Dead Donor Rule Transgressions
Brain Death, DCD, and NRP

1

Thaddeus Pope

for

Loyola University Chicago
October 24, 2023

2

nothing
to disclose

3

LOYOLA UNIVERSITY CHICAGO
NEISWANGER INSTITUTE for BIOETHICS & HEALTHCARE LEADERSHIP

4

5

violating
the dead donor rule

6

7

almost
took organs before death

8

9

Los Angeles Times

close call in death ruling of potential organ donor

John Foster at Fresno Community (April 12, 2007)

10

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

syracuse.com

11

American Journal of Case Reports

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

Annie Bao

Shiping Bao

12

accidental DDR violations

13

but

14

OCT 24

15

deliberate violations

16

17

3 recent examples

18

example 1

19

20

21

UNITED NATIONS
HUMAN RIGHTS
SPECIAL PROCEDURES
SPECIAL RAPPORTEURS, INDEPENDENT EXPERTS & WORKING GROUPS

22

Forced Organ Harvesting in China: Examining the Evidence

Date: Thursday, May 12, 2022 - 10:30am

23

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

American Journal of Transplantation

Matthew P. Robertson[1] | Jacob Lavee[2]

24

example 2

25

26

Bar & Bench

News | Columns | Interviews | Law Firms | Apprentice Lawyer | Legal Jobs | हिंदी

Litigation News

Kerala court issues summons to Lakeshore Hospital, 8 doctors on allegations of illegal organ transplantation

27

Kerala High Court stays proceedings against Lakeshore Hospital, doctors in illegal organ transplantation case

Justice PV Kunhikrishnan issued the order dated October 3, staying the proceedings, including the summons issued to the hospital and doctors by a magistrate court.

October 2023

Bar & Bench

28

stay civil case

while **criminal** case proceeds

29

example **3**

30

31

32

CORREIO BRAZILIENSE

JUSTICE

Doctor sentenced to 21 years for death after removing boy's organs

33

34

35

1968

36

37

38

Tucker v. Lower

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

39

53-Year-Old Richmond Man

Heart Donor Identified

The Medical College of Virginia's heart transplant patient was listed as satisfactory yesterday afternoon; meanwhile, the identity of the donor was learned late yesterday.

He was Bruce Oliver Tucker, 53, of 109 E. Charity St. here, who suffered fatal brain injuries last Friday evening when he fell from a three-foot high wall he was sitting on and hit his head on concrete, according to a friend. The accident occurred between 11th and 12th Sts. on East Cary Street.

Tucker, who was a Negro, died Satruday at MCV of "irreparable" brain injuries, according to one source. He worked at the Schluderberg-Kurdle Co., Inc., (Esskay) a packing firm. More specifically, he worked at the firm's egg plant at 1114 E. Cary St.

J. O. Bowles, manager of the Esskay egg plant, said Tucker had worked there for "26 or 27" years, and described him as a "good employe who was always punctual." Eggs are candled and graded at the Cary Street Esskay plant.

Bowles said he was not at work last week due to illness, but understood that Tucker's accident occurred sometime after the plant had closed Friday evening.

A brother of the donor, Grover Tucker of Dinwiddie, when asked if his brother were the donor, said "Yes, he's the one."

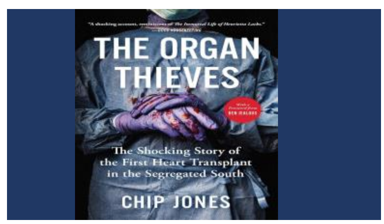
Another brother, William Tucker of Richmond, declined to confirm or deny that Bruce Tucker was the donor, but added, "If it were done, it was done without authorization." He declined further comment.

State medical officials could not be reached for comment

Bruce O. Tucker
Dinwiddie Native

Continued on Page 2, Col. 3

40



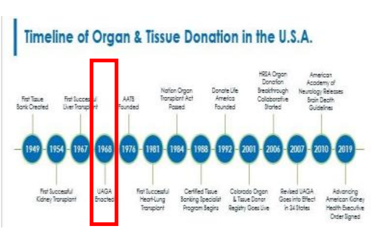
41

motivator

BD laws

1970 →

42



43

2000s

44

3 cases

45

case 1

46

47

Hootan Roozrokh

48

Ruben Navarro

49

DCD

50

patient did **not** die after withdrawing LST

51

SO…

52

53

220mg morphine
+
84mg Atavan

54

nurse reported to **police**

55

charged & prosecuted

56

DISTRICT ATTORNEY
Veritas et Justitia
1850
COUNTY OF SAN LUIS OBISPO

57

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

58

jury acquitted

59

but

60

2-month trial

61

3 years of his life
personal & professional

62

case **2**

63

64

DONATE LIFE CORE
Center for Organ Recovery & Education
A Pledge for Life

65

DBD

66

67

68

not BD

69

hastened death
or
started ODT before BD

70

$1,200,000

71

case **3**

72

73

LiveOnNY

Organ Donation Saves Lives

74

New York Law Journal

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

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

75

1 in 5

76

3 cases

77

more

78

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NORTH CAROLINA

Vincent Procopio, individually and as Personal Representative of the Estate of Robert Procopio, Jr.

Plaintiff,

vs.

Super 8 Worldwide, Inc., a subsidiary of Wyndham Worldwide;

Raleigh Police Department;

WakeMed Raleigh Campus;

Jeffrey Abrams, M.D.

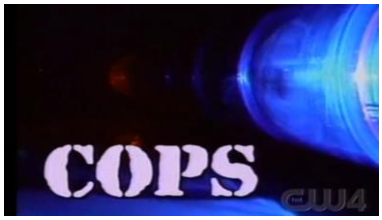
Case No. 5:22-cv-00293-BO

COMPLAINT FOR DAMAGES

79

80

81



82

clinicians **know** DDR has teeth

83

84

law professor

85

1 more case

86

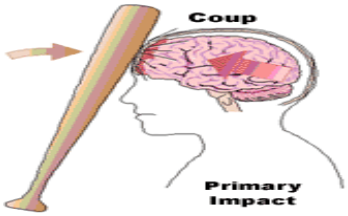
Munchkins
v.
Wicked Witch of the East

87

88

89

90



91

92

93

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

94

so …

95

96

She's not only
merely dead,

She's really most
sincerely dead

97

98

need
certainty
clarity

99

life death

100

life death

101

dead *or* alive

102

U.S. clinicians make **lots** of medical errors

103

5 major reports

104

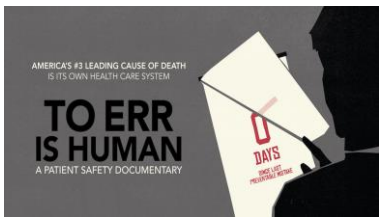
1999

105

106

98,000 deaths each year from preventable medical error

107



108

2010

109

Department of Health and Human Services
OFFICE OF
INSPECTOR GENERAL

ADVERSE EVENTS IN HOSPITALS:
NATIONAL INCIDENCE AMONG
MEDICARE BENEFICIARIES

110

180,000 deaths

111

in addition to deaths

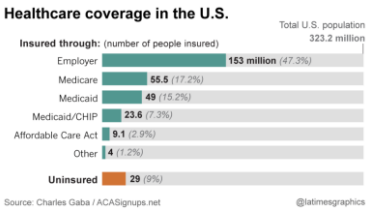
1.4 million **injured** each year

112

just Medicare beneficiaries

just hospitals

113



114

2013

115

A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care

John T. James, PhD

116

400,000

premature deaths from preventable harm to patients

117

2016

118

119

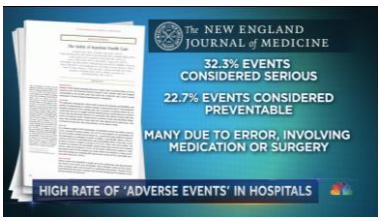
250,000

but understated

120

2023

121



122

lots of different studies

123

whichever estimate we use

it is **too** many

124

place in **context**

125

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

126

CONTRAST

is the arrangement of opposite elements and effects in an artwork.

127

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

128

we want **zero** false positives

129

never want to say someone is dead when they are not

130

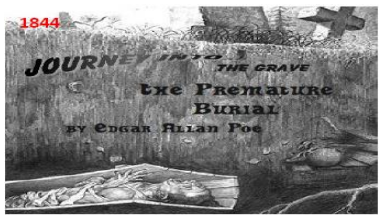
131

1844

132

taphophobia

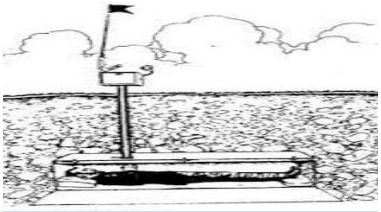
133



134

135

136



137

138

never want to say someone is dead

when they are not

139

especially in context of **ODT**

140

that's why we have the

dead donor rule

141

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

142

but

143

144

roadmap

145

146

4 parts

147

organ transplantation

148

dead donor rule

149

4 **violations** of the DDR

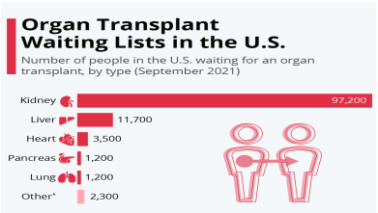
150

what to do **next**

151

organ transplantation

152



153

154

living donors
or
deceased donors

155

most organs
from **deceased**
donors

156

2022

157

6500
43,000

158

15%
transplants from
living donors

159

85%
transplants from
deceased donors

160

161

162

deceased donation

163

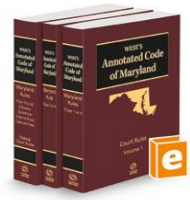
dead donor rule

164

procure vital single organs

only from donors **already** dead

165



Maryland

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

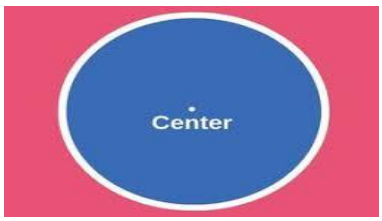
166

"pronouncement of death … shall be made **before** any vital organ is removed for transplantation."

167

even where not codified

168



169


Ethics

OPEN

Legislation and Policy Recommendations on Organ and Tissue Donation and Transplantation From an International Consensus Forum

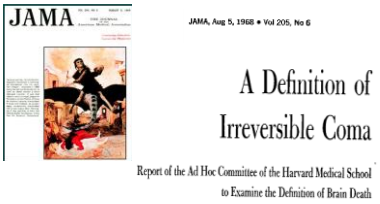
Maeghan Toews, BA, JD, LLM,[1] Jennifer A. Chandler, BSc, LLB, LLM,[2] Thaddeus Pope, JD, PhD, HEC-C,[3,4] Roger Pape, MA, BA,[5] Matthew Weiss, MD,[6,7,8] and Alberto Sandiumenge, MD, PhD[9]

170

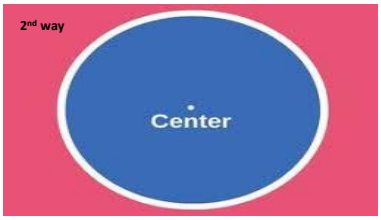
1968

171

172



173



174

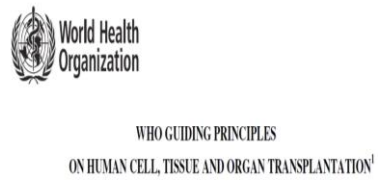
175

176

also built
2nd fence
for DDR

177

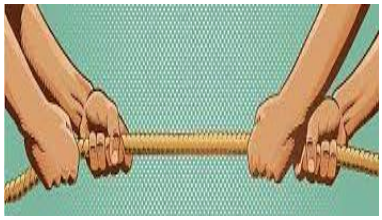
178



179

"physicians determining that a potential donor has died should **not be directly involved** in … transplantation …"

180



181

182

screen COI that might cause DDR violations

183

so…

184

not only

185

follow DDR

186

but also

187

avoid even **appearance** of impropriety

188

DDR stated strongly

189

3rd

190

burden of proof

191

DDR

192

~~PDDR~~

193

presumed alive until rebutted

194

195

196

that's the DDR

197

first determine death

198

then
take organs

199

when are donors dead

200

2 ways to be dead

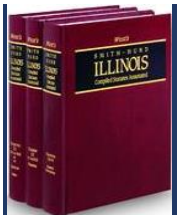
201

UDDA

202

law on death in all U.S. jurisdictions

203



755 ILCS § 40/10

204

2 ways
to determine death

205

"irreversible cessation of **circulatory & respiratory** functions"

206

or

207

"irreversible cessation of all functions of the entire **brain**"

208

circulatory criteria
or
neurologic criteria

209

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

210

just **13%** after CD

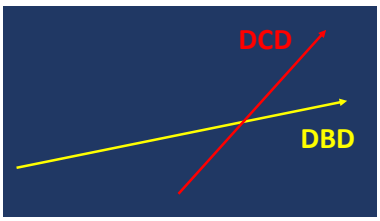
211

but

212

2010 - 2023

213



214

OPTN Organ Procurement & Transplantation Network
U.S. Department of Health & Human Services
HRSA
Health Resources & Services Administration

215

	To Date	2023	2022	2021	2020	2019	2018	2017
All DCD + non-DCD	267,927	2,515	14,905	13,863	12,588	11,870	10,721	10,286
Brain Death Donor	206,453	1,673	10,127	9,673	9,364	9,152	8,589	8,403
DCD Donor	33,926	841	4,778	4,190	3,224	2,718	2,132	1,883

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

216

DCD

217

>110% increase last 5 years

218

DBD

219

only **17%** increase last 5 years

220

221

DCD **>** 1/3

DBD < 2/3

222

DDR violations

223

4 violations

224

DBD

225

DCD

226

NRP

227

PMI

228

DBD

229

problem 1

230

231

law | medicine

232

clinicians do **not** assess what **UDDA** requires

233

UDDA

234

law on death in all U.S. jurisdictions

235

irreversible cessation
all functions
entire brain

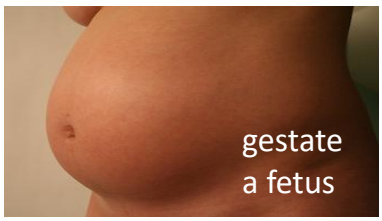
236

but

237

brain dead people **do** stuff

238



239

240

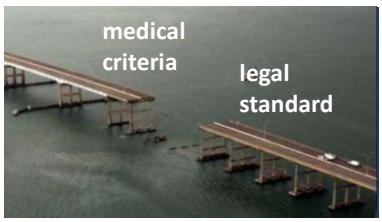
241

clinicians only assess cessation
some functions
part of brain

242

UDDA requires
all functions
entire brain

243



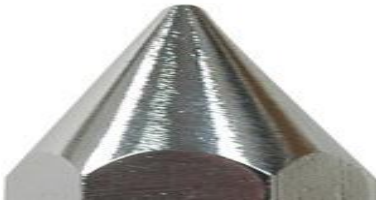
244

medically dead

≠

legally dead

245

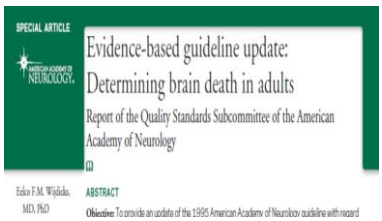


246

Most authoritative criteria

AMERICAN ACADEMY OF NEUROLOGY

247


SPECIAL ARTICLE

Evidence-based guideline update: Determining brain death in adults

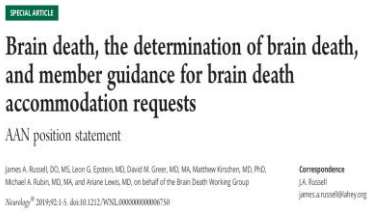
Report of the Quality Standards Subcommittee of the American Academy of Neurology

Erik F.M. Wijdicks, MD, PhD

ABSTRACT

Objective: To provide an update of the 1995 American Academy of Neurology guideline with regard

248


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. Greer, MD, MA, Matthew Kirschen, MD, PhD, Michael A. Rubin, MD, MA, and Ariane Lewis, MD, on behalf of the Brain Death Working Group

Neurology® 2019;92:1-5. doi:10.1212/WNL.0000000000006750

Correspondence
J.A. Russell
james.a.russell@ahey.org

249

patient can **satisfy** BD guidelines

250

dead

251

yet…

252

"neuro-endocrine function **may be present**"

253

AMERICAN ACADEMY OF NEUROLOGY

254

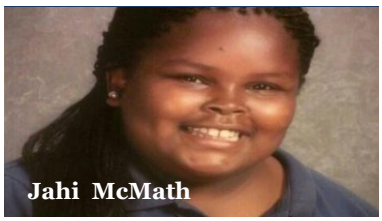
may determine BD **despite** function hypothalamus

255

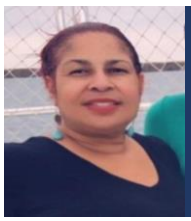
"**not inconsistent** with the whole brain standard of death"

256

257



258



Beverly Whitehead

259

WRONG

260

UDDA

requires

261

irreversible

cessation of

262

all functions

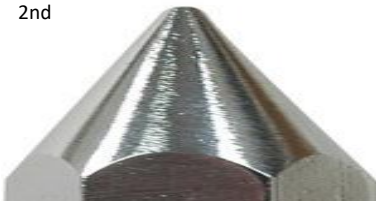
of the

entire brain

263

264

2nd



265

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

Krishanu Chatterjee, BA[1],
Mohamed Y. Rady, BChir, MB (Cantab), MA, MD (Cantab)[2],
Joseph L. Verheijde, PhD, MBA, PT[3], and Richard J. Butterfield, MA[4]

266

200 clinicians

Mayo Clinic

267

1. use AAN protocol
2. get positive result

3. does that demonstrate loss of "all functions of the entire brain"?

268

269

270

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

271

require cessation of **critical** functions

272

273

but

274

lack authority to do that

275

analogy

276

277

278

279

280

UDDA **gives** standards

281

medical profession only **applies** them

282

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

283

that's problem **1**

284

mismatch
legal criteria to medical standards

285

problem 2

286

even if guidelines **were** legally valid

287

widespread **non**compliance

288

UDDA

289

when making determinations of irreversible cessation

290

"accordance with **accepted medical standards**"

291

but

292

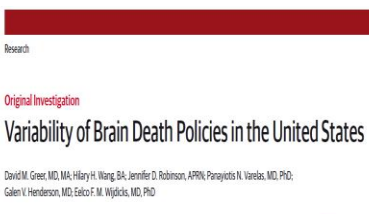
which medical standards are accepted **?**

293

294

variability

295



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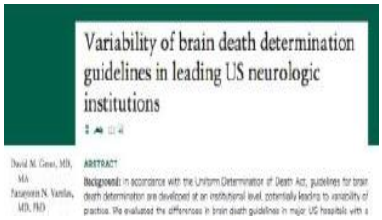
297


Variability of brain death determination guidelines in leading US neurologic institutions

ABSTRACT

298


Neurology

February 26, 2019; 92 (9) ARTICLE

Variability in reported physician practices for brain death determination

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

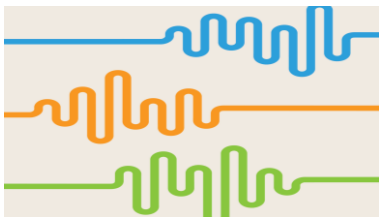
299

number of physicians

qualifications

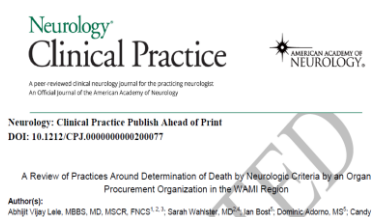
how tests administered

300



301

302


Neurology Clinical Practice

AMERICAN ACADEMY OF NEUROLOGY

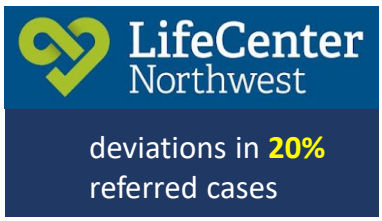
A peer-reviewed clinical neurology journal for the practicing neurologist
An Official Journal of the American Academy of Neurology

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

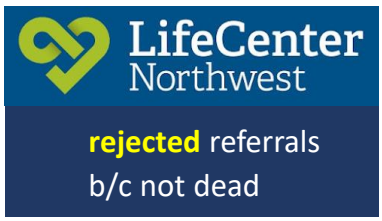
Author(s):

303


LifeCenter Northwest

deviations in **20%** referred cases

304


LifeCenter Northwest

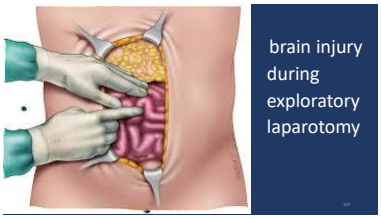
rejected referrals b/c not dead

305

306

307

308



309

met AAN criteria for brain death

310

311

312

dad loses

313

trial court

AAN criteria met

→ Aden is dead

314

315

dad **wins**

316

Supreme Court of Nevada

317

irrelevant Aden meets AAN criteria

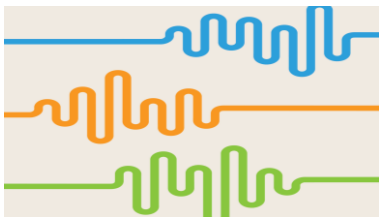
not the "right" criteria

318

unclear they are "**accepted** medical standards"

as UDDA requires

319



320

state 1 ≠ state 2

321

hospital 1 ≠ hospital 2

322

MD 1 ≠ MD 2

323

324

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

325

Supreme Court of Nevada

326

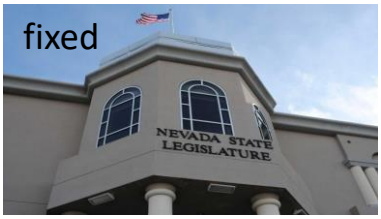
327

fix

328

Nevada
A.B. 424 (2017)

329



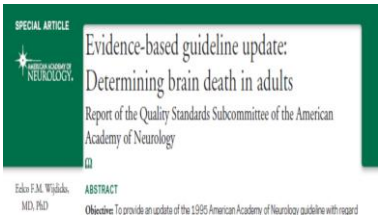
330

amended NUDDA
A.B. 424 (2017)

331

determination of BD "must be made in accordance **with** …"

332


SPECIAL ARTICLE

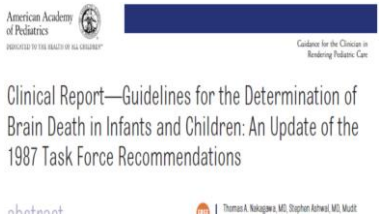
Evidence-based guideline update: Determining brain death in adults

Report of the Quality Standards Subcommittee of the American Academy of Neurology

ABSTRACT

Objective: To provide an update of the 1995 American Academy of Neurology guideline with regard

333

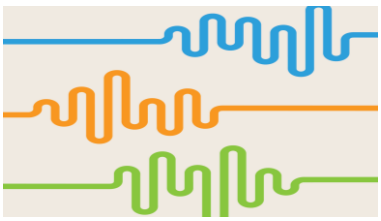


334

335

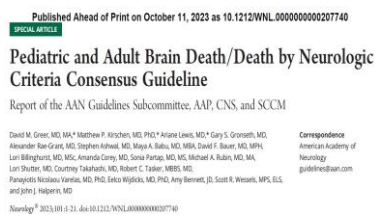
336

337



338

339



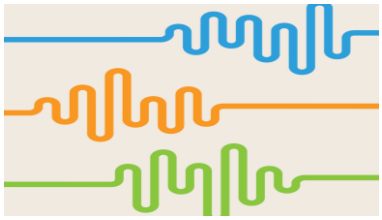
340

341

342

4000
6000

343



344

that's
problem **2**

345

failure

determine BD using
"accepted standards"

346

that's

DBD

347

let's move to
a **second**
DDR violation

348

DCD

349

1960s
ODT was
DCD

350

1968

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

351

1970 →

352

50 years
almost all
ODT was BD

353

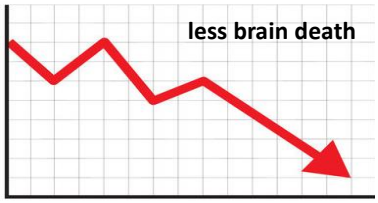
354

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

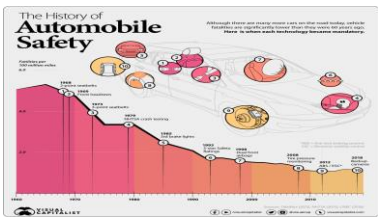
355

but

356



357



358

359

360

361

DCD

362

363

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

364

family makes decision to **stop** LST

365

likely that heart will **stop**

366

even when heart stops

367

not dead **yet**

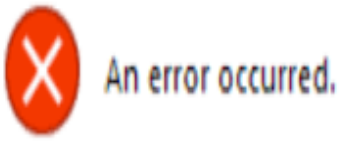
368

UDDA

369

"**irreversible** cessation of circulatory & respiratory functions"

370



371

2 problems

372

problem **1**

373

cessation is **not irreversible** as UDDA requires

374

we **can** reverse cessation of circulatory function

375

we **won't**

(because Pt does not want that)

376

377

but

378

we **could**

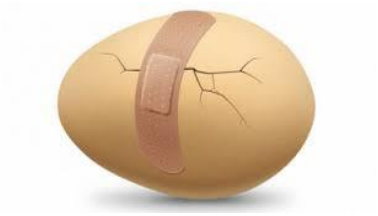
379

response

380

we interpret "irreversible" as "**permanent**"

381



382

not what UDDA says

383

problem **2**

384

even if UDDA requires only "permanent" cessation

385

is even **that** satisfied?

386

after heart stops

387

standoff

388

ensure heart does not restart spontaneously

389

how long?

390

391

after 5 min

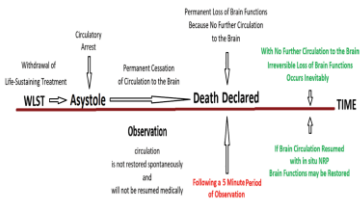
392

if **no** circulatory function

393

→ dead

394



395

why
5 min

396

hearts **have** restarted at 4:20

397

problem

398

some clinicians wait only **2 min**

399

400

unclear that circulatory cessation was **irreversible**

401

heart **might** have restarted

402

at 2:09
or
at 3:44

403

DDR

404

~~PDDR~~

405

~~DEDR~~

406

~~ADDR~~

407

DDR

408

409

let's move to a specific **type** of DCD

410

NRP

411

normothermic
regional
perfusion

412

DCD requires absence of circulation

413

but

414

bad for organs, especially heart

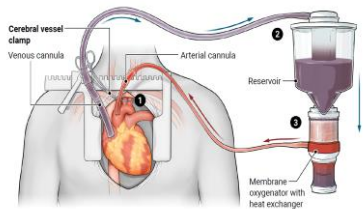
415

so …

416

minimize warm ischemia → restart circulation **in the donor**

417



418

improves organ quality

419

problem

420

said dead **because** irreversible cessation circulatory function

421

reversed it

422

basis for death determination no longer true

423

response

424

before restart → cut or clamp vessels to brain

425

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

426

427

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

428

"ethical & legal propriety … has **not** been met"

429

430

"**unclear** whether NRP violates the DDR"

431

NRP

432

really only regional?

433

only a **hypothesis**

do not **know** no perfusion to brain

434

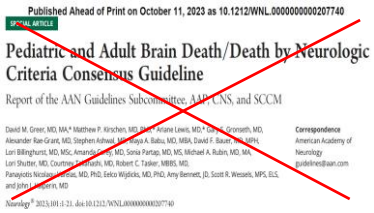
do not **know** donor is dead

435

may be
- consciousness
- pain perception

436

437



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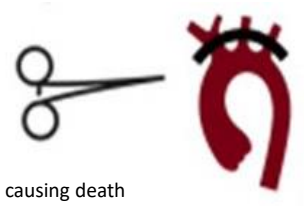


causing death

439

DDR

440

death → ODT

441

442

ODT → death

443

444

recap

445

DBD
DCD
NRP

446

1 more DDR violation

447

PMI

448

DCD entails some ischemic damage

449

SO …

450

pre-mortem
non-therapeutic
interventions

451

MV CPR
vasopressors
hormonal therapy

452

heparin
femoral cannulation

453

not for patient
only for **organ**

454

organ **protection** therapy
donor **optimization** procedures

455

donor management

456

DDR

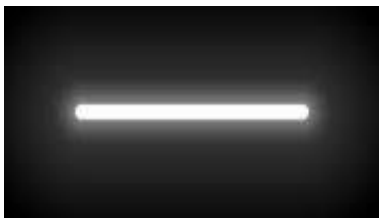
457

alive	dead
focus on patient	focus on organ

458

alive	dead
treatment team	transplant team

459



460

PMI

461

alive	dead
focus on patient	focus on organ

462

463

Fact

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

464

Not True!

465

466

donor	patient

467

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

468

recap

469

DBD NRP
DCD PMI

470

we **breach**
the DDR

471

every
single day

472

what to do next

473

4 paths

474

475

476

continue
ODT **as is**

477

478

479

480

481

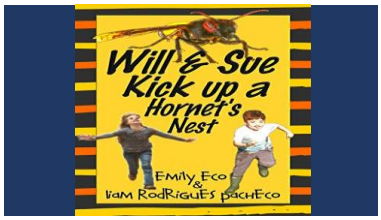
482

483

484

485

486



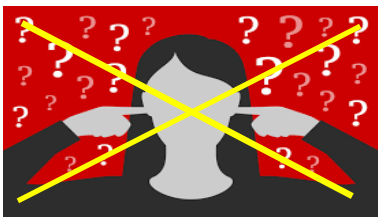
487

488

489

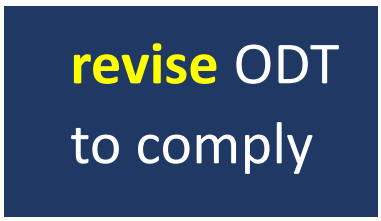
490

491



492

493



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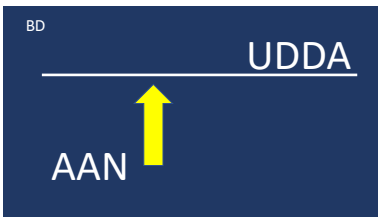


495

BD **only** when no neuroendocrine function

496

DCD > 5 min

497

no NRP

498

continue NRP

as human subjects **research** - with IRB approval & oversight

499

but

500

501

UDDA is strict & demanding

502

we would **lose** many organs

503

504

change UDDA

505

instead of aligning **guidelines** to law

506

align **law** to guidelines

507

BD

UDDA

AAN

508

509

2020 2022
2021 2023

510

Uniform Law Commission
Better Laws. Stronger States.

511

UDDA → **R**UDDA

512

certainty
clarity

513

match
legal criteria to medical standards

514

clarify **which** medical standards to use

515

but

516

517

518

so …

519

~~RUDDA~~

520

521

drop DDR

522

~~DDR~~

523

let people **decide** when they are "dead enough" to donate organs

524

525

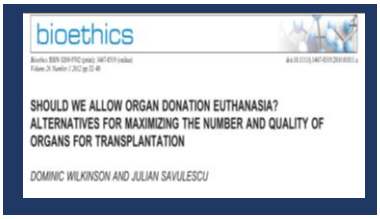
1 growing calls

526

527

2 foremost bioethicists

528



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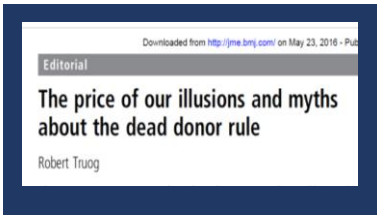

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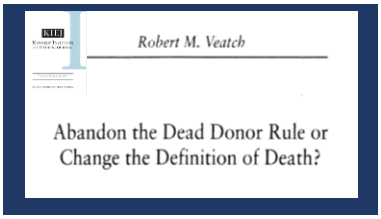


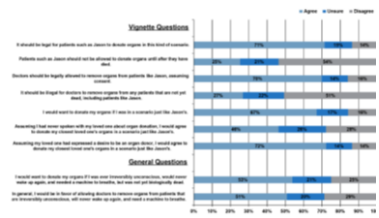
531

3 public opinion

532

533

534

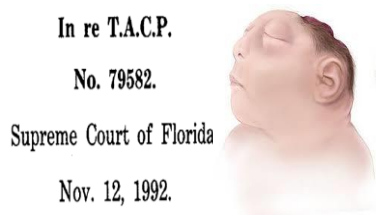


535

536

4 already tried & trying

537



538

539

5 honest transparent

540

not expanding

541

matching rules to practice

542

543

SO…

544

~~DDR~~

545

but

546

547

DDR

548

protect patients

preserve public trust

549

550

31%

Trust the US healthcare system as a whole

551

conclusion

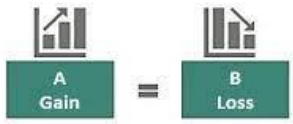
552

increase

number & quality of organs

553

Zero-Sum Situation



554

more certain death → fewer organs

555

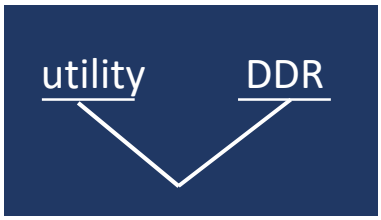
more organs → less certain death

556

557

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

558



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