughout the entire procedure.
 - Follow up blood gases should be obtained to monitor the rise in PacO₂ while the patient remains disconnected from mechanical ventilation.
 - If no respiratory effort is observed from the initiation of the apnea test to the time the measured PaCo₂ ≥ 60 mm Hg and ≥ 20 mm Hg above the baseline level, the apnea test is consistent with brain death.
 - The patient should be placed back on mechanical ventilator support and medical management should continue until the second neurologic examination and apnea test confirming brain death is completed.
 - If oxygen saturations fall below 85%, hemodynamic instability limits completion of apnea testing, or a PacO₂ level of ≥ 60 mm Hg cannot be achieved, the infant or child should be placed back on ventilator support with appropriate treatment to restore normal oxygen saturations, normocarbia, and hemodynamic parameters. Another attempt to test for apnea may be performed at a later time or an ancillary study may be pursued to assist with determination of brain death.

- Evidence of any respiratory effort is inconsistent with brain death and the apnea test should be terminated.
- Flaccid tone and absence of spontaneous or induced movements, excluding spinal cord events such as reflex withdrawal or spinal myoclonus.
 - The patient's extremities should be examined to evaluate tone by passive range of motion assuming that there are no limitations to performing such an examination (eg, previous trauma, etc) and the patient observed for any spontaneous or induced movements.
 - If abnormal movements are present, clinical assessment to determine whether or not these are spinal cord reflexes should be done.

→* Criteria adapted from 2010 American Academy of Neurology criteria for brain death determination in adults (Wijdicks et al. 2010).

Court Exhibit 5

Brain Death Examination for Infants and Children

Two physicians must perform inde Age of Patient Term newborn 37 weeks gestational age and up to 30 days old	up to First exam may be performed 24 hours after birth OR following cardiopulmonary resuscitation or other severe brain injury				Intervals, Inter-exam, interval At least 24 hours Interval shortened because ancillary study (section 4) is consistent with brain death		
31 days to 18 years old First exam may be perfe- following cardiopulmonar other severe brain injury				L At least 121 Linterval sho because ancilli (section 4) is c	At least 12 hours OR Interval shortened because ancillary study (section 4) is consistent with brain death		
Section 1. PREREQUISITES for brain death exa A. IRREVERSIBLE AND IDENTIFIABLE Caus			•				
Traumatic brain injury Anoxic brain injury	Known metabolic disorder	Other (Spe	safe)				
The state of the s	Kinton income manner	Outer caps	,,				
B. Correction of contribution factors that can be	refere with the e-moligic	Examination	on One	Examina	tion Two		
examination		l			magnessy gramm		
a Core Body Temp is over 95° F (35° U)		Yes	No	1 Yes	No		
 Systotic blood pressure or MAP in acceptable 		Yes	No	: Yes	No		
less than 2 standard deviations below age ap	aktohusie votu) paveg ou	1					
age.	. seemilemine it will			- V	- 51-		
 Sedative/analgesic drug effect excluded as a Metabolic intoxication excluded as a control 		Yes	No No	E Yes	- No		
		Yes	No No	CYes	No		
 Neuromisseular blockade excluded as a cont If ALL prerequisites are marked YES, then proceed 		1,0	1. 500	Yes	No		
confounding variable was present.		ne porformad i	in docume	ont benin death	(Section 4)		
Section 2. Physical Examination (Please check)	Tribellary stoot was therein	Examinat		Examina			
NOTE: SPINAL CORD REFLEXES ARE ACCE	PTABLE	Date/time		Date/ Tin			
 Flaccid tone, patient unresponsive to deep p 		Yes	No	i Yes	No		
 Pupils are undposition or fully dilated and li 		Yes	No	Yes	No -		
c. Corneal, cough, gag reflexes are absent		Yes	No	Yes	No		
Sucking and rooting reflexes are absent (in a	neonates and infants)	. Yes	No	1 Yes	No		
d. Oculovestibular reflexes are absent					No		
e. Spontaneous respiratory effort while on med	chanical ventilation is absent	Yes	No	(- Yes	No		
	e exam could not be performs	ed because					
Ancillary study (EEG or radionic fide CBF) was the Section 3. APNEA Test	refore performed to docume	t brain death. Examination Date/ Time	n One	4). Examinat Date/ Tin			
No spantaneous respiratory efforts were observed de-	spite final PaCO ₂ ≥ 60 mm	Pretest PaC	0,:	Pretest Pa	CO2:		
Hg and a ≥ 20 mm Hg increase above baseline. (Exa-	mination One)	Apnea durat	ion:	Aprica du	ration:		
No spontaneous respiratory efforts were observed de-	quite final PaCO; 2 60 mm	min		thin			
Hg and a ≥ 20 mm Hg oncrease above baseline. (Exar	nination Two)	Postlest PaC	O _F	Posttest P	aCO ₂ :		
Apnea test is contraindicated or could not be perform							
Ancillary study (EEG or radionactide CBF) was then Section 4. ANCILLARY testing is required when cannot be completed; (2) if there is uncertainty about medication effect may be present. Ancillary testing can be performed to reduce the in	 any components of the ex- the results of the neurologic ater-examination period ho 	amount on or examination; wever a seco	upmen test or (3) if a nd neuro	ang Date/T	lme:		
examination is required. Components of the neuro		be performe	d safely				
should be completed in close preximity to the anci- Electroencephalogram (EEG) report documents ale				Yes	No		
Cerebral Blood Flow(CBF) study report documents				Yes	No		
Section 5. Nignatures	- in service by image	,		1.55			
Examiner One							
I certify that my examination is consistent with cessar	ion of function of the brain a	ad brainstem.	Confirm	atory examt to fo	diev		
(Printed Name)	(Signature)						
(Specialis) Examiner Two	(Page: #/Livense #)		hate mustel				
I certify that my examination — and/or ancillary test		and meversi	ore cessar	non or runction	or one brain		
and brainstem. The patient is declared brain dead at it Date/Time of death:	us come,						
Extract that an extract							
(Printed Name)	(Signature)						
(Specialis)	(Pages #/License #)			d/yyyy) (Tim	e)		

Edibit 24

Court Exhibit 6

1	- 1 0 0 V 0(201)
2	Douglas C. Straus (Bar No. 96301) Brian W. Franklin (Bar No. 209784)
3	Noel M. Caughman (Bar No. 154309) dstraus@archemorris.com
4	ARCHER NORRIS A Professional Law Corporation
5	2033 North Main Street, Suite 800 Walnut Creek, California 94596-3759
6	Telephone: 925.930.6600 CLERK OF THE SUPERIOR COURT Facsimile: 925.930.6620 By Deputy
- 7	Attorneys for Respondent CHILDREN'S HOSPITAL & RESEARCH
8	CENTER AT OAKLAND
9	SUPERIOR COURT OF THE STATE OF CALIFORNIA
10	COUNTY OF ALAMEDA
11	•
12	, Case No.
13	Plaintiff, PHYSICIAN DECLARATION
14	v. Posin Shanahan
15	CHILDREN'S HOSPITAL & RESEARCH
16	CENTER AT OAKLAND,
17	Respondent.
18	
19	•
20	
21	
22	
23	
24	
25	
26	
27	
28	C0413001/1720\$16-1
	PHYSICIAN DECLARATION

I, Robin Shanahan, M.D., hereby declare as follows:

- I am a duly licensed physician, board certified in the specialty of neurology with special competence in child neurology. I am a member in good standing of the medical staff of Children's Hospital & Research Center at Oakland (Children's).
- On December 11, 2013, a brain death evaluation (the "Test") was ordered for
 patient Jahi McMath ("Ms. McMath"). The purpose of this Test was to determine whether Ms.
 McMath had sustained an irreversible cessation of all functions of her entire brain, including her
 brain stem.
- 3. The Test was performed on the morning of December 11, 2013. I personally performed the Test, which included review of her electroencephalogram (EEG) and clinical history, and performed a physical examination which included whether she responded to pain or other noxious stimuli and an evaluation of multiple brain stem reflexes. The Test revealed that Ms. McMath had sustained an irreversible cessation of all functions of the entire brain, including her brain stem. In addition, the results of the EEG revealed no cerebral activity.
- The results of the Test confirm that Ms. McMath is considered brain dead in accordance with all accepted medical standards.
- I also examined Ms. McMath before 9 a.m. on December 12, 2013, and found no changes in her condition.
- 6. There is absolutely no medical possibility that Ms. McMath's condition is reversible or that she will someday recover from death. Brain death is always followed by somatic death, i.e., it is inevitable that the heart will stop beating. Thus, there is no medical justification to provide any further medical treatment whatsoever to Ms. McMath.

I declare under the penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed this 20th day of December at Oakland, California.

ROBIN SHANAHAN, M.D.

C0413001/1720516-1

DECLARATION OF R. SHANAHAN, M.D.

Edibit 25

Court Exhibit 7

Court Exhibit 7 intentionally omitted because Superior Court ordered sealed.

Exhibit 26

10522610°

FILED ALAMEDA COUNTY

DEC 2 8 2013

SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF ALAMEDA

Case No. RP13-707598

Case No. RP13-707598

ORDER (1) DENYING PETITION FOR MEDICAL TREATMENT AND (2) GRANTING IN PART APPLICATION TO SEAL PORTIONS OF RECORD.

CHILDREN'S HOSPITAL OAKLAND, Dr. David Durand M.D. and DOES 1 through 100, inclusive

Respondents

Case No. RP13-707598

ORDER (1) DENYING PETITION FOR MEDICAL TREATMENT AND (2) GRANTING IN PART APPLICATION TO SEAL PORTIONS OF RECORD.

Date: December 23, 2013

Time: 9:30 am

Dept: 31

The Petition of Latasha Winkfield as mother of Jahl McMath, a minor, and the motion of petitioner to seal came on for hearing on December 23 and 24, 2013, in Department 31 of this Court, the Honorable Evelio Grillo presiding. After consideration of the briefing and the argument, IT IS ORDERED: (1) the Petition of Latasha Winkfield as mother of Jahl McMath, a minor, is DENIED and (2) the motion of petitioner to seal is GRANTED IN PART.

24 ///

///

PREOCEDURAL AND FACTUAL BACKGROUND1

On December 9, 2013, Jahi McMath, a thirteen year old child, had a tonsillectomy performed at Children's Hospital of Oakland ("CHO"). Following the tonsillectomy Jahi began to bleed profusely from her mouth and nose, and within a matter of minutes, went into cardiac arrest and lapsed into a coma. As of December 26, 2013, Jahi is currently being maintained on a ventilator at CHO.

On December 20, 2013, Latasha Winkfield, the mother of Jahi McMath filed a verified petition and ex parte application with the court pursuant to Probate Code section 3200 et seq. and 4600 et seq., seeking an order (1) authorizing the petitioner (Jahi's mother) to make medical care decisions for Jahi and for an injunction under to prohibit respondent CHO from withholding life support from Jahi. (Probate Code 3201, 4776, 4770.) The court set the application for hearing at 1:30 p.m. on December 20, 2013, in Department 31, and requested respondent CHO to submit written opposition to petitioner's ex parte application.

On December 20, 2013, the court heard Petitioner's application in Department 31.

Christopher B. Dolan appeared for the petitioner and Douglas C. Strauss appeared for respondent CHO. At the hearing, respondent CHO submitted its opposition papers and argued that respondent CHO had no duty to continue mechanical ventilation or any other medical intervention for Jahi, because she was deceased as the result of an irreversible cessation of all functions of her entire brain, including her brain stem. Health & Safety Code section 7180. In support of its position, respondent submitted the physician declarations of Robert Heidersbach,

¹ Due to the confluence of facts concerning the medical records of a minor and the publicity that accompanied this case, the parties presented many of their arguments to the court in chambers and supported those arguments with offers of proof. The court has attempted in this order to reflect and address all the issues raised in the case even if they were not formally presented and preserved in court filings and transcribed hearings.

touching of her feet.

 the examining physicians who determined Jahi's medical status, i.e., brain dead. The physician declarations, read together, unequivocally stated that Jahi was considered brain dead in accordance with accepted medical standards, and that there was no medical possibility that Jahi's medical condition was reversible, or that she would recover from her present condition and that there was no medical justification to provide further medical intervention. Stated more plainly, CHO argued that Jahi was legally dead, as defined by Health and Safety Code section 7180 and 7181, and that neither Probate Code sections 3200 or 4600 et seq. authorized medical treatment of legally dead persons.² Petitioner responded with anecdotal evidence regarding Jahi's condition, and stated that Jahi was responsive to her mother's verbal stimulation, and to physical

MD, Sharon Williams, MD, and Robin Shanahan, MD. Dr. Heidersbach and Dr. Shanahan were

During oral argument on December 20, 2013, the court asked respondent's counsel whether the two examining physicians were affiliated with CHO.³ Respondent's counsel responded that Drs. Heidersbach, and Shanahan did not work for CHO, that each satisfied the criteria for independence under Health and Safety Code section 7181, and thus intervention by the court was neither warranted, nor authorized by law. In effect, respondent's counsel argued that the court did not have jurisdiction to review the physicians' diagnosis of brain death because

It would appear to be self evident that where legal death has occurred, one cannot invoke the provisions of Probate Code sections 3200 and 4600 to appoint a guardian to make health care decisions on behalf of a deceased person, i.e., a person for whom additional medical treatment would be futile. There are specific statutory requirements for dealing with the remains of deceased persons. (Health and Safety Code 7000 et seq.) The issue presented by the petitioner in the instant matter was more complex: whether the petitioner's daughter was entitled to medical treatment in the form of life support (nutrition, intravenous fluids, ventilator breathing support, etc.) because her daughter was not legally dead. The issues in this case as presented by the petitioner necessarily required the court to reach the threshold issue of whether petitioner's daughter was legally dead.

³ Health and Safety Code section 7181 states that a diagnosis of brain death requires confirmation by a second, independent physician.

 two independent physicians had made the determination in compliance with Health and Safety Code section 7180 and 7181. On further questioning by the court, however, respondent's counsel conceded that both Drs. Heidersbach, and Shanahan maintained hospital privileges with CHO. The declarations submitted by Drs. Heidersbach, and Shanahan both self-describe their status as "a member in good standing of the medical staff of Children's Hospital & Research Center at Oakland." (Heidersbach Dec., Para 1; Shanahan Dec., para 1.)

Because Health and Safety Code section 7181 requires confirmation of brain death by an independent physician (but does not define or otherwise set a standard for determining independence), the court determined that, on the unique facts of this case, the independent second opinion required by section 7181 should be provided by a physician who had no affiliation with CHO. The court ordered the parties to meet and confer to select a physician unaffiliated with CHO to provide the second independent opinion required by Health and Safety Code section 7180 and 7181. The parties met and conferred during a break in the hearing and presented the court with the names of five physicians affiliated with the University of California San Francisco Medical School.

By order dated December 20, 2013, the court temporarily restrained CHO from changing Jahi's level of medial support. The order stated in part: "Respondent CHO, its agents, employees, servants and independent contractors are ordered to continue to provide Jahi McMath with the treatment and support which is currently being provided as per the current medications

The unique facts of this case include the fact of both affiant physicians being members of the CHO medical staff, the complete absence from the record of any information from which the court could determine whether the physician providing the second opinion was an "independent physician" within the meaning of Health and Safety Code section 7181, and the facts and circumstances surrounding Jahi's treatment while under the care of CHO, i.e., immediate and dramatic death following a routine surgical procedure (a tonsillectomy), with virtually no information surrounding the circumstances of her treatment and death provided by CHO other than publically describing the outcome of the surgery as "catastrophic."

 and physicians orders until further order of the court." The order also continued the hearing to Monday, December 23, 2013, and directed the parties to contact the UCSF physicians to determine whether any of them was available to examine Jahl and to provide the second independent opinion required by section 7181.

On Monday December 23, 2013, the court reconvened the hearing. At the hearing, respondent's counsel advised the court that the UCSF physicians had declined to provide a second section 7181 opinion on the advice of counsel as pending merger discussions between UCSF and CHO could raise concerns regarding the independence of the UCSF physicians. In place of the UCSF physicians, respondent's counsel offered, and petitioner's counsel agreed to, the appointment of Paul Fisher MD, the Chief of Child Neurology for the Stanford University School of Medicine, as the physician to provide the second, independent physician's opinion pursuant to Health and Safety Code section 7181. During the December 23 hearing, petitioner's counsel also requested that Paul A. Bryne, MD be allowed to examine Jahi and provide a second 7181 opinion, or alternatively, to provide expert testimony at the hearing.

By order dated December 23, 2013, appointed Dr. Fisher as the independent 7181 physician. Pursuant to that order, Dr. Fisher examined Jahi the afternoon of December 23, 2013. The court also continued the hearing to December 24, 2013, to receive Dr. Fisher's report and testimony from a CHO physician (Dr. Shanahan) who first determined that Jahi was brain dead, as of December 11, 2013. By separate order dated December 23, 2013, the court extended the restraining order through December 30, 2013, or such other date as the court might later determine.

On December 24, 2013, this court, during closed and public sessions received testimony from Dr. Shanahan and Dr. Fisher. During the course of the hearings, the court was presented

S

 with and entered into evidence Dr. Shanahan's and Dr. Fisher's examination notes, as well as documents setting forth the standards for determining brain death in infants and children. (See, e.g., Exhibit 1 (Dr. Fisher's examination notes); Exhibit 2 (Guidelines for Determination of Brain Death in Infants and Children: An Update of the 1987 Task Force Recommendation.

Court); Exhibit 3 (Pediatrics, Official Journal of the American Academy of Pediatrics, August 28, 2011, Guidelines for Determination of Brain Death in Infants and Children: An Update of the 1987 Task Force Recommendation); Exhibit 4 (Table 3 of Exhibit 3); Exhibit 5 (Checklist, Brain Death Examination for Infants and Children); Exhibit 6 (Shanahan Declaration filed 12/20/13); and Exhibit 7 (Consultation and Examination notes of Robin Shanahan MD dated 12/11/2013). The court provided Petitioner's counsel the opportunity to cross examine both Dr. Fisher and Dr. Shanahan.

Dr. Fisher initially testified in a closed session. Dr. Fisher's written report served as his opening statement and counsel for petitioner in cross-examination questioned Dr. Fisher about the accepted medical standards for determining brain death in minors, his physical examination of Jahi, and his analysis. At the conclusion of Dr. Fisher's cross-examination, petitioner's counsel stipulated that Dr. Fisher conducted the brain death examination and made his brain death diagnosis in accord with accepted medical standards. In the open session immediately following, Dr. Fisher opined that Jahi was brain dead under accepted medical standards.

Dr. Shanahan then testified in a closed session. Dr. Shanahan testified as to the accepted medical standards for determining brain death in minors, the examination of Jahi that she conducted on December 11, 2013, and her conclusion on December 11, 2013, that Jahi was brain

⁵ The court also received and considered the vita curricula of Dr. Fisher and Dr. Byrne. To provide a complete record, the court on its own motion augments the record to include those two documents as Exhibits 8 and 9.

 dead as of that date. Petitioner's counsel was then provided with the opportunity to cross examine Dr. Shanahan.

At the conclusion of Dr. Shanahan's cross-examination in closed session, petitioner's counsel requested a continuance to review Jahi's medical records more carefully, to have time to consult an expert regarding Dr. Shanahan's examination of Jahi, and, if appropriate, to conduct further cross-examination of Dr. Sheehan. The court denied the request for a continuance. The court reasoned that the issue before the court was limited to whether the attesting physicians had conducted the 7180 and 7181 examinations in accord with accepted medical standards. The court determined, based on the testimony and medical records provided in the closed session (Exhibits 1 [Fisher notes] and 8 [Shanahan notes]), that although Jahi's complete medical records were relevant to the cause of her death they were not relevant to whether she had suffered brain death as defined under section 7181. Dr. Shanahan was then sworn in open court, and testified that Jahi was brain dead on December 11, 2013, under accepted medical standards.

The Court then took the matter under submission. The court returned to the bench after a brief recess and then denied the petition and dissolved the TRO effective 5:00 p.m. December 30, 2013.

ANALYSIS:

JURISDICTION OF THE COURT

During the initial and subsequent hearings, respondent's counsel argued that after two attesting physicians have determined a person to be brain dead pursuant to Health and Safety Code sections 7180 and 7181, that the court had no jurisdiction to review the issue. Or stated another way, counsel argued that the determination of brain death was a matter for physicians,

1.2

and not judges to decide, and the court lacked jurisdiction to review the physicians' determination of brain death.

It is true that physicians, and not courts, are uniquely qualified (and authorized by statute) to make the determination of brain death, but it does not follow that such determinations are insulated from all judicial review. (Dortty v. Superior Court (1983) 145 Cal. App.3d 273, 278.) In Dortty the trial court appointed a guardian for an infant who had been determined by physicians to be brain dead under Health & Saf. Code, § 7189, subd. (a)⁶, and after hearing unrefuted medical testimony concluding that the infant was brain dead, the trial court ordered the temporary guardian to give the appropriate consent to the health care provider to withdraw life support. (Dority, 145 Cal. App.3d at 276.) The child's parents and counsel for the minor petitioned for a writ of prohibition against removing the life support device. The Court of Appeal denied the writs and held that the trial court's order for withdrawal of the life support system, after hearing the medical evidence and taking into consideration the rights of all the parties involved, and after finding that the infant was dead in accordance with applicable statutes, was proper and appropriate. (Dority, 145 Cal. App.3d at 279.)

Dority acknowledged "the moral and religious implications inherently arising when the right to continued life is at issue," but concluded that the court has jurisdiction to resolve the issue. Dority recognized "the difficulty of anticipating the factual circumstances under which a decision to remove life-support devices may be made, [and] determined that it would be

R

It appears that the reference to Health & Saf. Code, § 7189(a) might be a typographical error. Former § 7189, as operative during 1983, was added by Stats.1976, c. 1439, § 1, related to the revocation of health care directives, and was repealed by Stats.1991, c. 895 (S.B.980), § 1. Health & Saf. Code 7180, the operative section for determining death as of 1983 (the year in which the events underlying *Dority* occurred) was added by Stats.1982, c. 810, p. 3098, § 2, and would have been the operative statute for determining death at that time.

 "unwise" to deny courts the authority to make such a determination when circumstances warranted." (Dority, 145 Cal.App.3d at 275.)

Dority states "[t]he jurisdiction of the court can be invoked upon a sufficient showing that [1] it is reasonably probable that a mistake has been made in the diagnosis of brain death or [2] where the diagnosis was not made in accord with accepted medical standards." (Dority, 145 Cal.App.3d at 280.) Dority is silent on what showing is necessary to establish "reasonable probability of a mistake." Dority and the statutes, sections 7180 and 7181, are silent as to when a diagnosis is made "in accord with accepted medical standards." Dority does not state that the two identified bases for jurisdiction are exclusive and the statute does not state they are exclusive. The court interprets the statute and holds that application of the statute permits an inquiry into whether the second physician was independent. The court's jurisdiction can be invoked on a showing that the second physician required by section 7181 was not "independent."

In this case there is clearly was a conflict between the party representing Jahi and the health care providers as to whether brain death had occurred and whether further medical intervention was warranted. Petitioner presented evidence that her daughter, Jahi, was responsive (reacted to) her touch (Winkfield Decl. at para. 9), arguably suggesting that it was possible that a mistake has been made in the diagnosis of brain death. Petitioner presented evidence that CHO denied petitioner's request to have an independent physician examine Jahi and her studies and records (Winkfield Decl., para. 19) and that CHO repeatedly refused to provide petitioner with Jahi's medical records under the rationale that the hospital does not provide medical records of patients that they are still treating (Winkfield Decl. at paras. 20, 21). These facts cast doubt on the neutrality of CHO and therefore also on the independence of the

As of the hearing on Friday December 20, 2013, petitioner and petitioner's counsel had not yet received copies of Jahi's medical records.

 physicians who were "member[s] in good standing of the medical staff of Children's" who had examined Jahi and made findings of brain death. These facts are sufficient to invoke the jurisdiction of the court to review whether the diagnosis was made by an independent physician in accord with acceptable medical standards.

NATURE OF THE HEARING AND RELATED DUE PROCESS CONCERNS.

Counsel for petitioner objected that petitioner was not provided a full and fair opportunity to present evidence regarding whether Jahi had suffered brain death. Specifically, counsel for petitioner asserted that petitioner was not provided timely access to Jahi's complete medical files, that he needed additional time in which to prepare for cross-examination, and that he had the right to present a competing physician to provide testimony on the issue of brain death.

Health and Safety Code sections 7180 and 7181 do not provide any guidance regarding the nature of a proceeding to address brain death under those sections. *Dority*, supra, 145 Cal.App.3d 273, 276, did not address the nature of a proceeding under section 7181. The Uniform Determination of Death Act prepared by the Uniform Law Commission does not address the nature of a proceeding. The court can discern three options for categorizing the nature of the proceeding: (1) a summary judicial review of physician reports; (2) a focused proceeding that permits limited discovery and presentation of evidence; and (3) a civil

There was some conflict in the argument at the December 20 hearing as to whether petitioner had been allowed to have a physician examine Jahi and/or review the records of Drs. Shanahan and Heidersbach, the physicians who declared Jahi to be brain dead. CHO's counsel (Mr. Strauss) contended that petitioner had consulted with three physicians of her choosing, each of whom confirmed the diagnosis of brain death. Petitioner's counsel denied Mr. Strauss' representation and further alleged that Jahi's medical records had not been provided to petitioner or petitioner's designated physicians, thereby precluding any meaningful review of Drs. Shanahan's and Heidersbach's diagnoses of brain death.

24

25

26

proceeding with challenges to the pleadings under CCP 430.10 and 435, discovery rights under CCP 2016 et seq, motions for summary judgment under CCP 437c, and a full trial on the merits.

The court rejects the first option as failing to provide appropriate due process to the interested parties. If the determination were so simple that the court could resolve it on the basis of declarations, then the court would not need to be involved at all in the process. (Dority, 145 Cal.App.3d at 278 [If the family and physicians agree, then "we find it completely unnecessary to require a judicial "rubber stamp" on this medical determination"].) If the determination is not simple, then the interested parties are entitled to cross-examine the physicians and to present their own evidence.

The court finds the second option consistent with the apparent intent of the legislature, California case law, and due process. Health and Safety Code sections 7180 and 7181 concern a single factual issue that is medical in nature. Physicians should be able to make the required examination and complete the required analysis in a relatively short time period. The legislature in Health and Safety Code 1254.4 states that after a finding of brain death under section 7180 that a hospital must continue previously ordered cardiopulmonary support for a "reasonably brief period" to afforded family or next of kin the opportunity to gather at the patient's bedside before removal of the support and that "in determining what is reasonable, a hospital shall consider the needs of other patients and prospective patients in urgent need of care." This suggests that following a finding of brain death under section 7180 that any challenge to the finding also be completed in relatively brief period.

California case law indicates that trial courts have conducted hearings under section 7180 expeditiously. In Dority, the physicians found no brain activity on November 22 and again about about one month later (mid-December), and the trial court held a hearing on January 17 and 21.

1.0 1.1

 The testimony at the *Dority* trial court hearing was unrefuted. Although *Dority* did not address the nature of the proceeding or hearing, if also did not criticize the conduct of the trial court. (Kinsman v. Unocal Corp. (2005) 37 Cal.4th 659, 680 [An opinion is not authority for propositions not considered].)

Regarding due process, the Court has considered the following general principles as stated in Oberholzer v. Commission on Judicial Performance (1999) 20 Cal. 4th 371, 390-391:

Under the California Constitution, the extent to which procedural due process is available depends on a weighing of private and governmental interests involved. The required procedural safeguards are those that will, without unduly burdening the government, maximize the accuracy of the resulting decision and respect the dignity of the individual subjected to the decision making process. Specifically, determination of the dictates of due process generally requires consideration of four factors: [1] the private interest that will be affected by the individual action; [2] the risk of an erroneous deprivation of this interest through the procedures used and the probable value, if any, of additional or substitute safeguards; [3] the dignitary interest of informing individuals of the nature, grounds and consequences of the action and of enabling them to present their side of the story before a responsible governmental official; and [4] the government interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirements would entail.

The first three considerations, the private interest, the risk involved, and the dignitary interest of the proceeding, all suggest that the due process rights of the party affected by a physician's determination of death are substantial. The fourth factor, the government interest in the form of administrative burden, is addressed by the focused nature of the inquiry under Health and Safety Code sections 7180 and 7181.

 The court finds the third option to be inconsistent with the apparent purpose of the statute and the related statutes. The inquiry is focused and the Health and Safety Code 1254.4 suggest that the proceedings be commenced and concluded in a "reasonably brief period."

The court finds that the nature of the proceedings is that of a regular civil proceeding, but that the trial court has the discretion to focus the case on the limited issues presented and to expedite and narrow the proceedings accordingly. Paraphrasing *Dority*, 145 Cal.App.3d at 275, "Considering the difficulty of anticipating the factual circumstances under which a decision to remove life-support devices may be made, [limiting the discretion of the court to fashion the proceedings to the circumstances] may ... be unwise." The trial court may issue orders shortening time to ensure that the case is not unduly prolonged, the trial court may expedite and limit discovery under CCP 2019.020(a) and 2019.030, and the court may limit the scope of the evidence presented at the hearing under Evidence Code 352.

This court endeavored to provide petitioner with due process while completing the proceeding in a "reasonably brief period." CHO provided some medical records to petitioner late on Friday December 20 and provided more complete records to petitioner's counsel on Monday December 23, 2013. The court appointed its own independent physician to examine Jahi on Monday December 23, and counsel for petitioner was present during that examination. On Tuesday December 24, counsel for petitioner had the opportunity to cross-examine both Dr. Fisher and Dr. Shanahan.

During the proceedings, counsel for petitioner at various times requested that Paul A.

Bryne, MD be allowed to examine Jahi and provide a second 7181 opinion, or provide expert testimony at the hearing, or to review Jahi's records to assist in the cross-examination of Dr.

Shanahan. Petitioner withdrew the request that Dr. Bryne be allowed to examine Jahi and

 provide an opinion based on his own examination. Petitioner did not pursue his request that Dr. Byrne provide expert testimony. During the discussions between the court and counsel it became apparent through a review of Dr. Byrne's publications that were the court to hold an Evidence Code 402 hearing to determine whether Dr. Byrne was qualified as an expert under Evidence Code 720 and Sargon Enterprises, Inc. v. University of Southern Cal. (2012) 55

Cal.4th 747, that Dr. Byrne might not qualify as an expert based on his religious and philosophical approach to the definition of death and the possibility that he would not be able to apply accepted medical standards. In addition, it became apparent that testimony and documents regarding the cause of death, as opposed to the fact of death, were not relevant to the court's inquiry. The court exercised its discretion in not continuing the hearing to permit petitioner to review Jahi's records to assist in the cross-examination of Dr. Shanahan. The court reasoned that the examinations were both under the accepted medical standards, the medical determinations were consistent, and that the detriment of a prolonged proceeding would materially outweigh any probable benefit to the court in making the limited finding required by section 7181.

The court acted consistent with the trial court in Alvarado by Alvarado v. New York City Health & Hospitals Corp. (N.Y.Sup.,1989) 145 Misc.2d 687, 698, 547 N.Y.S.2d 190, order vacated and appeal dismissed as moot. 157 A.D.2d 604, 550 N.Y.S.2d 353 (1st Dep't 1990), where the court addressed a similar situation and stated, "In the instant case, the Alvarados were notified before a determination was made, were given an opportunity to obtain an independent medical evaluation, and were offered a chance to have the matter discussed with religious leaders and friends. Therefore, it cannot be said that the family was deprived of its due process rights to participate in the medical care of the child."

 FINDING OF BRAIN DEATH UNDER HEALTH AND SAFETY 7180 AND 7181.

A trial court may "hear testimony and decide whether the determination of brain death was in accord with accepted medical standards." (*Dority*, 145 Cal.App.3d at 279.) The law is unclear whether the court's determination is under the preponderance of the evidence standard, the clear and convincing evidence standard, or some other standard. This court applies the clear and convincing evidence standard.

The court is guided by *In re Christopher I* (2003) 106 Cal.App.4th 533, 552, where the court addressed the standard to be applied when removing life support from a minor who was in a persistent vegetative condition. In *Christopher*, the Court of Appeal noted that the Welfare and Institutions Code requires either proof by a preponderance of the evidence or clear and convincing evidence, depending on the rights being adjudicated and then stated, "Given the impact of this decision on Christopher, imposition of the highest standard within the Welfare and Institutions Code-the clear and convincing standard of proof-is appropriate." The court went on to review the law in different states and concluded "The evidentiary standards employed by other courts considering withholding or withdrawal of life-sustaining treatment from incompetent patients reinforce our belief that the clear and convincing standard is the correct one."

The court notes that although Christopher concerned a minor in a persistent vegetative condition and there are medical differences between a coma, a persistent vegetative state, and brain death, those differences pale in comparison to the difference between being legally alive and being legally dead. When a court is called on to determine whether a person has suffered brain death and is now dead under the law or can have support withdrawn and will become dead under the law, the court must make that finding by clear and convincing evidence.

 The court heard the testimony of Dr. Fisher and Dr. Shanahan. Both doctors presented consistent testimony that established the accepted medical standards for determining brain death in minors. Dr. Shanahan conducted a physical examination of Jahi on December 11, 2013, and Dr. Fisher conducted an examination on December 23, 2013. Both doctors conducted their examinations consistent with the accepted medical standards and both doctors reached independent conclusions of brain death based on their application of the standards to Jahi's condition. In addition, Dr. Shanahan reviewed an EEG taken on or about December 11, 2013, and Dr. Fisher reviewed a different EEG taken on December 23, 2013, and those tests reinforced their conclusions. Dr. Fisher conducted an additional test, a cerebral profusion test, and that test was also consistent with the conclusion of brain death. This clear and convincing evidence was the basis of the court's conclusion on December 24, 2013, that Jahi had suffered brain death and was deceased as defined under Health and Safety Code 7180 and 7181.

The court is mindful of the language in *Dority* that states the fact of brain death "does not mean the hospital or the doctors are given the green light to disconnect a life-support device from a brain-dead individual without consultation with the parent or guardian. Parents do not lose all control once their child is determined brain dead," and that a parent should be fully informed of a child's condition and have the right to participate in a decision of removing the life-support devices. (*Dority*, 145 Cal.App.3d at 279-280.) (See also, Health & Safety Code section 1254.4 [requiring reasonable amount of time to accommodate family in event of declaration of brain death].) The court expressly does address whether that consultation and opportunity for participation required by Health & Safety Code section 1254.4 occurred in this case.

APPLICABILITY OF PROBATE CODE 4735 AND 4736.

Petitioner's initial memorandum argued that if under Probate Code 4735 CHO made a determination to decline to comply petitioner's instructions on the basis that it would be "medically ineffective health care or health care contrary to generally accepted health care standards," then under Probate Code 4736 CHO had the obligation "to make all reasonable efforts to assist in the transfer of the patient to another health care provider or institution that is willing to comply with the instruction or decision" and had the obligation to "[p]rovide continuing care to the patient until a transfer can be accomplished or until it appears that a transfer cannot be accomplished."

Probate Code 4736 appears to apply only when is it arguable whether the proposed health care would be medically effective. The court finds that Probate Code 4736 does not apply after a determination of death. The court notes that Probate Code 4736 provides for some time to move a patient and Health and Safety Code 1241.4 provides a "reasonably brief period" for family to gather at the bedside. Therefore, both statutes provide for a brief period following a determination of brain death before a hospital can remove all support. The court makes no findings and issues no orders under Probate Code 4735 and 4736.

MOTION TO SEAL

The Order of December 23, 2013, stated, "The court anticipates that the hearing will be closed to the public under CRC 2.550 et seq. because it involves the medical records of a minor."

On December 23 and 24, 2013, petitioner moved to close the hearing in part and to seal and/or redact certain exhibits.

 The court CLOSED the courtroom and SEALS the record on the oral testimony provided by Dr. Fisher and Dr. Shanahan in which they detailed their examinations of Jahi. This testimony was provided in chambers with a court reporter present.

The court REDACTS Exhibit 1 (Dr. Fisher's examination notes) in part because the redacted portion is not pertinent to the issues before the court and Jahi's family has an overriding privacy interest in the material that outweighs the public interest in the information. The court permits disclosure of the remainder of Exhibit 1. Although the exhibit reflects Dr. Fisher's examination of Jahi, Dr. Fisher was acting as a court appointed expert on a matter that petitioner had placed at issue in this case.

The court DOES NOT SEAL Exhibits 2-5. These are documents that reflect the accepted medical standards.

The court DOES NOT SEAL Exhibit 6 (Shanahan Declaration filed 12/20/13). This is already in the public file. In addition, although it concerns the medical information of a minor it is conclusory and does not disclose private information.

The court SEALS Exhibit 7. This exhibit reflects Dr. Shanahan's and Dr. Heidersbach's pre-litigation examinations of Jahi. These doctors were acting as agents of CHO and their notes reflect the medical information of a minor.

EXTENSION OF RESTRAINING ORDER, STAY OF THIS ORDER, AND PREPARATION OF JUDGMENT.

The court ORDERS that the Temporary Restraining Order is extended through Monday, December 30, 2013, a6 5:00 pm. Until that time, Respondent CHO, its agents, employees, servants and independent contractors are ordered to continue to provide Jahi McMath with the treatment and support which is currently being provided as per the current medications and physicians orders until further order of the court.

 In the event that before Monday, December 30, 2013, at 5:00 pm there is a change in Jahi's physiological condition despite CHO provision of the current level of treatment and support and petitioner wants an increased level of treatment and support that CHO is unwilling to provide, then the parties may seek the assistance of the court at any time. The court has provided its contact information to counsel.

The court STAYS the effect of this order until Monday, December 30, 2013, at 5:00 pm to permit petitioner or CHO to file a petition for relief with the Court of Appeal and to seek further relief from that court.

CHO is to submit a proposed final judgment consistent with this order on or before January 9, 2014. (C.R.C. 3.1312.)

The court sets a further case management conference for 1:30 pm on January 16, 2014, in Dept 31. If the case has been resolved or all further near term proceedings will be in the Court of Appeal, then counsel may so inform the court and the court will continue the case management conference to a later date.

IT IS SO ORDERED.

Dated: December 26, 2013

Evelio Grillo Judge of the Superior Court