

Dead Donor Rule
Violations Are
Rampant: Brain
Death, DCD, NRP

1

Thaddeus Pope
for
Tulane School of Medicine
May 3, 2024

2

nothing
to disclose

3



4



5

“removed the organs of
hundreds of his patients
before they were declared
dead ... colleagues thought
he was committing murder”

6

death → remove organs

7



8

remove organs → death

9

violating
the dead
donor rule

10



11

almost
took organs
before death

12

Arizona College Student Bounces Back From the Dead After Nearly Giving Organs
May 9, 2014

By SUEAN DONALDSON JAMES on GOOD MORNING AMERICA

13

Los Angeles Times

close call - in death ruling of potential organ donor

John Foder at Fresno Community (April 11, 2007)

14

St. Joe's "dead" patient awoke as docs prepared to remove organs

By John O'Brien
on July 17, 2013 at 2:50 AM, updated July 18, 2013

15

American Journal of Case Reports

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DOI: 10.12301/AJCR.191005

Pronounced Dead Twice: What Should an Attending Physician Do in Between?

Author Contributions: ABC2019-1 Amie Bao
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16

accidental
DDR
violations

17

but

18



19

deliberate violations

20



21

3 recent examples

22

example 1

23



24



25



26



27



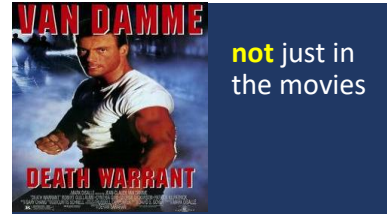
28

Execution by organ procurement: Breaching the dead donor rule in China

American Journal of Transplantation

Matthew P. Robertson | Jacob Lavee

29



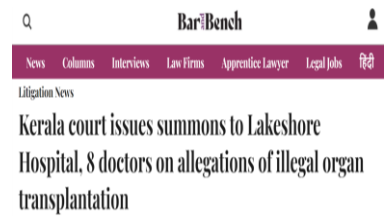
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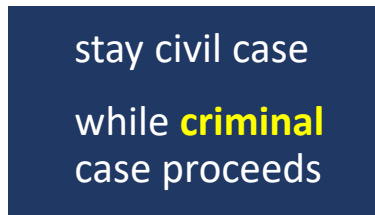


33

Kerala High Court stays proceedings against Lakeshore Hospital, doctors in illegal organ transplantation case
Justice PV Kamalishnan issued the order dated October 3, staying the proceedings, including the summons issued to the hospital and doctors by a magistrate court.



34



35

Fresh investigation under way into irregularities in harvesting organs from brain-dead patient
Special team to investigate allegations that the organs were transplanted on foreign nationals overlooking Indian patients on wait list



36



37



38



Paulo Pavesi

39



40



41



42



43



44



45



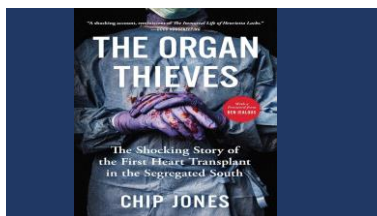
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Tucker v. Lower
 No. 2831 (Richmond, Va., L. & Eq. Ct., May 23, 1972).

47



48



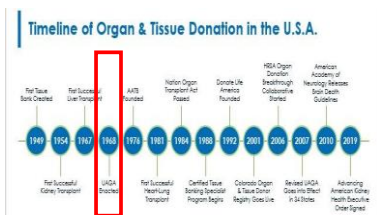
49



50

motivator
BD laws
 1970 →

51



52

2000s

53

3 cases

54

case **1**

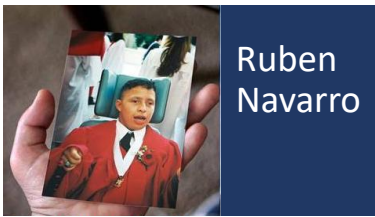
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56



57



58

DCD

59

patient did **not** die after withdrawing LST

60

SO...

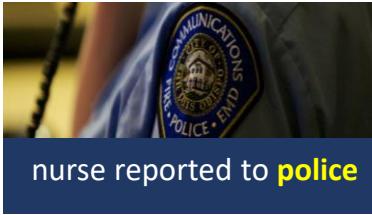
61



62

220mg morphine + 84mg Atavan

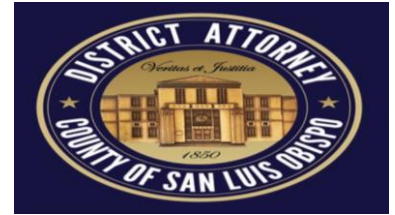
63



64

charged &
prosecuted

65



66

"The defendant a transplant surgeon administered excessive amounts of narcotics and tranquilizers ... to **hasten his death**, so that he could **harvest his organs**."

67

jury
acquitted

68

but

69

2-month
trial

70

3 years of his life
personal &
professional

71

case **2**

72



73



74



75



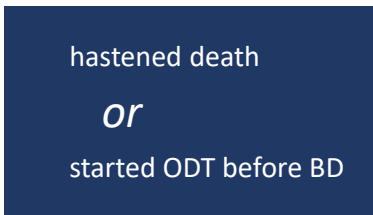
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77



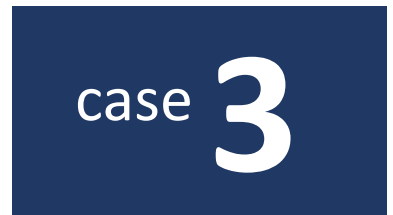
78



79



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81



82



83

New York Law Journal

McMahon v. N.Y. Organ Donor Network, Inc.

Patrick McMahon, Whistleblower, Claims Organ Donor Network Harvested From Living Patients

84



85



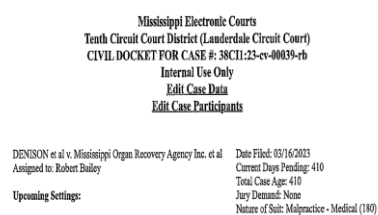
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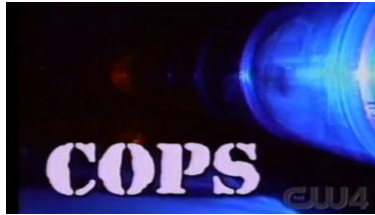
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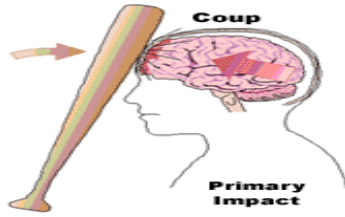
98



99



100



101



102



103

we've got to **verify** it legally,
to see if she
is morally, ethically
spiritually, physically
positively, absolutely
undeniably and reliably Dead

104

SO ...

105



106

She's not only
merely dead,
She's really most
sincerely dead

107

*what is the
point?*

108

need
certainty
clarity

109

life death

110

life death

111

dead
or
alive

112

U.S. clinicians make
lots of medical errors

113

5 major
reports

114

1999

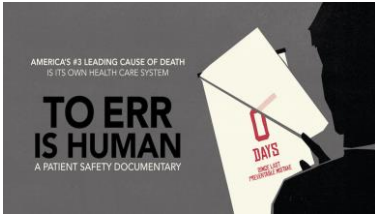
115



116

98,000 deaths
each year from
preventable
medical error

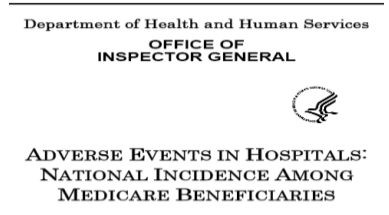
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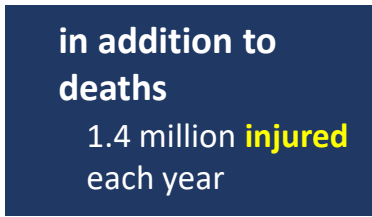
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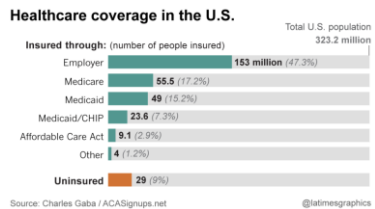
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122



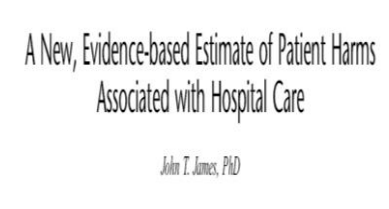
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124



125



126

400,000

premature deaths from
preventable harm to patients

127

2016

128



129

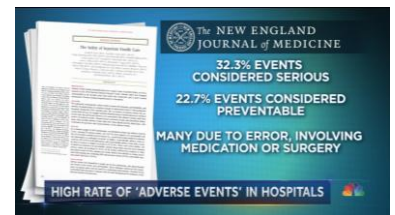
250,000

but understated

130

2023

131



132

lots of
different
studies

133

whichever
estimate we use
it is **too** many

134

place in
context

135

heart disease	600,000
cancer	600,000
medical error	400,000
COPD	140,000
stroke	130,000
accidents	120,000

136



137

with **death**
determination, we
want **100% accuracy**

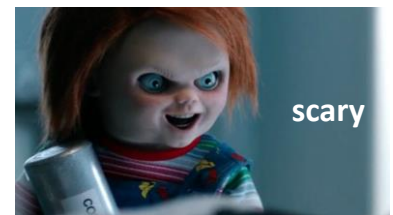
138

we want **zero**
false positives

139

never want to say
someone is dead
when they are not

140



141

1844

142

taphophobia

143



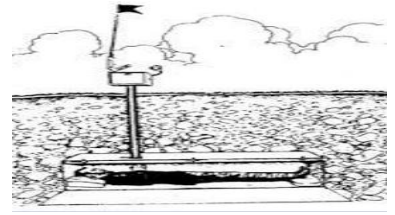
144



145



146



147



148

never want to say
someone is dead
when they are not

149

especially in
context of **ODT**

150

that's why we have the
dead donor rule

151

never take vital organs
until **after** individual
determined dead

152

but

153



154



155



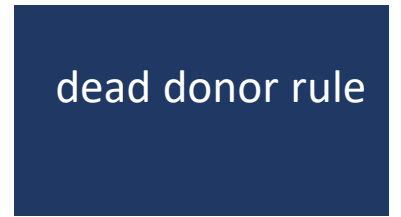
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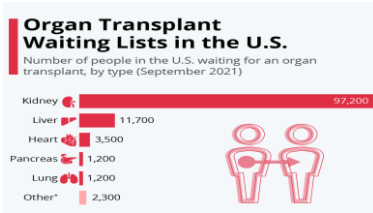
160



161



162



163



164

living donors
or
deceased donors

165

most organs from deceased donors

166

2023

167

7000 living
40,000 deceased

168

15% transplants from living donors

169

85% transplants from deceased donors

170



171



172

deceased
donation

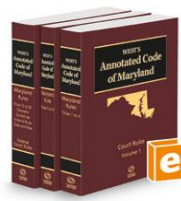
173

dead
donor
rule

174

procure vital
single organs
only from donors
already dead

175



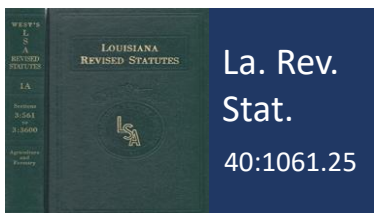
176

Maryland

Maryland Health -
General § 5-202(b)(2)

“pronouncement of
death ... shall be made
before any vital organ
is removed for
transplantation.”

177



178

La. Rev.
Stat.
40:1061.25

“**dead donor rule** ...
protects the integrity of
human organ donation
by providing that ...”

179

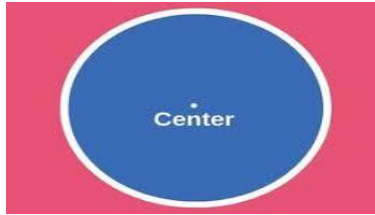
“donors must be dead **before**
procurement ... begins”

“organ procurement itself
must **not cause** the death”

180

even where
not codified

181



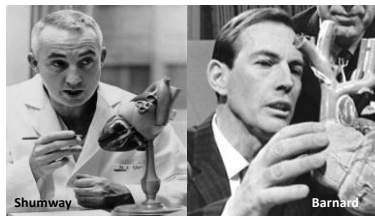
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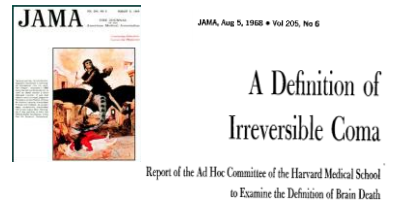
183

1968

184



185



186



187



188



189

also built
2nd fence
for DDR

190



191

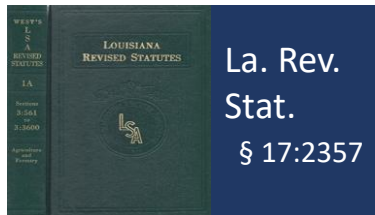


WHO GUIDING PRINCIPLES
ON HUMAN CELL, TISSUE AND ORGAN TRANSPLANTATION¹

192

“physicians determining
that a potential donor has
died should **not be**
directly involved in ...
transplantation ...”

193

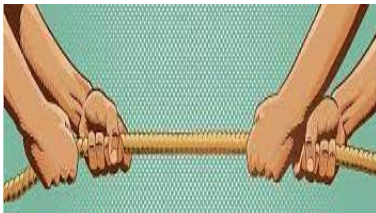


La. Rev.
Stat.
§ 17:2357

194

“Neither ... physician
who **determines ... death**
may participate in the
procedures for **removing**
or **transplanting ...**”

195



196



197

screen COI that
might cause
DDR violations

198

SO...

199

not only

200

follow DDR

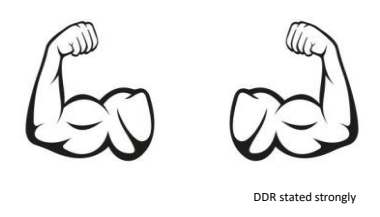
201

but also

202

avoid even
appearance
of impropriety

203



204

3rd

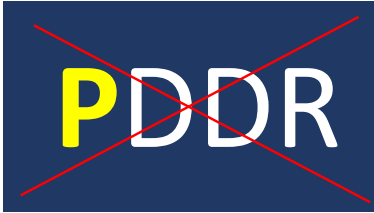
205

burden
of proof

206

DDR

207



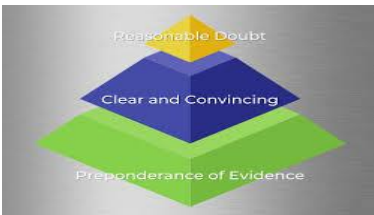
208

presumed
alive until
rebutted

209



210



211

that's the
DDR

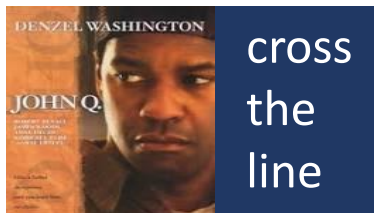
212

first
determine death

213

then
take organs

214



215

when are
donors dead

216

2 ways to be dead

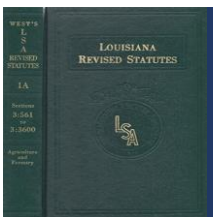
217

UDDA

218

law on death in all U.S. jurisdictions

219



La. Rev. Stat. § 9:111

220

2 ways to determine death

221

“irreversible cessation of **circulatory & respiratory** functions”

222

or

223

“irreversible cessation of all functions of the entire **brain**”

224

circulatory criteria **or** neurologic criteria

225

to date, **87%**
deceased donation
is after **BD**

226

just **13%**
after CD

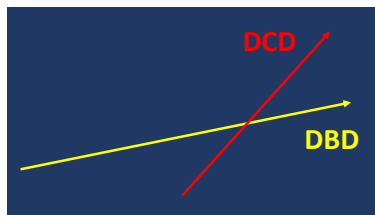
227

but

228

2010 - 2023

229



230



231

	To Date:	2024	2023	2022	2021	2020	2019	2018	2017
All DCD + non-DCD	979,478	11,765	46,630	42,889	41,356	39,036	39,719	36,530	34,770
Brain Death Donor	633,814	6,894	29,722	28,729	27,770	27,462	27,306	25,721	25,131
DCD Donor	72,391	3,141	9,958	7,692	7,044	5,847	5,016	3,960	3,457

<https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/>

232

DCD

233

>110% increase
last 5 years

234

DBD

235

only **17%** increase
last 5 years

236

DCD > 1/3
DBD < 2/3

237

**DDR
violations**

238

4 violations

239

DBD

240

DCD

241

NRP

242

PMI

243

DBD

244

2 problems

245

problem 1

246



247

law | **medicine**

248

clinicians do **not**
assess what
UDDA requires

249

UDDA

250

law on death
in all U.S.
jurisdictions

251

irreversible cessation
all functions
entire brain

252

but

253

brain dead
people
do stuff

254



255



256



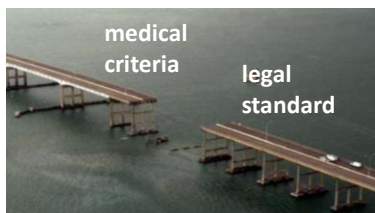
257

clinicians assess only
some functions
part of brain

258

UDDA requires
all functions
entire brain

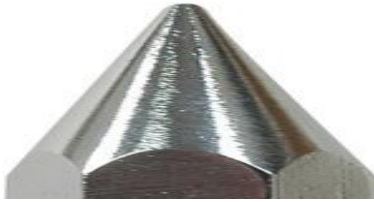
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260

medically dead
≠
legally dead

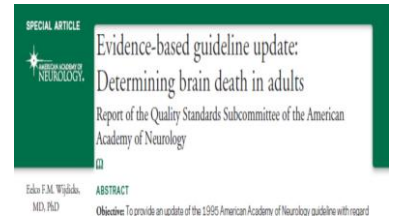
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262



263



264

SPECIAL ARTICLE

Brain death, the determination of brain death, and member guidance for brain death accommodation requests

AAN position statement

James A. Russell, DO, MS, Leon G. Epstein, MD, David M. Green, MD, MA, Matthew Kirshner, MD, PhD, Michael A. Rubin, MD, MA, and Aislinn Lewis, MD, on behalf of the Brain Death Working Group

Correspondence: J.A. Russell, james.a.russell@ahajny.org

Neurology® 2019;92:1-6. doi:10.1212/WNL.0000000000006750

265

patient can **satisfy** BD guidelines

266

dead

267

yet...

268

“neuro-endocrine function **may be present**”

269



270

may determine BD
despite function
hypothalamus

271

“not inconsistent
with the whole brain
standard of death”

272



273



274



275



276

UDDA
requires

277

irreversible
cessation of

278

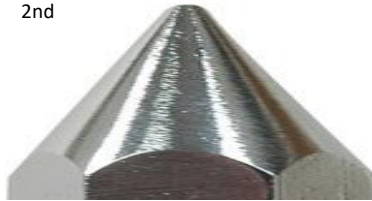
all functions
of the
entire brain

279



280

2nd



281

A Framework for Revisiting Brain Death: Evaluating Awareness and Attitudes Toward the Neuroscientific and Ethical Debate Around the American Academy of Neurology Brain Death Criteria

Journal of Intensive Care Medicine
1-18
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10.1177/10755420231186282
https://doi.org/10.1177/10755420231186282
jicm.sagepub.com/home/jicm
SAGE

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Mohamed Y. Rady, BChir, MB (Cantab), MA, MD (Cantab)²,
Joseph L. Verheijde, PhD, MBA, PT¹, and Richard J. Butterfield, MA¹

282

200 clinicians
Mayo Clinic

283

1. use AAN protocol
2. get positive result
3. does that demonstrate loss of "all functions of the entire brain"?

284



285



286

medical criteria do **not** require cessation of **all** functions

287

require cessation of **critical** functions

288



289

but

290

lack authority
to do that

291

analogy

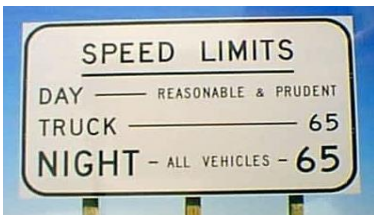
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293



294



295



296

UDDA gives
standards

297

medical profession
only **applies** them

298

1. all functions
2. entire brain
3. cessation
4. irreversible

299

that's
problem **1**

300

mismatch
legal criteria to
medical standards

301

problem **2**

302

even if guidelines
were legally valid

303

widespread
noncompliance

304

UDDA

305

when making
determinations of
irreversible cessation

306

“accordance with
**accepted medical
standards”**

307

but

308

which medical
standards are
accepted ?

309



310

variability

311

Research

Original Investigation

Variability of Brain Death Policies in the United States

David M. Greer, MD, MA, Hilary H. Wang, BA, Jennifer D. Robinson, APRN, Parajoy N. Vireks, MD, PhD, Galen I. Henderson, MD, Eelco F. M. Wijdicks, MD, PhD

312

Improving uniformity in brain death determination policies over time

OPEN

Hilary H. Wang, MD **ABSTRACT**

313

Variability of brain death determination guidelines in leading US neurologic institutions

ABSTRACT

David M. Greer, MD, MA, Parajoy N. Vireks, MD, PhD

314

Neurology

February 26, 2019; 92 (9) **ARTICLE**

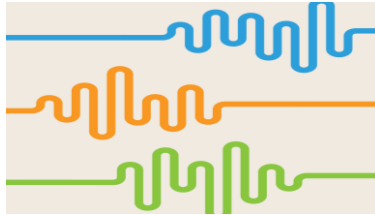
Variability in reported physician practices for brain death determination

Sherril A. Braksick, Christopher P. Robinson, Gary S. Gronseth, Sara Hocker, Eelco F.M. Wijdicks, Alejandro A. Rabinstein

315

number of physicians
qualifications
how tests administered

316



317



318

Neurology
Clinical Practice

A peer reviewed clinical neurology journal for the practicing neurologist
An Official Journal of the American Academy of Neurology


AMERICAN ACADEMY OF NEUROLOGY

Neurology: Clinical Practice Publish Ahead of Print
DOI: 10.1212/CPJ.0000000000200077

A Review of Practices Around Determination of Death by Neurologic Criteria by an Organ Procurement Organization in the WAMI Region


Author(s):
Abhijit V Jay Lee, MBBS, MD, MSCR, FNCS^{1,2}; Sarah Wainwright, MD³; Jan Boer⁴; Dominic Adomo, MD⁵; Candy

319

 LifeCenter Northwest

deviations in **20%**
referred cases

320

 LifeCenter Northwest

rejected referrals
b/c not dead

321



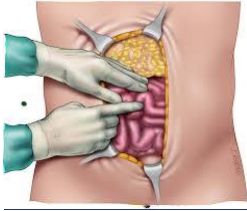
322



323



324



brain injury during exploratory laparotomy

325

met AAN criteria for brain death

326



327



328

dad loses

329

trial court
AAN criteria met
→ Aden is dead

330



331

dad wins

332



333

Supreme Court of Nevada

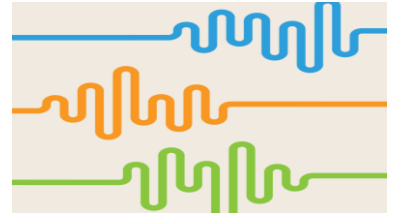
irrelevant Aden
meets AAN criteria

not the
“right” criteria

334

unclear they are
“**accepted** medical
standards”
as UDDA requires

335



336

state 1
≠
state 2

337

hospital 1
≠
hospital 2

338

MD 1
≠
MD 2

339



Supreme Court of Nevada

340

uncertainty



341

fixed



342



Nevada
A.B. 424 (2017)

343

amended
NUDDA

A.B. 424 (2017)

344

determination of BD
“must be made in
accordance **with ...**”

345

SPECIAL ARTICLE
 Evidence-based guideline update:
 Determining brain death in adults
 Report of the Quality Standards Subcommittee of the American
 Academy of Neurology

Edou F.M. Wijaya, MD, PhD
 ABSTRACT
 Objective To provide an update of the 1995 American Academy of Neurology guideline with regard

346

American Academy of Pediatrics
 GUIDELINES 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

Thomas A. Nakagawa, MD, Stephen Arthwell, MD, Mudd

347

accepted
medical
standards

348

NEW YORK STATE
 Department of Health

349



350

Board Adopted Resolution as Amended
 (January 2021)
 (Affirmed; 2021 Annual Meeting)

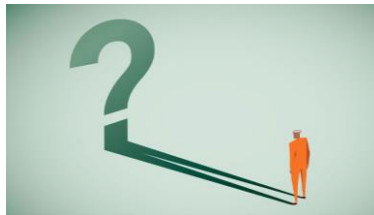
ILLINOIS STATE MEDICAL SOCIETY
 Resolution 09.2020-08
 (A-21)

Introduced by: Megan Finneran, DO, MS, ISMS Member
 Subject: Statewide Brain Death Protocol
 Referred to: Medical Legal Council

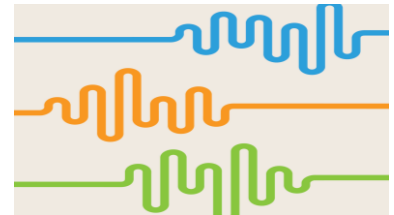
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352



353



354

October 2023						
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16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

355

Published Ahead of Print on October 11, 2023 as 10.1212/WNL.000000000207740

SPECIAL ARTICLE

Pediatric and Adult Brain Death/Death by Neurologic Criteria Consensus Guideline

Report of the AAN Guidelines Subcommittee, AAP, CNS, and SCCM

David M. Green, MD, MA,* Matthew P. Kirschner, MD, PhD,* Aruna Lewis, MD,* Gary S. Gronseth, MD, Alexander Rae-Grant, MD, Stephen Ashwal, MD, Migo A. Babu, MD, MBA, David F. Bauer, MD, MPH, Lori Blaugher, MD, MSc, Amanda Cray, MD, Sonal Parag, MD, MSc, Michael A. Rubin, MD, MA, Lori Shuster, MD, Courtney Takahashi, MD, Robert C. Taylor, MBE, MS, Parasidis Nicosia Vardas, MD, PhD, Gokul Wigle, MD, PhD, Amy Bennett, JD, Scott R. Weisbart, MSc, ELS, and John J. Hobbins, MD

Correspondence: pubinfo@aan.com

Neurology® 2023;101(17-21):doi:10.1212/WNL.000000000207740

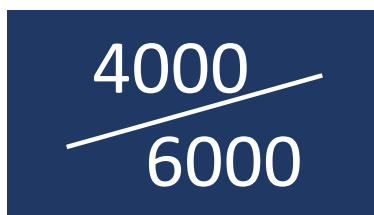
356



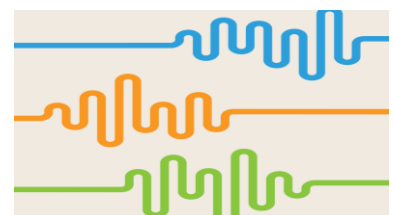
357



358



359



360

that's
problem 2

361

failure
determine BD using
"accepted standards"

362

that's
DBD

363

let's move to
a second
DDR violation

364


DCD

365



1960s
ODT was
DCD

366



JAMA, Aug 5, 1968 • Vol 205, No 6

A Definition of
Irreversible Coma

Report of the Ad Hoc Committee of the Harvard Medical School
to Examine the Definition of Brain Death

1968

367

1970 →

368

50 years
almost all
ODT was BD

369



370

BD – can keep organs perfused **whole** time

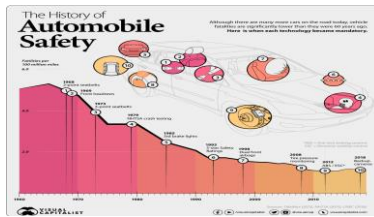
371

but

372



373



374



375



376



377

DCD

378



379

catastrophically
critically ill
(but **alive** patient)

380

family makes
decision to
stop LST

381

likely that
heart will **stop**

382

even when
heart stops

383

not dead **yet**

384

UDDA

385

“**irreversible** cessation of
circulatory & respiratory
functions”

386

2 problems

387

problem **1**

388

cessation is
not irreversible
as UDDA requires

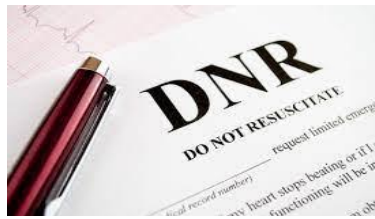
389

we **can** reverse
cessation of
circulatory function

390

we **won't**
(because Pt does
not want that)

391



392

but

393

we **could**

394

response

395

we interpret
“irreversible” as
“**permanent**”

396



397

not what
UDDA says

398

problem **2**

399

even if UDDA requires
only “permanent”
cessation

400

is even **that**
satisfied?

401

after heart
stops

402

standoff

403

ensure heart
does not restart
spontaneously

404

how long?

405



406

after 5 min

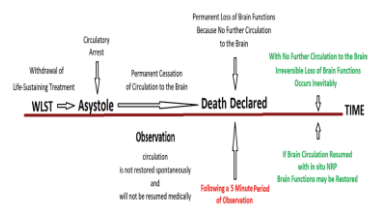
407

if **no** circulatory function

408

→ dead

409



410

why 5 min

411

hearts **have** restarted at 4:20

412

problem

413

some clinicians wait only **2 min**

414



415



An error occurred.

416

unclear that
circulatory cessation
was **irreversible**

417

heart **might**
have restarted

418

at 2:09
or
at 3:44

419

DDR

420

~~PDDR~~

421

~~DEDR~~

422

~~ADDR~~

423

DDR

424



425

let's move to
a specific
type of DCD

426

NRP

427

normothermic
regional
perfusion

428

TA-NRP

429

DCD requires
absence of
circulation

430

but

431

bad for organs,
especially heart

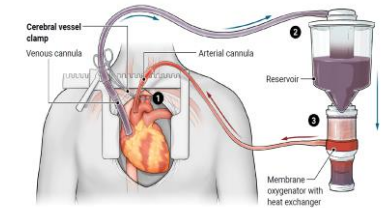
432

SO ...

433

minimize warm
ischemia → restart
circulation
in the donor

434



435

improves
organ quality

436

problem

437

said dead **because**
irreversible cessation
circulatory function

438

reversed it

439

basis for death
determination
no longer true

440

response

441

before restart →
cut or clamp
vessels to brain

442

even if no longer
circulatory dead, w/o
perfusion to brain,
patient is **brain** dead

443



444



445



Ethics, Determination of Death, and Organ Transplantation in Normothermic Regional Perfusion (NRP) with Controlled Donation after Circulatory Determination of Death (cDCD):
American College of Physicians Statement of Concern

446

“ethical & legal
propriety ... has
not been met”

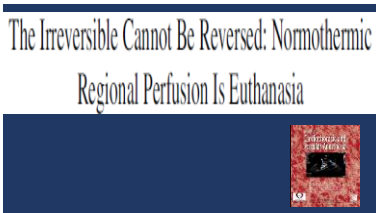
447



448

“**unclear** whether
NRP violates the
DDR”

449



450



451

really only regional?

452

only a hypothesis
do not know no perfusion to brain

453



454

do not know donor is dead

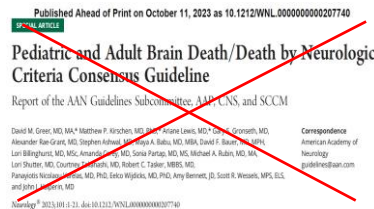
455

may be consciousness pain perception

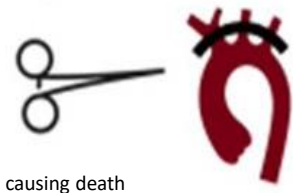
456



457



458



459

DDR

460

death → ODT

461



462

ODT → death

463

recap

464

DBD
DCD
NRP

465

1 more DDR violation

466

PMI

467

DCD entails some ischemic damage

468

SO ...

469

pre-mortem
non-therapeutic
interventions

470

MV CPR
vasopressors
hormonal therapy

471

heparin
femoral
cannulation

472

not for patient
only for organ

473

organ protection
therapy
donor optimization
procedures

474

donor
management

475

DDR

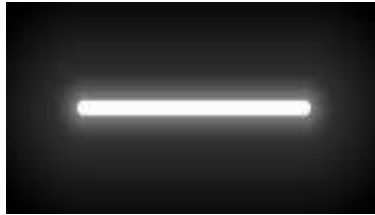
476

alive	dead
focus on patient	focus on organ

477

alive	dead
treatment team	transplant team

478



479



480

alive	dead
focus on patient	focus on organ

481



482



483

Fact

When you are sick or injured and admitted to a hospital, the one and only priority is to save your life.

484

Not True!



485



486

donor | patient

487

clinicians have the
very **COI** that DDR
aims to prevent

488

~~consent
transparency~~
DDR

489

recap

490

DBD NRP
DCD PMI

491

we **breach**
the DDR

492

every
single day

493

what to
do next

494

4 paths

495



496



497



498



499



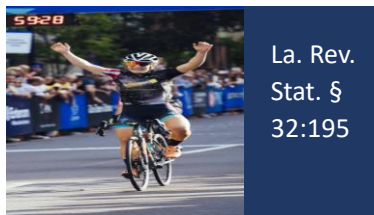
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501



502



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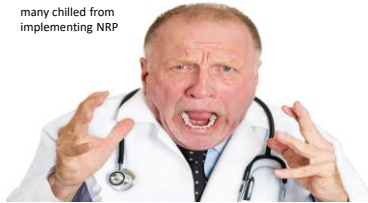


504



505

many chilled from implementing NRP



506



507



Request Legal Help

508



509



510



511



512



513

revise ODT
to comply

514



515

BD **only** when no
neuroendocrine
function

516

DCD > 5 min

517

no NRP

518

continue NRP

as human subjects
research - with IRB
approval & oversight

519

but

520



521

UDDA is strict
& demanding

522

we would **lose**
many organs

523



524

change
UDDA

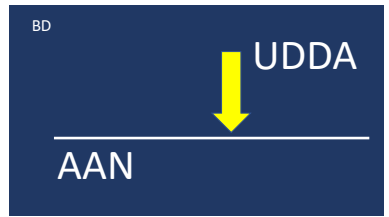
525

instead of aligning
guidelines to law

526

align **law** to
guidelines

527



528



we tried that

529

2020 2022
2021 2023

530



531

UDDA →
RUDDA

532

certainty
clarity

533

match
legal criteria to
medical standards

534

clarify **which**
medical standards
to use

535

but

536



537



538

SO ...

539

~~**R**UDDA~~

540



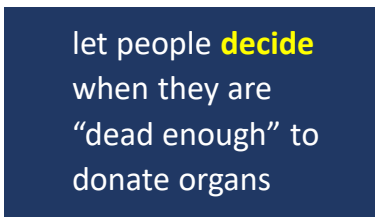
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542



543



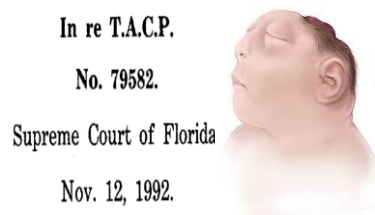
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545



546



547



548



549

3 foremost bioethicists

550

Downloaded from <http://jme.bmj.com/> on May 23, 2016 - Pub

Editorial

The price of our illusions and myths about the dead donor rule

Robert Truog

551

bioethics

Volume 33(3) (2016) pp. 147-157
doi:10.1017/S0007122615000114

SHOULD WE ALLOW ORGAN DONATION EUTHANASIA? ALTERNATIVES FOR MAXIMIZING THE NUMBER AND QUALITY OF ORGANS FOR TRANSPLANTATION

DOMINIC WILKINSON AND JULIAN SAVULESCU

552

Robert M. Veatch

Abandon the Dead Donor Rule or Change the Definition of Death?

553

4 public opinion

554

Advantages of public opinion polls

- Online public opinion polls are easier to respond
- Public opinion poll serves an essential aspect of democracy
- Public opinion polls are faster and more accurate
- Online opinion polls have a wider reach

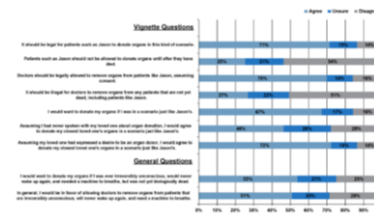
QuestionPro

555

Abandoning the dead donor rule? A national survey of public views on death and organ donation

Michael Nair-Collins, Sydney R. Green, Angelina R. Sutin

556



557

Death and organ donation: what do the Australian public think?

Alfred George Stevenson, Alastair Michael Clancy, Melissa O'Connell, Debra Lynne Stewart, Paul Cameron, David P. Barker, George

558

5 honest
transparent

559

not
expanding

560

matching rules
to practice

561

SO...

562

~~**DDR**~~

563

but

564

IT'S A
BIG
DEAL

565

CAUTION

566

DDR

567

keep public trust
protect patients

568

trust

569



570

31%
Trust the US
healthcare system
as a whole

571

safety

572



573

but

574



575



576

anencephalic
PVS/UWS
more

577

in sum

578

conflict
DDR v. ODT

579

ignore mismatch
change law
change CPG
drop DDR

580

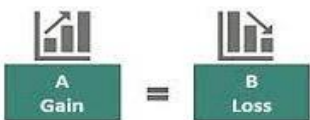
conclusion

581

increase
number & quality
of organs

582

Zero-Sum Situation



583

more certain death → fewer organs

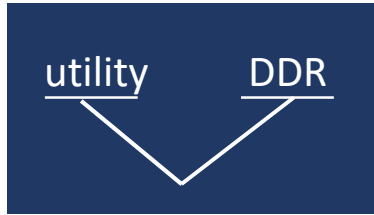
584

more organs → less certain death

585



586



587

how much **uncertainty of death** can we tolerate?

588



589

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