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AMELIORATING LETHAL INJECTION BY USING BISPECTRAL INDEX MONITORING OF INMATES TO HELP ENSURE A MORE HUMANE DEATH

*Jennifer E. Mayer**

I. INTRODUCTION

As compared to hanging, firing squad, electrocution, or lethal gas, death by lethal injection appears more humane and painless because it mimics medical anesthesia.¹ Drugs are even manufactured to ensure that terminally ill patients can end their lives painlessly and that pets can be put down humanely, of which the general public is aware.

For a condemned prisoner, the reality may be very different. Approximately seven percent of executions by lethal injections are “botched,” leading to disturbing spectacles in the death chamber.² No other method of execution has a higher error rate recorded in U.S. history.³ The reasons are multifold: drug regimens selected without scientific validation, lack of medical expertise among the execution team, and drug shortages causing prison officials to scramble to throw together untested drug combinations purchased from poorly regulated compounding pharmacies.⁴

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1. AUSTIN SERAT ET AL., GRUESOME SPECTACLES: BOTCHED EXECUTIONS AND AMERICA’S DEATH PENALTY 118-19 (2014).

2. *Id.* at 120-23 (finding the rate of botched lethal injection is seven percent, in part, because its protocols are more detailed than those involved in alternative methods and more difficult to follow as a result).

3. Austin Sarat et al., *Bad Drugs, Veins and Policy: Oklahoma Fits a Pattern of Botched US Executions*, GUARDIAN (May 2, 2014, 6:15 AM), <https://www.theguardian.com/commentisfree/2014/may/02/oklahoma-botched-executions-us-history-clayton-lockett>.

4. *See, e.g.*, OKLA. DEP’T OF PUB. SAFETY, THE EXECUTION OF CLAYTON D. LOCKETT 1-2, 5, 13-19, 22, 24-27 (2014), <http://deathpenaltyinfo.org/documents/LockettInvestigationReport.pdf> (detailing the use of an untested mixture of midazolam, vecuronium bromide, and potassium chloride, obtained from undisclosed sources, repeated intravenous line failures, and drug shortages in the execution chamber, all resulting in Lockett’s inhumane death more than forty minutes after

Lethal injection is, in effect, human experimentation that exploits vulnerable prisoner populations without the usual safeguards of informed consent and approval by scientific review boards.⁵ Such haphazard execution designs might be repugnant to the Cruel and Unusual Punishment Clause in the Eighth Amendment to the U.S. Constitution.⁶ Indeed, data from executions has shown that even when cocktails are administered perfectly the protocols may fall short of their stated aim, to cause death without inflicting inhumane punishment, especially when the anesthetic component is given slowly, as opposed to a rapid bolus.⁷

To date, the Supreme Court has not addressed these underlying issues. In a seminal case, the Court accepted the argument that the lethal injection protocols would produce a painless, humane death if the massive dose of the first barbiturate drug were properly administered. Yet, the Court rejected the claim that under a variety of foreseeable scenarios the administration might be bungled and result in a death analogous to torture.⁸ Most recently, the Supreme Court held that to prevail on a challenge to the use of the sedative midazolam as the first drug of a three-drug protocol for lethal injection—a drug neither recommended nor approved for use as the sole anesthetic during painful surgery—inmates must identify a “known and available alternative method” that has a lower risk of pain.⁹ The Court found that the inmates had not met this burden.¹⁰

Originally, most states adopted a three-drug protocol consisting of an initial dose of an ultra-short acting anesthetic to eliminate perception of pain, a paralyzing agent to immobilize the prisoner, and a lethal agent to stop the heart. Most, if not all, can agree this would be excruciatingly

the execution began).

5. See Leonidas G. Koniaris et al., *Ethical Implications of Modifying Lethal Injection Protocols*, 5 PLOS MED. 845 (2008).

6. See *id.*

7. See *id.*

8. *Baze v. Rees*, 553 U.S. 35, 41, 44-51, 53-57, 62 (2008). The states have subsequently compiled a sorry record of failed intravenous access, improper calculation of lethal drug doses, and failure of anesthesia, all magnified by the ethical refusal of medical professionals to participate in executions and the states’ efforts to conceal the details of their execution procedures. There is thus every reason to believe the Supreme Court will revisit its decision in *Baze*.

9. *Glossip v. Gross*, 135 S. Ct. 2726, 2731-42 (2015).

10. *Id.* at 2738. The decision allowed states using midazolam, such as Oklahoma, to resume executions, but these states have still faced a variety of obstacles. More broadly, two dissenting Justices in *Glossip* raised deep concerns about the death penalty itself as having the following fundamental constitutional defects: (1) serious unreliability, (2) arbitrariness in application, (3) unconscionably long delays that undermine the penological purposes, and (4) most places in the United States have abandoned its use. *Id.* at 2755-56 (Breyer, J. & Sotomayor J., dissenting).

painful were the inmate conscious.¹¹ Issues with the three-drug protocol are well recognized. Prisoners have continued to breathe as the anesthetic is injected slowly over a prolonged period, and their hearts have continued to beat after the potassium infusion.¹² Although continued breathing and heartbeat are not conclusive proof of suffering since the drugs can render inmates unconscious without completely stopping their respirations or myocardial contractions, these signs increase the likelihood that condemned inmates will experience suffocation akin to drowning from the paralyzing agent pancuronium while conscious and unable to move, as well as intense burning pain from the potassium injection.¹³

Drug shortages have led to secretly developed combinations of untested drugs that are supplied by compounding pharmacies devoid of U.S. Food and Drug Administration (“FDA”) oversight and, likewise, that are susceptible to untoward effects. Judge Gregory L. Frost has stayed all Ohio executions in order to allow the Ohio Department of Rehabilitation and Correction to attempt securing adequate supplies of pentobarbital and thiopental for its new two-drug protocol execution.¹⁴ Nebraska has been forced to turn to overseas suppliers of thiopental and pancuronium but has been thwarted thus far by the FDA, which recently impounded similar shipments from India headed to departments of corrections in Arizona and Texas.¹⁵

More recently, many states have moved to a single-drug barbiturate protocol relying on the drug to rapidly render the prisoner unconscious, stop respirations, and cause death.¹⁶ Although infiltration of intravenous

11. 18 JAMIE FELLNER & SARAH TOFTE, HUMAN RIGHTS WATCH, SO LONG AS THEY DIE: LETHAL INJECTIONS IN THE UNITED STATES 21-28 (James Ross & Iain Levine eds., 2006). The three-drug protocol is described as follows:

[T]he prisoner lies strapped to a gurney, a catheter with an intravenous line attached is inserted into his vein, and three drugs are injected into the line by executioners hidden behind a wall. The first drug is an anesthetic (sodium thiopental), followed by a paralytic agent (pancuronium bromide), and, finally, a drug that causes the heart to stop beating (potassium chloride).

Id. at 1. Should the thiopental be improperly administered or wear off, the conscious, paralyzed inmate may experience suffocation and burning pain from the potassium infusion, a point uncontested in *Baze*. *Id.* at 27.

12. *Id.* at 23, 51.

13. *Id.* at 36-37.

14. See Press Release, JoEllen Smith, Ohio Dep’t of Rehab. & Corr., Execution Dates Revised (Jan. 30, 2015), <http://www.drc.state.oh.us/public/press/press437.htm>.

15. See Joe Duggan, *Nebraska Prison Officials Tried Unsuccessfully to Buy Legal Injection Drug from U.S. Distributor*, OMAHA WORLD-HERALD (Nov. 3, 2015), http://www.omaha.com/news/crime/nebraska-prison-officials-tried-unsuccessfully-to-buy-lethal-injection-drug/article_4e3f5d0e-8185-11e5-9ed6-4786e0cbd875.html.

16. See *State by State Lethal Injection*, DPIC, <http://www.deathpenaltyinfo.org/state-lethal-injection> (last visited Dec. 31, 2016).

lines can always occur, albeit with less frequency than the three-drug protocol's higher drug volumes, there is the omnipresent possibility of the barbiturate wearing off before its lethal intent is consummated if administration problems result in an inadequate amount of barbiturate reaching the central nervous system.¹⁷ Drug efficacy diminishing over time has not yet jeopardized the states' goal of achieving efficient, humane deaths in the more than ninety single-drug lethal injections performed to date.¹⁸ Nevertheless, this concern could result in a live, awake inmate facing the trauma of a second execution.¹⁹

A series of dramatic episodes in the past several years have highlighted these realities. Eyewitnesses to the January 20, 2014, execution by lethal injection of Ohio convicted rapist and murderer, Dennis McGuire, reported the inmate gasping for air, convulsing, and clenching his fists for over twenty-six minutes as a new, previously untested two-drug protocol of midazolam and hydromorphone was used.²⁰ The spectacle of the McGuire execution resulted in another stay of executions in Ohio until prison officials can appropriately study and revise their lethal injection methodology.²¹ On April 29, 2014, Oklahoma murderer Clayton Lockett died forty-three minutes after the lethal injection of an unvalidated triple drug cocktail of midazolam, vecuronium, and potassium was injected not into the circulatory system but tissue surrounding the vein. By the time delayed absorption of the drugs occurred, Lockett died from paralysis and suffocation, but only

17. See 18 HUMAN RIGHTS WATCH, *supra* note 11, at 46, 50-53.

18. See *Facts About the Death Penalty*, DPIC, <http://www.deathpenaltyinfo.org/documents/factsheet.pdf> (last updated Dec. 9, 2016); see also Denise Grady, *Three-Drug Protocol Persists for Lethal Injections, Despite Ease of Using One*, N.Y. TIMES (May 1, 2014), http://www.nytimes.com/2014/05/02/science/three-drug-protocol-persists-for-lethal-injections-despite-ease-of-using-one.html?_r=0 (noting that barbiturates alone have been used in seventy-one U.S. executions, but time to death may be markedly prolonged).

19. This is a morally repugnant but most likely constitutional outcome according to *Louisiana ex rel. Francis v. Resweber*, 329 U.S. 459, 462-66 (1947) (concluding that it is not unconstitutional to force a prisoner to undergo a second attempt at electrocution after a mechanical malfunction thwarts the first attempt); see *Ohio Execution Halted After First Attempt Is Botched*, DPIC, <http://www.deathpenaltyinfo.org/ohio-execution-halted-after-first-attempt-botched> (last visited Dec. 31, 2016) (noting that Romell Broom is in exactly this position after his execution by lethal injection was halted due to two hours of unsuccessful attempts to puncture his veins).

20. Nick Barrickman, *Ohio Prison Suffers Horrific Death in Botched Execution*, WORLD SOCIALIST WEB SITE (Jan. 17, 2014), <http://www.wsws.org/en/articles/2014/01/17/ohio-j17.html>. In sworn testimony, Ohio's medical expert Dr. Mark Dershwitz admitted that the government was gambling: "I truly don't know how many minutes it will take an inmate to stop breathing [using the new two-drug mixture]. . . . There is no science to guide me on exactly how long this is going to take." *Id.*

21. See Mark Kovac, *Ohio Ordered to Postpone Scheduled Executions*, DAILY REC. (Aug. 12, 2014, 4:00 AM), <http://www.the-daily-record.com/local%20news/2014/08/12/ohio-ordered-to-postpone-scheduled-executions>.

after the state had called off his execution as he lay on the gurney writhing and gasping for air.²² Yet another example is Joseph Rudolph Wood's July 2014 lethal injection in Arizona, which involved an experimental combination of midazolam and hydromorphone. The execution lasted so long—nearly two hours—that his lawyers actually had time to seek stays from state and federal courts, in an unsuccessful attempt to abort.²³

The numerous ways in which lethal injection protocols may fail preclude the possibility of designing an entirely reliable system.²⁴ The situation would be improved if a method were developed to increase the likelihood that a condemned prisoner could be made fully unconscious. When combined with the requisite degree of medical knowledge, the method would need to be a simple, reliable, and useful aid in assessing anesthetic depth. Noteworthy, this very technology has been available for the past twenty years and used in operating rooms across the United States every day, despite the various issues that arise as described below. The technology is based on the Bispectral Index (“BIS”).²⁵ The failure to integrate this useful, validated technology into lethal injection protocol is distinctly troubling from a policy perspective. Moreover, the ready availability of the technology has significant legal implications.²⁶

In a hospital setting, anesthesiologists do not blindly rely on BIS monitors alone but instead use them in ongoing patient assessment for indicators of adequate depth of anesthesia, which are interpreted with a level of medical training, sophistication, and clinical judgment generally unavailable in the death chamber scenario.²⁷ Accordingly, while BIS

22. See OKLA. DEP'T OF PUB. SAFETY, *supra* note 4, at 1-2, 5, 13-19, 22, 24-27 (finding multiple failures, including the failure to anticipate problems with venous access, failure to have appropriate supplies on hand, failure to have clear communication among the execution team members, frantic improvisation when problem arose, and no systematic and transparent method of learning from experience over time).

23. See Matt Pearce et al., *Arizona Killer Takes 2 Hours to Die, Fueling Lethal-Injection Debate*, L.A. TIMES (July 23, 2014, 11:17 PM), <http://www.latimes.com/nation/nationnow/la-na-nn-arizona-execution-20140723-story.html>.

24. See, e.g., Associated Press, *Patient Survives Doctor-Assisted Suicide Attempt: Terminally Ill Cancer Victim Awakes from Coma After 3 Days*, NBC NEWS, <http://www.nbcnews.com/id/7090928/ns> (last updated Mar. 4, 2005, 3:29 PM) (referencing the Oregon protocol under which patients have taken days to die and a few have survived the process).

25. See *infra* Part II.A.

26. See *infra* Part II.B.

27. H.L. Kaul & Neerja Bharti, *Monitoring Depth of Anesthesia*, 46 INDIAN J. ANESTHESIA 323, 326 (2002) (describing subjective methods for assessing depth of anesthesia, such as autonomic responses of hemodynamic changes, lacrimation, sweating, pupillary dilatation, and isolated forearm techniques; as well as objective methods, such as spontaneous surface electromyogram, lower esophageal contractility, heart rate variability, electroencephalogram derived indices, and evoked auditory, visual, and somatosensory potentials).

monitors are a reasonable adjunct to existing lethal injection protocols, they require competent medical supervision for effective use.²⁸ Further, ethical guidelines of many national medical associations now condemn participation of physicians, emergency medical technicians, nurses, and other medical professionals in executions.²⁹ This has forced prison wardens, guards, and other relatively medically untrained individuals to conduct lethal injection procedures absent adequate medical back-up. Even in this context, however, the use of BIS monitors would be an improvement on the existing situation, and one whose current state gives rise to a potential legal claim.

The U.S. Supreme Court held in *Baze v. Rees* that although there were enough redundancies and safeguards in Kentucky's lethal injection protocol as not to subject an inmate to "substantial risk of serious harm," in future cases, a state's deliberate indifference to a readily available, validated alternative might violate the Eighth Amendment's proscription on cruel and unusual punishment.³⁰ Arguably, BIS monitoring is a readily available, validated alternative. A number of states obdurately insist on using paralytic drugs, despite abundant evidence that they are unnecessary and can cause torture.³¹ In these recalcitrant states, BIS monitors used as an aid by competent practitioners could provide additional information to help assess anesthetic depth.³² The failure of such states' department of corrections to include the validated alternative of BIS monitoring in their lethal injection protocol provides a strong basis for a constitutional challenge.

II. HOW BIS MONITORING COULD AMELIORATE LETHAL INJECTION

In many respects, the situation of the prisoner on the gurney is analogous to a patient who by all rights should be unconscious during a surgical procedure but instead experiences the sights, sounds, and sensations of the hospital operating room, often in extreme pain and with

28. *Id.* at 328-29.

29. *See, e.g.*, COUNCIL ON ETHICAL & JUDICIAL AFFAIRS, AM. MED. ASS'N, CODE OF MEDICAL ETHICS OF THE AMERICAN MEDICAL ASSOCIATION, Op. 2.06 (2012-2013 ed. 2012).

30. *See Baze v. Rees*, 553 U.S. 35, 52 (2008).

31. At present, Alabama, Colorado, Delaware, Florida, Indiana, Mississippi, Nebraska, Nevada, New Mexico, Oklahoma, Pennsylvania, South Carolina, Utah, Virginia, and Wyoming cling to the use of paralytics in a three-drug protocol. *See State by State Lethal Injection*, *supra* note 16.

32. Of course, this only applies where the inmate is in fact paralyzed, so that observers are unable to tell that he is in pain. If there is no paralysis, the inmate can, and will, show that he is suffering by moving, writhing, or crying out. Because McGuire and Wood were not paralyzed, the addition of BIS monitoring would have been of little benefit in ameliorating the problems inherent in their executions.

lasting traumatic effects. This is a well-recognized problem that the medical profession has long sought to address.

A. *Anesthesia Awareness and Depth of Anesthesia Monitoring*

Anesthesia awareness, or unintended intraoperative awareness, occurs during general anesthesia when the patient has not been given enough general anesthetic or analgesic to render or keep the patient unconscious.³³ It can occur when the medical procedure involves administering paralytic agents to an inadvertently conscious patient, leading to post-operative explicit recall of intraoperative events.³⁴ This problem is closely analogous to that presented by the troublesome triple drug-protocol for lethal injection where an inmate might be awake, yet be paralyzed, and unable to move or cry out while dying in agony.³⁵ The overall incidence of intraoperative awareness with recall has been estimated at 0.2% to 3% of all surgeries performed, but it may be much greater in high-risk patients with multiple trauma, caesarean section, cardiac surgery, and hemodynamic instability.³⁶ In the case of executions, empirical evidence will likely be difficult to obtain because prisoners ordinarily do not subsequently awaken to report their experiences. But the incidence is likely higher than in a surgical setting, if for no other reason than that during an execution the “patient” may not be under the observation and professional judgment of a trained anesthesiologist, or even a physician.³⁷

The essential features of successful general anesthesia are loss of consciousness, lack of awareness, and unresponsiveness to painful stimuli.³⁸ A humane execution by lethal injection would have the same features. Important signs of inadequate general anesthesia are movement, increased breathing or heart rate, and increased blood pressure in response to painful stimuli.³⁹ Notwithstanding the absence of

33. Michael Avidan & George Mashour, *Prevention of Intraoperative Awareness with Explicit Recall: Making Sense of the Evidence*, 118 ANESTHESIOLOGY 449, 449-50 (2013).

34. *Id.* at 449-51.

35. See OKLA. DEP'T OF PUB. SAFETY, *supra* note 4, at 1-2, 5, 13-19, 22, 24-27.

36. See Kaul & Bharti, *supra* note 27, at 323.

37. This means that even if it were possible to overcome the risk of unintended awareness, the inmate would necessarily face risks that never arise in a surgical setting. See Abby Ohlheiser, *New Photos Reveal What a Botched Lethal Injection Procedure Looks Like*, ATLANTIC (May 29, 2014), <http://www.theatlantic.com/national/archive/2014/05/new-photos-reveal-what-a-botched-lethal-injection-procedure-looks-like/371840> (releasing photographs taken during the thirty-four minute lethal injection of Angel Diaz in Florida in 2006, showing large chemical burns on his left arm from tissue infiltration of drugs caused by a blown intravenous site).

38. Amornyotin Somchai, *Monitoring for Depth of Anesthesia: A Review*, J. BIOMED. GRAPHICS & COMPUTING, Dec. 2012, at 119, 120.

39. *Id.* at 120-22.

medical professional monitoring of the inmate, which is an essential component of sound medical practice,⁴⁰ the execution chamber (like the operating theatre) could benefit from some form of direct mechanized monitoring of anesthetic depth—such is the role of BIS monitors.

BIS monitors use computer hardware and signal processing algorithms to process electroencephalogram (“EEG”) signals into simplified numerical indices.⁴¹ Although the underlying science has not been fully developed,⁴² the system is based on the established fact that transition from a state of wakefulness to a state of unconsciousness is accompanied by profound changes in the brain’s spontaneous electrical activity, as recorded by an EEG.⁴³ While these characteristic changes in EEG were appreciated more than seventy-five years ago, their use in an operating room was not always considered practical, as the multitasking anesthesiologist does not have time to continuously scrutinize the complex waveforms.⁴⁴ Also, subtle EEG frequency shifts occurring with incremental changes in consciousness could be missed with the naked eye.⁴⁵

Fast Fourier transform (“FFT”) computer processing has enabled the development of quantitative BIS indices to yield a simple numerical index from 0 to 100, indicating whether the patient is awake, sedated, unaware, or deeply anesthetized.⁴⁶ The BIS monitor was approved by the FDA in 1996 “as an aid in monitoring the effects of certain anesthetic[s].”⁴⁷ Patient awareness is “unlikely” with a number less than 70 and “extremely unlikely” with a number greater than 60.⁴⁸

40. George A. Mashour et al., *Prevention of Intraoperative Anesthesia Awareness with Explicit Recall in an Unselected Surgical Population: A Randomized Comparative Effectiveness Trial*, 117 *ANESTHESIOLOGY* 717, 718, 724 (2012).

41. See Peter S. Sebel, *Can We Monitor Depth of Anesthesia?*, *ANESTHESIOLOGY & ANALGESIA*, Mar. 2001, at 94, 95.

42. See, e.g., *id.* at 96-97 (noting that the reliability of BIS monitoring has been questioned, in part, because its calculation does not rely on any underlying physiological model of how the brain functions or how awareness is generated).

43. *Id.* at 95-96 (explaining that in a relaxed, awakened state, alpha waves predominate; with light anesthesia, beta waves increase; with deepening of anesthesia, slow delta and theta waveforms are seen; and, with cortical silence, a flat line or isoelectric EEG is noted).

44. See MICHAEL AVIDAN, *READING YOUR MIND: MONITORING THE BRAIN UNDER ANESTHESIA* 1 (2012).

45. Michael S. Avidan et al., *Prevention of Intraoperative Awareness in a High-Risk Surgical Population*, 365 *NEW ENG. J. MED.* 591, 596-97 (2011).

46. Sebel, *supra* note 41, at 95-96.

47. Aspect Med. Sys., *Aspect Medical Systems Receives FDA Clearance for BIS View Monitoring System*, *BUS. WIRE* (June 27, 2007, 8:30 AM), <http://www.businesswire.com/news/home/20070627005073/en/Aspect-Medical-Systems-Recieves-FDA-Clearance-BIS>.

48. See Michael S. Avidan et al., *Anesthesia Awareness and the Bispectral Index*, 358 *NEW ENG. J. MED.* 1097, 1104-07 (2008).

The BIS monitor is user friendly in the clinical setting. A sensor tape is adhered to the patient's forehead, which connects via wire to the BIS unit.⁴⁹ When activated, the monitor displays an easy to see real-time number between 0 and 100 that appears in the upper left of the screen.⁵⁰ Dr. Floyd Forbes, a senior attending anesthesiologist at Northwell Health in New York, has suggested that the “deeply anaesthetized” category, or a BIS value of 60, is the highest acceptable level for execution by lethal injection, with the ultimate goal being cortical silence, or a BIS value of 0.⁵¹

If that goal is reached, one has overcome a core deficiency in governments' paralyzing lethal injection programs: an inability to ensure the condemned prisoner is rendered, and remains, unconscious for the duration of the execution. Even though paralytic drugs have been administered and mask the prisoner's condition,⁵² BIS values will guide the execution team on when to administer additional sedative drugs to prevent consciousness, guidance that is now sorely lacking. If something goes awry in an execution involving a paralytic—whether as a result of intravenous blowouts, human error, untested drug combinations, compounded drug inefficacy, drug tolerance, drug clearance before the desired lethal effect, or any other reason—officials viewing the screen of a BIS monitor would be alerted that a problem exists regardless of the prisoner's ability to speak. Under a properly designed protocol, officials would then take predetermined measures to return the prisoner's index number to an acceptable level before continuing with the execution.

As noted, this solution is a “half-loaf” but better than none. The absence of qualified medical personnel trained in assessment of anesthetic depth from execution teams limits the interpretation and

49. *Id.* at 1099.

50. See Robert Steinbrook, *New Technology, Old Dilemma—Monitoring EEG Activity During Executions*, 354 NEW ENG. J MED. 2525, 2525 (2006).

51. Interview with Dr. Floyd Forbes, Senior Attending Anesthesiologist, Northwell Health, in Huntington, N.Y. (Apr. 7, 2014).

52. For a series of good reasons, the current trend is away from such protocols. Indeed, three-drug protocols are under strong legal attack due to a lack of any functional rationale for inclusion of paralytic drugs, as well as Eighth Amendment concerns that such cocktails violate evolving standards of decency. See Expert Declaration of Dr. David Lubarsky at 3-12, *Nixon v. Palmer*, No. 3:14-cv-01152-MMH-JBT (M.D. Fla. Dec. 1, 2014), ECF No. 15-5; Expert Declaration of Deborah Denno at 11-15, *Nixon*, No. 3:14-cv-1152-MMH-JBT, ECF No. 15-8. At present, single-drug lethal injection has been used, or is intended for use, in fourteen states. On December 8, 2009, Kenneth Biros became the first person executed using Ohio's new single-drug execution protocol. He was pronounced dead at 11:47 A.M., ten minutes after receiving the injection. To date, barbiturates alone have been used in a total of seventy-one executions without significant mishap. See Ian Urbina, *New Execution Method Is Used in Ohio*, N.Y. TIMES (Dec. 8, 2009), <http://www.nytimes.com/2009/12/09/us/09ohio.html>.

potential benefit of the BIS monitor.⁵³ Ideally, a board certified anesthesiologist or nurse anesthetist would be present to monitor not only the BIS but also other clinical indices of depth of anesthesia. However, the constraints of medical ethics often prevent this.⁵⁴ Even in a less than ideal scenario, lay prison officials could read a number on a readily visible scale of 0 (no brain activity) to 100 (wide awake) and follow an algorithm to administer more of a particular drug if the number rises above 60.⁵⁵ Complex interpretation would be unnecessary because, unlike operating rooms where patients are anesthetized and expected to awaken following the procedure, executions conclude in death.

But is BIS monitoring scientifically validated to reduce the likelihood of problems with such lethal injections despite various concerns that emerge from a survey of the medical literature?

B. *Scientific Validation of BIS Monitoring*

The short answer is a qualified yes. Although a lay person is not a substitute for a board certified anesthesiologist or nurse anesthetist, the BIS is currently the sole type of anesthetic depth monitoring proven by scientific evidence to reduce intraoperative awareness.⁵⁶ Two large, prospective trials have both found an approximate eighty percent reduction in the incidence of awareness when using BIS.⁵⁷ The studies also provide a clinical management framework for effective use of BIS monitoring. In one trial, the anesthesia staff was instructed to maintain BIS values within a range of 40 to 60, and to avoid values greater than 60 during induction and maintenance of anesthesia.⁵⁸ This management resulted in significant benefit: only 2 of the 4945 patients treated had

53. See Daniel N. Lerman, Note, *Second Opinion: Inconsistent Deference to Medical Ethics in Death Penalty Jurisprudence*, 95 GEO. L.J. 1941, 1958 (2007).

54. See, e.g., COUNCIL ON ETHICAL & JUDICIAL AFFAIRS, *supra* note 29 (stating that a physician is prohibited from selecting injection sites in lethal injection executions; starting intravenous lines; prescribing, administering, or supervising the use of lethal drugs; monitoring vital signs, on site or remotely; and declaring death).

55. Interview with Dr. Floyd Forbes, *supra* note 51 (explaining that in actual clinical practice, anesthesiologists run their intravenous sedation (total intravenous anesthesia (“TIVA”)) cases with BIS values in the 30s or 40s, and should it climb any higher, they immediately inject further drugs to lower the BIS value, often into the mid- to high-20s; these medical cases can last for many hours, supporting the proposition that there is scant reason why this cannot be done in the lethal injection scenario for five to ten minutes).

56. See A. Ekman et al., *Reduction in the Incidence of Awareness Using BIS Monitoring*, 48 ACTA ANAESTHESIOLOGICA SCANDINAVICA 20, 22 (2004).

57. *Id.* at 25; P S Myles et al., *Bispectral Index Monitoring to Prevent Awareness During Anaesthesia: The B-Aware Randomised Controlled Trial*, 363 LANCET 1757, 1762 (2004).

58. Ekman et al., *supra* note 56, at 20-21.

reported awareness, representing a seventy-seven percent reduction compared to the investigators' control group.⁵⁹ In the second study involving patients at higher risk for awareness, BIS monitoring was initiated prior to induction and the delivery of anesthetics was titrated to maintain BIS values between 40 and 60.⁶⁰ This resulted in an eighty-two percent reduction in the incidence of awareness.⁶¹ In the combined studies, a total of only four episodes of awareness were reported in thousands of patients using BIS monitoring, all occurring during periods of significant noxious stimulation (for example, intubation or surgical incision) and were all associated with BIS values near or greater than 60.⁶² These cases highlight the need to be particularly vigilant of BIS responses to noxious stimulation and prepared to intervene promptly by administering additional drugs when BIS values exceed 60.⁶³

BIS monitoring may be problematic when volatile gases are used to render the patient unconscious. A 2013 study noted that the BIS protocol prevented anesthesia awareness with recall so long as a "potent inhaled agent" was not used as the primary anesthetic.⁶⁴ This is not an issue in the death chamber, where those drugs are not used.

Anesthetic depth monitoring is best for total intravenous anesthesia ("TIVA") cases.⁶⁵ Lethal injection is more analogous to TIVA than to inhalational anesthesia, though barbiturates are not generally given for intravenous sedation in the clinical setting. Accordingly, in the execution context, there is an empirical gap as to whether the use of barbiturates for this purpose limits the usefulness of the BIS.⁶⁶ To the extent that states begin to move towards single-drug protocols and consider

59. *Id.* at 22-24.

60. Myles et al., *supra* note 57, at 1757-58.

61. *Id.* at 1762; see also Farouk M. Messahel & Mary June Gregorio, *Intraoperative Awareness: A Three Year Prospective Study Using Bispectral Index Monitor (BIS)*, 19 MIDDLE EAST J. ANESTHESIOLOGY 587, 590 (2007) (reporting no cases of awareness during the course of surgery from the 2328 patients in the study when BIS monitoring was used); Chen Zhang et al., *Bispectral Index Monitoring Prevent Awareness During Total Intravenous Anesthesia: A Prospective, Randomized, Double-Blinded, Multi-Center Controlled Trial*, 124 CHINESE MED. J. 3664, 3666-67, 3669 (2011) (finding that BIS-guided TIVA decreased the incidence of awareness as compared to routine TIVA in a 5228 patient cohort).

62. Ekman et al., *supra* note 56, at 23-24; Myles et al., *supra* note 57, at 1760-62.

63. See Ekman et al., *supra* note 56, at 24; Myles et al., *supra* note 57, at 1762.

64. Avidan & Mashour, *supra* note 33, at 450-51, 454.

65. Zhang et al., *supra* note 61, at 3668.

66. BIS has been used to successfully monitor barbiturate-induced coma in humans, but to state that it has been scientifically validated for general use with barbiturate drugs may be overreaching. See, e.g., Haren Heller et al., *Bilateral Bispectral Index Monitoring During Suppression of Unilateral Hemispheric Function*, 101 ANESTHESIA & ANALGESIA 235, 238-40 (2005); Sandra A. Prins et al., *Continuous Noninvasive Monitoring of Barbiturate Coma in Critically Ill Children Using the Bispectral Index Monitor*, 11 CRITICAL CARE R108 (2007).

the use of BIS monitoring as a guide to decisions about increasing dosages during the course of executions, this issue will need to be explored further.

A concern of more current relevance, directly applicable in the three-drug context, is that studies have suggested BIS indices may decline during neuromuscular blockade.⁶⁷ The fact that BIS values may be lower where non-depolarizing paralytics such as pancuronium or vecuronium are used provides yet another potential Eighth Amendment basis to invalidate triple-drug protocols entirely in favor of single-drug lethal injection regimens.⁶⁸ So long as three-drug protocols continue to be used, however, the appropriate response is to set the target BIS value at a very low number and require that more sedatives be administered when the value reaches the 40s range. Indeed, in the execution context, striving for cortical suppression with a BIS value near 0 might provide a hedge against a fictitiously low BIS value jeopardizing inmate unconsciousness.⁶⁹ Even then inmates would remain free to assert that their personal idiosyncratic medical situations rendered BIS monitoring an insufficient safeguard.⁷⁰ Certain medical conditions can distort BIS values.⁷¹ Inmates with pacemakers, for example, may have paradoxically increased BIS values.⁷² Those with low blood sugar, dehydration, low

67. See M. Messner et al., *The Bispectral Index Declines During Neuromuscular Block in Fully Awake Persons*, 97 ANESTHESIA & ANALGESIA 488, 488-90 (2003) (observing that BIS failed to detect awareness in three paralyzed volunteers and BIS values fell to 64, 57, and 33, respectively, when alcuronium and succinylcholine were administered, and, in a repeat experiment of one subject, from 33 to 9 when total neuromuscular blockade was achieved); see also Won Joon Choi & Yun Hong Kim, *How Do You Use Bispectral Index Effectively for Preventing Re-Awareness During General Anesthesia?*, 62 KOREAN J. ANESTHESIOLOGY 1, 2 (2012) (“If a neuromuscular block is conducted, the recommended BIS value would not fully guarantee complete hypnosis.”).

68. See Messner et al., *supra* note 67, at 490.

69. Interview with Dr. Floyd Forbes, *supra* note 51.

70. This suggestion is in accord with current law. The facial sufficiency of a state’s protocol does not preclude an inmate’s as-applied Eighth Amendment challenge to it. For example, over the past two years, the Supreme Court has repeatedly turned away challenges to the execution protocol in Missouri but granted a stay of execution and remanded for further fact finding in the case of an inmate who asserted the protocol posed special risks to him personally. See *Bucklew v. Lombardi*, 134 S. Ct. 2333, 2333 (2014); Eric M. Freedman, *Idea, No Execution if Four Justices Object*, 43 HOFSTRA L. REV. 639, 644 n.16 (2015) (listing cases).

71. For an anecdotal report suggesting that, in certain clinical contexts, the BIS readings may provide false assurance concerning the adequacy of anesthesia, see Sally E. Rampersad & Michael F. Mulroy, *A Case of Awareness Despite an “Adequate Depth of Anesthesia” as Indicated by a Bispectral Index Monitor*, 100 ANESTHESIA & ANALGESIA 1363, 1363-64 (2005) (reporting awareness in a high-risk patient who experienced vivid, painful recall of his surgery, including sensations that “people were ‘tearing at [him],’” though had he received neuromuscular blockade, unlike the lethal injection scenario where the patient received opioid drugs and gabapentin, preoperatively, and the inhalational gas sevoflurane during surgery, which may have modified the BIS readings).

72. See Leonardo Teixeira Domingues Duarte & Renato Ângelo Saraiva, *Quando o Índice*

body temperatures, or seizures may have fictitiously low values.⁷³ In short, BIS methodology—while not perfect—should be required under the Eighth Amendment because it nevertheless ameliorates the existing unsatisfactory situation.

Criticisms of BIS monitoring in ordinary medical practice have also focused on cost effectiveness of the technology in consideration of anesthesia awareness prevented.⁷⁴ It has been estimated that general use of BIS monitoring to reduce the incidence of intraoperative recall would cost about \$10,000 to \$25,000 per avoided event⁷⁵: “Total cost to the health care system would approach one billion U.S. dollars per year, just for routine use during general anesthetics.”⁷⁶ In medicine, “indiscriminate use of screening tests for low probability events is an extraordinarily expensive proposition.”⁷⁷ In the death chamber context, unlike the operating room, the use of BIS monitors would be much more cost-effective given the smaller prisoner population, and there would be a much higher risk of consciousness during the all too frequent “botched” lethal injection procedures. BIS has also been criticized for being no more effective in preventing anesthesia recall than cheaper monitoring like end-tidal anesthetic gas (“ETAG”) testing,⁷⁸ but such methodology is inapplicable to the intravenous route of administration used in lethal injection.

The addition of BIS monitoring to lethal injection protocols would be to take one, if only one, important and readily achievable step forward. Dr. Forbes helped put the issue in perspective during an interview:

Routine BIS monitoring would enable non-medical and quasi-medical personnel who run executions in this country to view a simple number and titrate drug doses appropriately to ensure the condemned prisoner is truly unconscious. BIS would also make a single drug execution feasible by reducing the chance of the prisoner waking up and having to be re-executed. All in all, I do not understand why it has not

Bispectral (BIS) Pode Fornecer Valores Espúrios [When the Bispectral Index (BIS) Can Give False Results], 59 REVISTA BRASILEIRA DE ANESTESIOLOGIA [REV. BRAS. ANESTESIOL.] 99, 106 (2009).

73. See SCOTT D. KELLEY, MONITORING CONSCIOUSNESS: USING THE BISPECTRAL INDEX (BIS) DURING ANESTHESIA 19 (2d ed. 2012), <http://www.covidien.com/imageServer.aspx/doc252087.pdf?contentID=77508&contentType=application/pdf>.

74. J.P. Abenstein, *Is BIS Monitoring Cost-Effective?*, in PROCEEDINGS OF THE ANNUAL INTERNATIONAL CONFERENCE OF THE IEEE ENGINEERING IN MEDICINE AND BIOLOGY SOCIETY 7041, 7041-42 (2009).

75. *Id.* at 7043-44.

76. *Id.*

77. Michael F. O'Connor et al., *BIS Monitoring to Prevent Awareness During General Anesthesia*, 94 ANESTHESIOLOGY 520, 521 (2001).

78. See Avidan & Mashour, *supra* note 33, at 450-51.

been adopted before now. It is nearly twenty-year-old technology, relatively cheap, about \$4,000 per unit; and, \$20 per disposable sensor strip. Compared to standard anesthesia monitoring, BIS reduces intraoperative awareness by eighty percent. It should do the same for lethal injection.⁷⁹

C. *A Glimpse Backwards into the Future*

On April 7, 2006, Judge Malcolm Howard ruled that convicted murderer Willie Brown's execution by the triple-drug protocol for lethal injection could proceed only if North Carolina had "execution personnel with sufficient medical training to ensure that [he] is in all respects unconscious *prior to* and *at the time of* the administration of any pancuronium bromide or potassium chloride."⁸⁰ In response, North Carolina revised its protocol to include use of a BIS monitor as interpreted by a certified registered nurse anesthetist ("CRNA").⁸¹ Only if the BIS value were under 60 would the state proceed to inject the pancuronium and potassium.⁸² In the event the BIS value went above 60, they would inject additional thiopental and wait for the value to fall below 60 before proceeding.⁸³ On this basis, the Court of Appeals for the Fourth Circuit ruled that the execution could go forward.⁸⁴ The U.S. Supreme Court denied Willie Brown's last minute application for a stay, and his death by lethal injection was scheduled.⁸⁵

On April 11, 2006, ten days before the execution date, a North Carolina corrections official called the toll-free sales line at Aspect Medical Systems ("Aspect") to purchase a BIS monitor, which was shipped the same day.⁸⁶ The written purchase order request sent from the department of corrections stated, "[t]his equipment is used to monitor vital signs and sedation scales of patients recovering from surgery."⁸⁷ According to anesthesiologist Scott Kelley, medical director of Aspect, "the purchasers 'never indicated in any way that they intended to use [the monitor] in connection with the execution.'"⁸⁸ Kelley further stated

79. Interview with Dr. Floyd Forbes, *supra* note 51.

80. *Brown v. Beck*, 445 F.3d 752, 753 (4th Cir. 2006) (per curiam) (Michael, J., dissenting) (quoting Order at 14, *Brown v. Beck*, No. 5:06-ct-03018 (E.D.N.C. Apr. 7, 2006), ECF No. 32, *cert. denied*, 547 U.S. 1096 (2006) (mem.)).

81. *Id.* at 753-54.

82. *Id.* at 755.

83. *Id.*

84. *Id.* at 752-53.

85. *Brown*, 547 U.S. at 1096.

86. Steinbrook, *supra* note 50, at 2527.

87. *Id.*

88. *Id.* (alteration in original).

that “the use of the BIS monitor in an execution was inconsistent with its intended use in health care facilities, as well as with his company’s ‘mission to improve people’s lives,’” pointing to earlier that year when they refused to sell California a BIS monitor for possible use in the execution of convicted murderer Michael Morales.⁸⁹ Although this bears watching, it is unlikely Aspect can effectively prevent its BIS units from being used in lethal injection procedures. As of 2006, 34,000 BIS monitors had been sold worldwide, a half dozen of which were sent to U.S. prison hospitals.⁹⁰ There is also an active secondary market, with more than 50 BIS monitors currently listed for resale on eBay, priced from \$35 to \$3295.⁹¹

On April 21, 2006, North Carolina became the first state in the country to use a BIS monitor during a lethal injection execution.⁹² In the early morning, “[a]t ten minutes to two, prison officials brought Willie Brown to the execution chamber at Central Prison in Raleigh.”⁹³ Intravenous lines were inserted and the standard three-drug cocktail was administered to him.⁹⁴ State corrections official Keith Acree stated: “The execution team administered the sedative and the monitor dropped below the reading of 60, which was the threshold here. No additional sedative was needed before the lethal drugs were administered.”⁹⁵ Defense attorney Don Cowan observed, “I saw a brief gasp. And then they pronounced Mr. Brown dead at 2:11 [AM].”⁹⁶ Although absolute scientific proof Willie Brown was adequately anesthetized during his lethal injection is impossible since, for obvious reasons, he could not be interviewed afterwards, BIS monitoring gave the attendant nurse anesthetist useful parameters that, together with other important safeguards and redundancies in the protocol, maximized the chance for a humane, painless death.

89. *Id.* at 2526.

90. *Id.* at 2526-27.

91. *BIS Monitor*, EBAY, <http://ebay.com> (search in search bar for “BIS Monitor”) (last visited Dec. 31, 2016).

92. Steinbrook, *supra* note 50, at 2525. For other death penalty cases referencing the potential use of a BIS monitor during lethal injection executions, see, for example, *Lightbourne v. McCollum*, 969 So. 2d 326, 333 (Fla. 2007); *Schwab v. State*, 973 So. 2d 427, 430 (Fla. 2007) (mem.); *Connor v. N.C. Council of State*, 716 S.E.2d 836, 838 (N.C. 2011); and Brief for Petitioners at 19, *Baze v. Rees*, 553 U.S. 35 (2008) (No. 07-5439).

93. Rusty Jacobs, *Brain Waves Monitored During N.C. Lethal Injection*, NPR (Apr. 21, 2006, 1:00 PM), <http://www.npr.org/templates/story/story.php?storyId=5355482>.

94. *Id.*

95. *Id.*

96. *Id.*

III. CONCLUSION

Standardized BIS monitoring of the depth of anesthesia would help ameliorate readily avoidable problems with lethal injection protocols in the obdurate states that persist in using paralytics, despite abundant evidence they are not only unnecessary but also can cause torture. By using BIS monitors, we would move a step beyond medicating an inmate to prevent him from moving or crying out—preserving the aesthetics of the execution for witnesses in the death chamber while masking potential torture—and towards preventing the infliction of gratuitous suffering violative of the Eighth Amendment. Departments of corrections should take all reasonable measures to ascertain whether an inmate is awake or asleep during lethal injection (that is to say, whether the inmate is truly anesthetized or not). One method of so doing is not to paralyze condemned prisoners. Another is to have board certified anesthesiologists or nurse anesthetists in attendance, if not proscribed by ethical mandates. In states that persist in paralyzing, even if they have a non-lay person assessing the inmate during the execution, an argument can be made that they are negligent at best, and reckless at worst, if they do not use BIS monitoring as a reasonable measure to assess anesthetic depth.

The U.S. Supreme Court has not to date invalidated a state's chosen method of execution as an infliction of cruel and unusual punishment.⁹⁷ However, the Court has left open the door to future challenges based upon a state's deliberate indifference to a "feasible, readily implemented" alternative to the current method of lethal injection that would "significantly reduce a substantial risk of severe pain."⁹⁸ The criminal justice community should remain cognizant of the BIS monitor as such an alternative. Should a state refuse to adopt its use without a legitimate penological justification, despite the obvious advantages, "then a State's refusal to change its method can be viewed as 'cruel and unusual' under the Eighth Amendment."⁹⁹

97. See, e.g., *In re Kemmler*, 136 U.S. 436, 447 (1890) (upholding death by electric chair); *Wilkerson v. Utah*, 99 U.S. 130, 135-37 (1879) (upholding death by firing squad).

98. *Baze v. Rees*, 553 U.S. 35, 52 (2008).

99. *Id.*