IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

MICHAEL ANTHONY TAYLOR	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 05-4173-CV-W-FJG
	)	
LARRY CRAWFORD, et al.,	)	
	)	
Defendants.	)	
	)	

PLAINTIFF'S OPPOSITION TO DEFENDANTS' PROPOSED PROTOCOL

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INTRODUCTION

In response to this Court's determination that Missouri's execution procedure exposes inmates to an unnecessary and unconstitutional risk of excruciating pain, Defendants ("the State") have submitted a vague, incomplete protocol that does not even attempt to comply with this Court's Order of June 26, 2006 ("Order") or minimize the likelihood of pain to inmates. Plaintiff established at trial, and this Court found, that the State's execution procedure has been plagued by "numerous problems." Order at 11. Instead of taking this opportunity to embark on a considered process of meaningful reform, the State has failed outright to address many deficiencies and papered over others. The result is not a true execution protocol -- which should take the form of a set of step-by-step instructions that can be followed precisely by the execution team -- but rather a set of provisions that only vaguely describes what personnel might do, or simply parrots the Order's language without explaining whether or how Defendants will actually alter their practices. The State's proposed protocol, if one can call it that, thus utterly fails to protect inmates from the errors, ad hoc improvisations, and poor judgment of inadequately trained personnel forced to carry out executions without adequate guidance.

Part I of this Opposition argues that this Court should reject the State's proposed protocol for two reasons. First, the State has not complied with many aspects of the Order, including its requirement that the State include a board-certified anesthesiologist. Instead, the State would allow any physician (including John Doe I), nurse, or even EMT to carry out the execution. Second, the proposed protocol is not an acceptable alternative to the Court's requirements because it perpetuates the unnecessary risk of excruciating pain present in the State's procedures to date, *see* Heath Decl. ¶ 2 (Exh. A), and thus does not comply with the Eighth Amendment. Part II argues that this Court should reject the State's claim that it was legal error to require the

participation of an anesthesiologist in its execution procedure.

I. THE STATE'S PROPOSED PROTOCOL MUST BE REJECTED.

A. Monitoring Anesthetic Depth.

Plaintiff established at trial that so long as potassium chloride is used in the execution procedure, it is necessary to induce general anesthesia to prevent the inmate from being subjected to the excruciating pain caused by the potassium. Trial Tr. 14; Heath Decl. ¶ 4. Assessing anesthetic depth is imperative, because the substandard practices of catheterization and drug administration used for executions create a significant and unnecessary likelihood that the intended dose of anesthetic will not in fact reach the inmate's circulatory system.[1] *Id.* ¶ 9.

1. The State's Proposed Protocol Does Not Comply with the Court's Order.

This Court ordered Defendants to adopt procedures to require a board-certified anesthesiologist to "adequately monitor the anesthetic depth of the inmate." Order at 14. As this Court noted, Defendants have to this point performed "little or no monitoring of the inmate to ensure that he has received an adequate dose of anesthesia." *Id.* at 13. The requirement of "adequate" monitoring necessarily entails having a board-certified anesthesiologist exercise his or her medical judgment as to how, and with what equipment, to monitor anesthetic depth, given the execution set-up and the excruciating pain that could be caused by potassium.

Defendants clearly have not complied with this crucial aspect of the Court's Order. Rather than use a board-certified anesthesiologist, Defendants propose to use a physician, nurse

[1] Defendants, however, consistently refuse to acknowledge this basic point, arguing that "if five grams of thiopental is administered, there would be no need to monitor the anesthetic depth of the condemned." Defs. Mem. at 8. As Defendants' own qualification implies, the need to monitor anesthetic depth arises from uncertainty regarding whether five grams of thiopental have in fact been administered into the inmate's circulation – where it must arrive in order to have any effect – and whether the thiopental has had the expected effect of causing unconsciousness. Trial. Tr. 253-56.

or EMT to monitor anesthetic depth. Such personnel lack the years of advanced training in anesthesiology that inform the decisions and performance of a board-certified anesthesiologist. *See* Heath Decl. ¶¶ 11-12.

2. The State's Proposed Alternative Creates An Unnecessary Risk Of Pain.

The State's proposed method of using "[a] physician, nurse, or emergency medical technician" to assess anesthetic depth in a manner prescribed by the State, *see* Protocol ¶ A.3, fails to minimize the risk that inmates will be subject to excruciating pain. It is therefore not an adequate substitute for the procedure ordered by the Court.

First, Defendants propose to use personnel untrained in anesthesiology to perform the monitoring function. Assessing and monitoring anesthetic depth is "inherently a complex task that requires the real-time and continuous integration of multiple lines of evidence and information." Heath Expert Report ¶ 17. Nurses, EMTs, and physicians who are not anesthesiologists all lack the advanced training in anesthesiology that is necessary to properly interpret the subtle indicia of consciousness, and therefore will not be able to accurately and reliably monitor anesthetic depth.[2] *See* Heath Decl. ¶¶ 11-12; Trial Tr. 26.

Second, the means of anesthetic monitoring that Defendants propose are completely inadequate to ensure that an inmate has reached, and remains in, a surgical plane of anesthesia. As Plaintiff has established, the injection of a high concentration of potassium into the veins is excruciatingly painful, akin to a surgical incision. Trial Tr. 57-60. Because anesthesia has many levels, an inmate can be lightly anesthetized, and therefore not responsive to mild stimuli (such

[2] Perhaps most disturbing is the State's statement that it might perform executions with *only* an EMT present. EMTs in Missouri may provide patient care only under the supervision of a doctor, 19 Mo. Code State Regs. § 30-40.303 -- which they would not have if no doctor were present at the execution. In addition, EMTs are trained to provide specific types of emergency care, and thus are not trained in inducing and monitoring anesthetic depth. *See* Heath Decl. ¶ 11.

as voice or touch), but still be fully aware of more painful stimuli. Heath Decl. ¶ 22. Thus, any assessment of anesthetic depth must effectively test whether the inmate is able to feel pain equivalent to surgery.

Instead of leaving assessment of anesthetic depth to an anesthesiologist who would be able to bring extensive training to bear on the task, the DOC has simply copied a non-exclusive list of monitoring techniques from a Practice Advisory meant for an audience of anesthesiologists. See Exh. 3 to Heath Decl.; Heath Decl. ¶¶ 15-23; Protocol ¶ E.3. The listed techniques, however, each have a specific purpose, and provide specific types of information to anesthesiologists, who have the tools necessary to interpret them. Some are effective only for measuring very shallow levels of unconsciousness. Heath Decl. ¶ 22. Using untrained personnel to employ some or all of the listed techniques, with no understanding of "what information each technique can provide and how each fits in to the broad suite of assessment techniques," *id.*, is wholly inadequate to ensure that the inmate is in fact sufficiently anesthetized.

Although the proposed protocol also appears to provide for remote monitoring of the inmate's face from the execution support room, *see* Protocol ¶ D.2, such monitoring will be ineffective, particularly after the pancuronium has paralyzed the inmate's face muscles. *See* Heath Decl. ¶ 23; Standards for Basic Anesthetic Monitoring, attached as Exh. 4 to Heath Decl. ("Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics . . . ."). Thus, this aspect of the proposal does not provide a substitute for bedside monitoring of the inmate by an anesthesiologist. *Id.*

Finally, the State offers no detail as to how it has improved the view from the support room to allow adequate monitoring, merely stating that "the gurney is positioned so that the medical personnel can observe the prisoner's face directly or with the aid of a mirror." *See*

Protocol ¶ D.2. [3] At a minimum, the vagueness of the State's representation indicates that it has not thought through how it actually will implement this part of the procedure.[4] Even more disturbingly, given that John Doe I already represented, incorrectly, that the prior set-up afforded an adequate view of the inmate's face, *see, e.g.,* Doe I Depo. Tr. at 41-42, it is entirely possible that the State has changed nothing at all or has made changes that are not meaningful.

B. IV Access.

1. The State's Proposed Protocol Does Not Comply with the Order.

This Court's Order provides that the State, in conjunction with an anesthesiologist, will have discretion to determine the site of IV access. *See* Order at 14. The State has procured no anesthesiologist and therefore cannot comply with this portion of the Court's Order.

2. The State's Proposed Alternative Creates an Unnecessary Risk of Pain.

Defendants' proposed plan for obtaining IV access is seriously flawed. First, the protocol fails to ensure that the process of inserting the IVs will be safe and humane. Although the protocol on its face provides medical personnel with discretion to determine the "most appropriate" location in which to insert the catheter, it does not specify whether the most "appropriate" location will be determined based on the medical judgment of a qualified individual. This vagueness is particularly disturbing in light of John Doe I's previous prioritization of aesthetic concerns -- speed of injection and concealment of the IV site -- in choosing the femoral line as the automatic means of IV access. *See* Doe I Depo Tr. 87, 104-05.

In fact, the protocol explicitly reserves the execution team's right to place central lines,

[3] Because the view of the inmate's face from the execution support room was obstructed, this Court noted that the State may have to reposition the gurney in order to render the inmate's face visible. *See* Order at 12, 14.

[4] Moving the gurney could affect other elements of the execution set-up, such as the length of the IV tubing.

even when they are not medically necessary.[5] Every type of central line is significantly more invasive than a peripheral line, and involves potentially agonizing complications. Heath Decl. ¶ 28. It is inhumane, therefore, to determine whether to use a central line based on considerations other than medical necessity.[6] *Id.* ¶ 25.

In addition, the protocol does not specify when the catheter site will be chosen. This is a determination that could be made ahead of time, based on an examination of the inmate, and need not be an on-the-spot decision. *Id.* ¶ 30. The protocol fails to recognize that allowing medical personnel to decide to place a central line once the inmate is already on the gurney could force personnel to perform the catheterization without the equipment necessary to treat the complications that could arise. *Id.*

These dangers are compounded by the fact that the protocol contemplates that personnel without current and regular experience placing central lines could have sole discretion over these aspects of the procedure. Nurses and EMTs alone do not place central lines, or determine that a central line is necessary, except in emergency circumstances. *Id.* ¶ 27. Many doctors do not regularly place central lines, and therefore are not proficient in the procedures. Trial Tr. 53. Delegating authority to these personnel to place central lines, perhaps without advance planning and the necessary equipment, creates a significant and unnecessary risk that the inmate will experience excruciating pain and complications from the IV procedure itself.

Second, these same inadequacies substantially increase the likelihood that the IV will not be a reliable one. *Id.* ¶¶ 24, 31. Plaintiff previously proffered substantial evidence regarding the

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[5] The protocol specifies that the backup line will always be peripheral, Protocol ¶ C.1, even if the primary IV is central -- which necessarily means that Defendants contemplate inserting central lines in inmates whose peripheral veins are undamaged.

[6] John Doe I believed that the invasive and risky femoral line was the most appropriate because the catheter site could be hidden from view under a sheet and the line would allow a very quick injection. Doe, Depo Tr. at 104-05.

potential that an IV line could become dislodged, infiltrated, or blocked, even when the catheterization is performed by a board-certified surgeon. Trial Tr. 77-82. These dangers are exacerbated by the proposed protocol, and by existing deficiencies in the procedure, such as the use of a sheet that hides the catheter site and IV tubing from view.[7]

C. Mixing the Chemicals.

1. The State's Proposed Protocol Does Not Comply with the Order.

This Court required that a board-certified anesthesiologist mix the drugs. *See* Order at 14. Instead, acknowledging that it has failed to comply with this requirement, the State has decided that a "physician, nurse, or pharmacist [will] prepare[] the chemicals." Protocol ¶ A.2; Defs. Mem. at 4. The State thus leaves open the door for John Doe I to continue to do the mixing. This Court was "gravely concerned that a physician who is solely responsible for correctly mixing drugs which will be responsible for humanely ending the life of condemned inmates" was unable to mix the thiopental correctly. Order at 12. The State flouts this concern by allowing the mixing to be performed by this very individual.

Adequate provision for proper mixing of the thiopental is crucial to complying with the Court's requirement that the "thiopental administered shall not be less than 5 grams." *Id.* at 14. The State's proposal states that it will use 5 grams, *see* Protocol ¶ B.2, but its lack of detail regarding the mixing procedure fails to guarantee that it will in fact successfully mix that amount. This concern is a very real one, as the State was unable to ensure that 5 grams would be mixed in previous executions, and previously used a type of thiopental kit that made mixing a larger-than-normal dose more difficult. *See* Heath Decl. ¶ 37. There is no indication that the

[7] That the State indicates it will inspect the catheter site when it checks anesthetic depth, *see* Protocol ¶ E.3, is not sufficient to guard against other foreseeable problems that might arise, such as leaks or kinks in the tubing.

DOC has considered or addressed these issues. *See id.* ¶ 36-37. The State's failure to protect against ad hoc deviations from the mixing procedure, and the participation therein of John Doe I, thus prevent the State from effectively guaranteeing that 5 grams will in fact be prepared and administered.

2. The State's Proposed Alternative Creates an Unnecessary Risk of Pain.

John Doe I's participation, of course, raises special concerns that the State will fail to mix 5 grams of thiopental. But even if he does not perform the mixing, the State's proposal fails to provide adequate assurance that the drugs will be successfully mixed. The State contemplates using personnel with little to no experience in mixing drugs to perform the task, *see* Protocol ¶ A.2, but has provided no instructions on how to perform the mixing. *See* Heath Decl. ¶ 36. Because personnel must prepare a dose of thiopental that is much larger than the standard clinical dose for which thiopental kits are designed, the mixer must deviate from the mechanical instructions provided in the package insert. *See id.* The State then creates a significant risk that untrained personnel will improvise a mixing process, leading to mistakes and an inability to prepare a full dose of anesthetic. *Id.* ¶ 37-38.

D. Drug Administration.

1. The State's Proposed Protocol Does Not Comply with the Order.

This Court required an anesthesiologist either to administer the drugs or directly oversee those individuals who do so. Order at 14. It further required the anesthesiologist to certify that the inmate has achieved sufficient anesthetic depth before the injection of the pancuronium bromide and potassium chloride. *Id.* Obviously, the State has failed to comply with this Court's direction that an anesthesiologist participate in the administration of the drugs, and certify anesthetic depth before the injection of the second and third drugs. The protocol also fails to

specify how certification of anesthetic depth should be communicated to each member of the execution team before the injection of the other drugs.

The Court also requires the Operations Room to be "sufficiently lighted so that the corrections personnel can see which drugs are being administered." *Id.* The proposed protocol merely parrots this language, stating that "[t]he lights in the execution support room are maintained at a sufficient level to permit proper administration of the chemicals." Protocol ¶ E.1. This statement does not indicate how -- or even whether -- the State will adjust the lighting, or how the adjusted lighting will interact with the State's anonymity concerns. Clearly, the State has not actually thought through what constitutes sufficient lighting, and thus has not meaningfully complied with the Court's order.

2. The State's Proposed Alternative Creates an Unnecessary Risk of Pain.

The fact that the protocol is silent regarding precisely how the drugs will be administered and how the IV equipment and gurney will be set up leads to the conclusion that Defendants intend to retain many of the dangerous elements of their existing execution procedure. Plaintiff previously offered extensive evidence regarding the numerous failings of the procedure, including remote drug administration, the failure to use an IV drip to ensure the patency of the IV line,[8] the inability to see the inmate clearly through the one-way glass and blinds, and the inability to monitor the IV tubing or catheter site visually because of the sheet covering the inmate. Trial Tr. 75-82. None of these issues is addressed or mentioned in the protocol; thus, it is reasonable to conclude that Defendants are planning to maintain these aspects of the

[8] The protocol states that a "sufficient quantity" of saline will be injected to confirm that the IV lines have been properly inserted before the injection process begins. While this technique, along with effective monitoring of the catheter site, can confirm that the catheter is properly inserted at that point in the procedure, this technique by itself will not reveal whether the catheter has become dislodged or has infiltrated at a subsequent point, after the drugs have begun to be administered. Trial Tr. 78-79; Heath Decl. ¶ 31.

procedure. In addition, the proposed protocol does not provide a means of certifying anesthetic depth, which would help prevent miscommunications among the execution team. *See* Heath Decl. ¶ 42. Individually and combined, these problems create a risk that the inmate will not receive the full dose of thiopental and the execution team will not be able to detect the problem.

Along similar lines, the proposed protocol and Defendants' memorandum are conspicuously silent on the question of whether John Doe I will continue to participate in executions. The proposed protocol is, as discussed above, vague on a number of crucial medical issues, apparently conferring unbridled discretion on the medical personnel. If John Doe I continues to supervise executions, therefore, he will be entrusted with same degree of discretion that he has enjoyed in the past. *See* Order at 11-12. Plaintiff proffered extensive testimony at trial regarding John Doe I's questionable medical judgment and the dangers created by his control over the procedure, and this Court expressed serious concerns regarding his participation. Trial Tr. 20-66; 152-68; Order at 8-12. Defendants' apparent reservation of their right to retain John Doe I is therefore completely unacceptable.

E. Contingency Plan.

1. The State's Proposed Protocol Does Not Comply with the Order.

This Court also required the State's protocol to contain a contingency plan in case problems develop during the execution procedure. Order at 15. The State has complied only in part, providing for a second IV line through which an additional 5 grams of thiopental will be administered if the initial 5 grams do not render the prisoner unconscious. *See* Defs. Mem. at 3. This Court, however, found that the State's lethal injection procedure created an unnecessary risk of pain, *see* Order at 13, so the State's contingency plan should be designed to address the contingencies that create a likelihood of pain.

The State did not do that. For instance, it has provided no contingency plan for treating complications arising out of IV access, including the numerous serious and painful complications of central line access. Rather, the State apparently contemplates leaving the treatment of such complications – and the placement of an alternative IV line in the event that the first results in some complication – to inexperienced or untrained personnel. These personnel, however, need a contingency plan to guide them because they cannot rely on their experience in these situations.

The State has also offered no contingency plan for problems arising during the mixing of the drugs. Mixing problems have plagued previous executions, and a failure to prepare a proper dose of thiopental indisputably creates a likelihood of pain. Nonetheless, the State has not considered its course of action if confronted with foreseeable mixing failures, such as inability to dissolve the thiopental. *See* Heath Decl. ¶¶ 38. The State's failure to offer a contingency plan regarding the mixing not only fails to comply with the Court's Order but is appalling in light of the numerous mixing problems that have already come to light in this case.

2. The State's Proposal Creates an Unnecessary Risk of Pain.

The State's failure to plan for contingencies creates an unnecessary risk of pain, because it forces personnel to confront difficulties that arise with ad hoc improvisation, rather than informed, careful decision making.[9]

F. Auditing Process.

1. The State's Proposed Protocol Does Not Comply with the Order.

The Court required the State to put in place an auditing process to ensure that the individuals carrying out the execution procedure are correctly following the protocol. *See* Order

[9] The above examples of contingencies not accounted for in the proposed protocol are not meant to be an exclusive list. It is the State's duty to gain the expertise necessary to anticipate the range of foreseeable contingencies and adequately provide for them.

at 15. The State's proposal does not ensure that the execution team will correctly follow the protocol. The State only offers *ex post* measures that require the execution team, *after* the procedure, to verify they have taken certain steps; it does nothing to ensure that the personnel will properly follow the protocol *during* an execution. Effective auditing requires a rigorous, on-the-scene system of checks and balances. *See* Heath Decl. ¶ 39. Only with contemporaneous oversight can the State be sure that execution personnel be constrained to perform their tasks properly and safely. Otherwise, a single individual can subvert the entire process and cause an inhumane execution, whether through error or malice. Indeed, experience in this case should demonstrate that ex post documentation of aspects of the procedure provide no constraint or assurance as to the performance of the execution. The "Chemical Log" referenced in the State's protocol has been used in previous executions, but was insufficient to ensure that the execution team prepared and injected the correct dose of thiopental, or even provide the State with any knowledge of what doses were prepared. *See* Doe I Depo. Tr. at 9-10, 14, 24-25. Disturbingly, despite this previous experience, the State has offered no procedural change that would render these *ex post* logs sufficient to guard against departures from the stated protocol.[10]

Additionally, the proposed protocol may retain John Doe I as part of the execution team. Given his track record of error and misrepresentations, and the extreme extent to which the execution team deferred to him, it is doubtful whether any execution procedure that includes John Doe I, without oversight by a doctor to whom he would report and defer, could provide meaningful, contemporaneous checks and balances that ensure that the procedure goes as planned and as stated. Certainly, the State has provided no basis for such confidence.

[10] Indeed, while deviations from the protocol are to be reported to the Director of Department of Corrections, *see* Defs. Mem. at 4, the proposal does not even indicate that such deviations would lead to changes in the procedure or disciplinary measures against those individuals responsible for the departure.

2. The State's Proposal Creates an Unnecessary Risk of Pain.

The State's failure to put in place sufficient auditing processes creates an unnecessary risk of pain, because it fails to provide sufficient guarantees that the execution procedure will be followed as planned.

G. Changes to the Lethal Injection Procedure.

Finally, this Court ordered that after its approval, "no further changes shall be made to the lethal injection protocol without seeking the prior approval of this Court." Order at 15. The proposed protocol, however, operates at such a broad level of generality that the State could make any number of changes in its actual practices without altering the language of the protocol. As noted above, in several instances, the State makes vague assertions about how it will carry out the executions -- with "sufficient" lighting, "appropriate" catheter sites, etc. -- but provides little or no detail as to the particulars. Because the State offers so little detail, it leaves itself enough leeway to make changes within the scope of its proposed protocol without having to seek approval from this Court. In other words, were this Court to approve the instant proposal, the State would have free rein to make significant changes without judicial oversight.

* * * * *

The State's proposal does not comply with this Court's Order, and the alternatives it proposes are inadequate and give rise to an unnecessary risk of unconstitutional pain and suffering. The proposal is also exceedingly vague on many points. This vagueness makes it impossible to determine what the State is planning to do. It also results in inadequate instructions on how to perform complicated tasks, a failing that is particularly troublesome in light of Missouri's failure to identify qualified personnel. The purpose of having a written protocol is to provide step-by-step instructions that are binding on execution team members in

order to ensure that executions are "carried out consistently," with no ad hoc improvisations "at a moment's notice." Order at 11. This would serve to protect the inmate and the State from the deviations and poor judgment that have marred executions in the past.

Creating a safe execution protocol that does not risk unnecessary pain requires careful analysis of each element of the procedure individually and in coordination with the others. Quite simply, the State has not invested the thoughtful consideration necessary to create a safe, humane procedure.

II. THIS COURT SHOULD REJECT THE STATE'S CHALLENGE TO ITS REQUIREMENT THAT AN ANESTHESIOLOGIST PARTICIPATE IN THE LETHAL INJECTION PROCEDURE.

The Order required that a board-certified anesthesiologist take part in the State's lethal injection procedure. The State admits that it has been "unable to comply with the Court's direction" in this regard. Defs. Mem at 4. The State's proposal, thus, is in essence a motion for reconsideration, contending that this Court erred in requiring an anesthesiologist. *Id.* at 6. There is no legitimate basis for reconsideration here.

The thrust of the State's argument is that because it has so far been unable to identify a board-certified anesthesiologist willing to participate in its execution procedure, it should be excused from that requirement. As an initial matter, though, the State plainly has not exhausted all avenues for compliance with the Order. It has sent form letters to 298 board-certified anesthesiologists – out of the over 39,000 in the country – and has not yet found a willing participant. *See* Moore Aff. ¶¶ 2-3; http://www.asahq.org/aboutAsa/membership.htm. The State does not explain why it has apparently not considered other means of recruiting an anesthesiologist, such as employing medical recruiters. Indeed, the State's insistence that it will be impossible for it to comply rings especially hollow in light of a survey indicating that 19% of

all doctors indicated willingness to personally take part in lethal injection procedures. *See Physicians' Willingness To Participate in the Process of Lethal Injection for Capital Punishment*, Ann. Intern. Med. 2001 Nov. 20, Exh. 5 to Heath Decl.; Heath Decl. ¶¶ 43-45.

Even more to the point -- and contrary to the State's contention -- this Court's requirement of an anesthesiologist does not bar implementation of the death penalty in Missouri. *See* Defs. Mem. at 6. There are methods of execution that do not require an anesthesiologist. Indeed, the State itself identifies one of those methods, when it notes that the *Morales* court offered the option of execution by a properly administered massive dose of a barbiturate "without any direction that a doctor be present." *Id*. at 7 (citing *Morales v. Hickman*, 415 F. Supp. 2d 1037, 1047 (N.D. Cal. 2006)). Plaintiff himself has also suggested this method. *See* Plaintiff's Pretrial Br. at 10. The State is thus flatly mistaken when it claims the Order imposes an insurmountable bar to carrying out the death penalty.[11] Instead, this Court merely required what was evident at trial: that if the State chooses to inject potassium chloride, then it must use a board certified anesthesiologist. Nothing, however, requires the State to continue to use the problematic three-chemical sequence it has selected.

* * * * *

For the foregoing reasons, this Court should reject the State's proposed protocol.

[11] In arguing that this Court committed "legal error" in requiring an anesthesiologist, the State misconceives the nature of the Court's decision. The Court found that the execution procedure violated the Eighth Amendment because it exposed prisoners to an unnecessary risk of pain. Order at 13. The Court then fashioned a remedy, including the use of an anesthesiologist, that it found was "necessary to ensure that lethal injections are carried out humanely." *Id.* The cases cited by the State are thus inapposite, as those decisions all found that the execution procedures at issue did not present an unnecessary risk of pain. Because no Eighth Amendment violation was found in those states, the courts in those cases issued no remedy and, accordingly, declined to order the participation of an anesthesiologist. *See Bieghler v. State*, 839 N.E. 691, 696 (Ind. 2005) (no showing of an "unacceptable risk of . . . wanton infliction of pain"); *Evans v. Saar*, 412 F. Supp. 519, 524 (D. Md. 2004) (no "substantial and unnecessary risks intrinsic to the procedure").

Respectfully submitted,

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Dated this 24th day of July, 2006.

Certificate of Service

I hereby certify a true and correct copy of the foregoing via the electronic filing system of the Western District of Missouri this twenty-fourth day of July, 2006, to the offices of:

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IN THE UNITED STATES DISTRICT COURT
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CENTRAL DIVISION

MICHAEL ANTHONY TAYLOR	)	
	)	
Plaintiff,	)	
vs.	)	No. 05-4173-CV-W-FJG
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LARRY CRAWFORD, et al.,	)	
	)	
Defendants.	)	
_____	)	

DECLARATION OF DR. MARK HEATH

1. Counsel for Mr. Taylor have asked me to comment on the proposed execution protocol submitted by the Department of Corrections ("DOC") on July 14, 2006. I read the judge's decision of June 26, 2006, and then I reviewed the DOC's new protocol. I think that the judge proposed an effective means of addressing the concerns about the practice of lethal injection in Missouri, but I do not believe that the DOC has listened to what the judge said or proposed an alternative remedy that is as good as what the judge proposed.

2. At the risk of repeating myself, it appears to me that the DOC in the past has not performed executions with the gravity, seriousness and care that ought to be observed. I do not see any attempt to make a clear break with their past systems and process in this proposed protocol. Instead, it appears to me that the DOC intends to keep as much of its previous procedure in place as is possible. Indeed, John Doe I may still run the execution process. The protocol as written also creates a significant and needless risk that the inmate will not be properly anesthetized prior to the administration of pancuronium and potassium.

I. The Requirement of a Board-Certified Anesthesiologist

3. The Court's Order of July 26, 2006 required that a board-certified anesthesiologist participate in executions by preparing and mixing the chemicals, determining the appropriate means of IV access, supervising or administering the injection, and verifying and certifying that, in the anesthesiologist's medical judgment, the inmate is sufficiently anesthetized prior to the administration of pancuronium and potassium.

4. I believe that a protocol containing these safeguards, and requiring that they be properly executed by a competent board-certified anesthesiologist with the ability and intent to physically examine the inmate, would reasonably minimize the risk that an inmate would be aware during the administration of the pancuronium and potassium. So long as potassium is used to cause

death, it is necessary to induce general anesthesia before injecting the potassium. A board-certified anesthesiologist has the advanced training necessary to allow him or her, using proper techniques, to ensure that general anesthesia has been successfully induced.

5. The court's requirement of a board-certified anesthesiologist to monitor anesthetic depth satisfies the standard of care that anesthesiologists and veterinarians agree is absolutely necessary when potassium is used to cause death. Dr. Orin Guidry, the president of the American Society of Anesthesiologists, recently published his observations regarding anesthesiologist participation in lethal injection, stating: "If the courts demand that inmates be sufficiently anesthetized, then I would have to agree with the court that the only way to assure that would be to have an anesthesiologist prepare and administer the drugs, carefully observe the inmate and all pertinent monitors, and finally to integrate all this information. I don't think that any of us would want to say that untrained individuals under current death chamber conditions can reliably produce a satisfactory level of unconsciousness." (Dr. Guidry's letter is attached as Exhibit 1.)

6. The 2000 Report of the Panel on Euthanasia of the American Veterinary Medical Association reaches the same conclusion. In discussing euthanizing animals using potassium chloride, the Report states: "It is of utmost importance that personnel performing this technique are trained and knowledgeable in anesthetic techniques, and are competent in assessing anesthetic depth appropriate for administration of potassium chloride intravenously. Administration of potassium chloride intravenously requires animals to be in a surgical plane of anesthesia characterized by loss of consciousness, loss of reflex muscle response, and loss of response to noxious stimuli." (Page 681, attached as Exhibit 2.)

7. I feel that it is necessary to note here that whenever one hires a doctor, one must take precautions to make sure that the doctor, in addition to being trained and board-certified, is also competent and will perform his or her duties in good faith. For instance, if the DOC were to hire an anesthesiologist who has been barred from practice, for example for incompetence or commission of a felony, or states that he believes inmates *should* be subject to excruciating pain, then I would be concerned that that doctor's participation in the execution procedure would create a significant risk that the inmate would suffer during the procedure. As the DOC has not yet found an anesthesiologist, however, this concern is purely theoretical at this point.

8. In sum, while no complex endeavor can be completely risk-free, I believe that the Court's requirement that a board-certified anesthesiologist monitor anesthetic depth prior to the administration of pancuronium and potassium will properly safeguard the inmate's and State's interest in a humane execution. By contrast, the DOC's proposed protocol does not provide these safeguards. Further, it appears that the DOC does not understand the need for these safeguards even after being informed about them during the hearings.

II. The Execution Protocol Submitted by the DOC

9. The execution protocol submitted by the DOC on July 14, 2006, fails to ensure that executions in Missouri are performed humanely. The DOC has chosen to execute prisoners by means of potassium, which everyone agrees requires the induction and maintenance of general anesthesia until the time of death. While the DOC's attempt to provide some form of monitoring

of anesthetic depth is a positive step, the monitoring contemplated is not meaningful, especially in light of the fact that the monitoring will not be performed by a board-certified anesthesiologist. Overall, the protocol is deficient in a number of respects, including its reliance on inadequately trained personnel, failure to provide meaningful monitoring of anesthetic depth, failure to provide specific instructions on a number of issues, and failure to anticipate a number of foreseeable contingencies.

A. Inadequately Trained Personnel

10. The execution protocol provides that "a physician, nurse, or emergency medical technician" will insert the IV lines, monitor the prisoner's anesthetic depth, and supervise the injection.

11. Physicians, nurses, and EMTs generally do not have any training in inducing general anesthesia. It is my understanding, based on my review of the protocol, that the DOC does not intend to require that the particular physician, nurse, or EMT who participates in executions have any training or background in the induction of general anesthesia.

12. As I testified at trial, inducing general anesthesia, and verifying that a patient has reached a surgical plane of anesthesia, is a complex task that requires the integration of multiple modalities of information. To perform this task reliably and properly, a person must have extensive training in the medical subspecialty of Anesthesiology. It is also necessary to have current and practical experience in monitoring patients' anesthetic depth (such as an anesthesiologist would gain during his or her training and residency) in order to be able to reliably discern when a patient has been insufficiently anesthetized. Doctors who are not anesthesiologists, nurses, and EMTs do not, except in rare cases, have this advanced training or experience.

13. Using personnel untrained in anesthesiology to induce general anesthesia and monitor anesthetic depth is not consistent with the standard of care in Missouri or elsewhere. In the medical context, only a fully trained anesthesiologist should supervise or perform the induction and maintenance of general anesthesia in a surgical setting; other doctors, nurses, and EMTs would not be credentialed (i.e., permitted by the hospital) to do so.

14. Not only does the protocol contemplate using medical personnel who have no background or training in anesthesia, but it is unclear whether these personnel would receive any instruction in how to perform the monitoring techniques required by the protocol (testing for physical movement, eyelash reflex, etc.). The protocol is noticeably silent regarding whether this type of instruction will take place, and if so, who will provide the instruction. Thus, the personnel asked to perform the monitoring may have absolutely no understanding of what they are supposed to do or what observations they need to make. A "crash course" on using specific methods of testing anesthetic depth would not substitute for the years of extensive training and practice that inform an anesthesiologist's exercise of medical judgment.

B. Inadequate Monitoring of Anesthetic Depth

15. The monitoring provided by the DOC's protocol is not an adequate substitute for using a board-certified anesthesiologist to ascertain and monitor anesthetic depth. In this respect, the

protocol fails to provide any reasonable assurance that inmates will be properly anesthetized prior to the administration of the pancuronium and potassium.

16. There are many useful tests, techniques, and monitors that anesthesiologists use in their assessment of anesthetic depth. It is important to understand that the ability to effectively and accurately use these techniques can only be developed through extensive clinical training in the field of anesthesiology. I note that while a board-certified anesthesiologist would be able to use his or her medical judgment to determine what techniques to use to monitor anesthetic depth, the DOC has had to specify what techniques will be used because it seeks to use personnel who have no background in anesthesiology that they can bring to bear on the situation. This is why the judge's order makes logical sense: rather than prescribing what tests should be used, he specified that an anesthesiologist should determine what to do using his or her training and judgment.

17. This point is underscored by the litigation preceding the Brown execution in North Carolina, in which the state proposed to substitute a BIS monitor for a professional assessment of anesthetic depth. Virtually everyone, including the medical director of the manufacturer of the BIS monitor and the American Society of Anesthesiologists (ASA), agreed that the BIS monitor cannot substitute for an anesthesiologist who, relying on multiple streams of information and their extensive training and experience, carefully synthesizes information to assess anesthetic depth. Only Dr. Dershwitz seemed to believe otherwise. The ASA's Practice Advisory for Intraoperative Awareness and Brain Function Monitoring is attached as Exhibit 3 (see pages 14-15, 21-22 for a discussion of the BIS monitor).

18. The protocol provides that the physician, nurse, or EMT will monitor anesthetic depth using "standard clinical techniques, such as checking for movement, opened eyes, eyelash reflex, pupillary responses or diameters, and response to verbal commands and physical stimuli." This language is lifted from the ASA Practice Advisory on Intraoperative Awareness. (See Exhibit 3, Part III.A.) This is particularly troubling because this document is intended for use by individuals who are trained and proficient in the administration and maintenance of general anesthesia. *See* Exhibit 3, Part D, p.4. It is not intended as a substitute for training and experience in anesthesiology, nor is it possible for any document or any set of documents or books to substitute for such training. The assessment of anesthetic depth, like driving or flying, is something that can only be learned from experience and practice. One cannot just "do a test"; one has to know which tests to perform, how to perform them, how to interpret them, and how to integrate the results with other streams of real-time data to form an impression or conclusion about anesthetic depth. Learning how to assess anesthetic depth requires formal anesthesia training from individuals who are themselves proficient in the assessment of anesthetic depth. The training necessarily includes extensive clinical experience in which anesthetic depth is assessed over and over again on many patients until one develops the intuitive capacity for doing it accurately and properly.

19. Not surprisingly, the DOC has misinterpreted the ASA guidelines. In addition to listing *some* of the "clinical techniques used to assess intraoperative consciousness," the ASA advisory mentions "conventional monitoring systems" that include "ASA standard monitoring." The audience for whom the Practice Advisory was written understands that "standards for basic anesthetic monitoring" include the measurement of blood pressure. *See* ASA Standards for Basic Anesthetic Monitoring, attached as Exhibit 4. No anesthesiologist would plan to monitor

anesthetic depth (as is necessary during the execution until the prisoner is dead) without measuring the blood pressure. The DOC's proposed protocol does not list this, because the DOC does not understand what is involved in assessing anesthetic depth, and it believes that assessing anesthetic depth is a simple matter that can be conveyed in a few short sentences.

20. Obviously the DOC is now, on the basis of the above criticism, going to revise the protocol by adding the measurement of blood pressure to their laundry list of tests. But this does not address the overarching problem, which is that the DOC believes that it can, without the on-site "in-the-room" supervision of an anesthesiologist, reliably and meaningfully assess (and if needed deepen) anesthetic depth. The very fact that it would propose that these tests be done by personnel untrained in anesthesiology shows that they do not understand what is at stake here.

21. For these reasons, the set of tests listed in the protocol is incomplete and inadequate. In my opinion, an anesthesiologist participating in an execution and exercising his or her medical judgment regarding how to verify and monitor anesthetic depth, given the execution set-up and the chemicals used, would not be satisfied or willing to proceed if they were restricted to this set of tests.

22. Any monitoring of anesthetic depth must test whether the inmate has reached a surgical plane of anesthesia. Some of the techniques listed in the proposed protocol are useful only for testing whether the inmate has reached a relatively shallow plane of anesthesia (an inmate might not respond correctly to verbal commands, and thus appear unconscious according to this technique, yet still be sufficiently aware to suffer when the potassium is injected). It is simply impossible to use personnel untrained in anesthesia to perform some or all of the listed tests, without any understanding of what information each technique can provide and how each fits in to the broad suite of assessment techniques, and gain any assurance that the inmate is in fact sufficiently anesthetized.

23. Moreover, the tests, taken together, are not sufficient to guarantee that the inmate remains sufficiently anesthetized until death. Once the pancuronium paralyzes the inmate, any assessment of anesthetic depth -- which remains necessary because the inmate could regain consciousness before the potassium is injected -- must take into account the fact that the inmate could not respond to stimuli or indicate distress even if he were fully conscious. Verifying the anesthetic depth of an individual paralyzed by pancuronium requires the assessment of extremely subtle indicators of consciousness that do not rely on the activity of facial muscles or any other motor responses. The DOC has not attempted to provide techniques for post-pancuronium monitoring, and obviously untrained personnel do not have any of the experience necessary to perform this type of monitoring.

C. Inadequate Provisions for Obtaining IV Access

24. As I testified during the hearing, successfully and humanely achieving IV access is a crucial element of a humane execution protocol. The provisions regarding IV access set forth in the DOC's new protocol do not, in my opinion, adequately ensure that the process of inserting the IV will be humane, or that the IVs placed will be sufficiently reliable to ensure successful delivery of the chemicals.

25. The Court's order contemplates that the anesthesiologist will have the authority to determine "the most appropriate location on the inmate's body to inject the drugs." I believe that the judge envisions that a board-certified anesthesiologist will exercise his or her medical judgment to determine what catheter location is medically indicated (and therefore "appropriate"), rather than choosing the catheter site based on non-medical considerations. I was concerned that John Doe I stated that he chose to use central lines in part based on the warden's desire to have a rapid execution, rather than on sound medical considerations. As a result of this, he ended up obtaining IV access in a manner that is not used as the first choice in any other setting, medical or execution, because it is much more invasive, painful, and risky. The judge's order is therefore a major improvement over the past practice of automatically placing a central line.

26. The protocol submitted by the DOC simply states that "medical personnel determine the most appropriate locations for" the IV lines. This vague language raises several concerns. It is not clear whether the most appropriate location will be chosen based on medical considerations, or on non-medical factors, such as penological and aesthetic concerns. For instance, John Doe I indicated that he used femoral catheterization, even though it was not medically indicated, in order to ensure that the injections could be performed very quickly.

27. The protocol also does not specify *which* medical personnel will be given authority to decide where to place the catheter. If John Doe I continues to participate in the execution process, I am extremely concerned that he will continue to insert central lines as a matter of course, because, as I testified during the hearing, his medical judgment during executions was in my opinion, rather poor. Moreover, nurses and EMTs do not determine whether to place central lines except in emergent circumstances and, depending on the individual nurse or EMT, may not be competent to make such a decision.

28. If sound medical judgment has determined that a central line is needed, it is also appropriate for a properly trained person to determine which kind of central line to use. Each type of central line (jugular, subclavian, femoral) has its own risks, its own benefits, and its own set of known complications. All types of central lines can lead to catastrophic bleeding. Placing a jugular line risks puncturing or lacerating the carotid artery, a not-infrequent complication, which could lead to a hematoma that obstructs the airway and causes death by asphyxiation if untreated. A massive stroke and paralysis could result from decreased blood flow in the carotid artery. Placing a subclavian line can also cause a pneumothorax, which is a collection of air inside the chest but outside the lungs. This can cause an agonizing death by asphyxiation and cardiovascular collapse. All of these complications are more likely to occur, and less likely to be adequately treated, if the catheterization is performed by personnel who are inadequately trained or inexperienced.

29. Nor does the protocol state whether the execution team will ensure that it has the equipment that is necessary to place central lines and deal with the potential complications of central lines. It is very important that any personnel placing a central line have the equipment necessary to react to the foreseeable complications that are known to arise, many of which are both excruciatingly painful and agonizing. Subclavian lines, for instance, require a bed that can tilt (lowering the head relative to the feet distends the subclavian vein so that the needle and catheter can enter the lumen) and the ability to place a chest tube should a pneumothorax occur.

Personnel placing jugular lines must be prepared, among other things, to intubate the inmate if the airway is obstructed, and must have chest tube capability. In fact, John Doe I agreed that additional equipment was necessary for subclavian lines, and that the execution team was not equipped to place them (although this knowledge did not deter him from using a subclavian line at least once).

30. The protocol also does not specify when the determination as to where to place the catheter is made. If an inmate were examined days or weeks before the execution date, as is the practice in several other states, the determination could be made at that point, and the execution team could be prepared in advance if, for instance, it were decided that only a subclavian line would provide reliable venous access. In contrast, if the determination is made on the night of the execution, the decision to do a central line could necessitate ad hoc improvisation, particularly if the team does not have the equipment necessary to ensure that the procedure is performed safely.

31. The protocol also does not contain adequate provisions for ensuring the patency of the IV lines. As was the case before the Court's order, the DOC intends to inject saline solution into the IV lines just after they are inserted to make sure that they have been inserted properly. There is no plan to monitor the patency of the IV lines during the injection process, however. It is standard medical practice to use an IV bag dripping saline or another solution in conjunction with the IV tubing used to deliver intravenous drugs because doing so enables medical personnel to ensure that fluids are properly flowing through the IV tubing. To my knowledge, this peculiar practice is not used in any other state. The use of the line without a drip was implemented by John Doe I, and so I am worried that the DOC's failure to use an IV bag in the new protocol indicates that John Doe I is still basically in charge of the procedure.

32. The judge commented in his order that the DOC needs to institute contingency plans to provide for foreseeable problems (such as leaking, infiltration, etc.). I completely agree with this. As the above discussion indicates, the DOC has not thought through a number of contingencies that could arise with respect to IV access, including the need to place a central line and failure of one IV line during the injection process. Not to belabor the point, but if a person trained in anesthesia were involved, it would be much less necessary to "game out" all of the contingencies, because that is an inherent and core feature of anesthesiology training.

D. Other Inadequacies in the Protocol

33. I have discussed above what I see as the major problems with the DOC's failure to be responsive to the judge's suggestions. In addition to these problems, there are a number of other unsatisfactory elements of the proposed protocol. The DOC has failed to provide specific instructions with regard to a number of additional issues. This may indicate that the DOC has failed to think through a number of aspects of the execution process, or it may reflect an assumption that execution personnel will improvise or use their discretion in a number of areas, much like what has occurred at previous executions. Either possibility is very concerning.

34. The lack of specific instructions is problematic for a number of reasons. Allowing unchecked discretion to any inadequately qualified individual or group of individuals can lead to errors in judgment and unjustifiable deviations from stated procedures, resulting in increased risk

to the inmate. John Doe I's questionable decisions with regard to aspects of the execution process demonstrate this point. In addition, when untrained or unqualified personnel are given roles in the execution procedure -- though I repeat that they should never be used to assess anesthetic depth in an execution -- increased detail and instructions are necessary to ensure that they can simply follow the steps provided without being forced to exercise their discretion.

35. Following are examples of areas in which the protocol is vague or incomplete.

36. Mixing the Thiopental. The protocol does not provide any instructions as to how the thiopental will be mixed. Most nurses and EMTs have little to no experience mixing anesthetic drugs, and would therefore need detailed instructions to guide them. The instructions provided in the package insert are insufficient in the execution context. Thiopental is generally packaged in 500-mg kits, and the kits are designed so that a medical professional can mix a single clinical dose of thiopental using the materials in the kit. The proposed protocol requires deviating from the instructions in the package insert, which addresses only the preparation of a standard individual dose of 500 mg or less, but does not give concrete mechanical instructions for doing so.

37. Such instructions would protect the inmate from the possibility of ad hoc deviations like those resorted to by John Doe I. He testified that he had created a mixing procedure because the thiopental kits procured by the DOC contained ready-made syringes that already contained the thiopental powder, and were not designed for creating a single overdose of thiopental. This scenario could easily arise again, and the need for untrained personnel to improvise a mixing process could lead to confusion, mistakes, and inability to prepare the full dose of anesthetic. John Doe I's mixing procedure, for instance, did not allow him to prepare the full five-gram dose of thiopental. This is a foreseeable situation and the protocol ought to address it.

38. Nor does the protocol provide any course of action if the execution team is unable to dissolve the thiopental in the diluent. Obviously, this contingency is foreseeable because, based on the testimony, it appears to have occurred in the past. Although the DOC states that the explanation for that problem was the high concentration used by John Doe I, I testified that there are other causes of insolubility, including that the thiopental was defective. The DOC has no way of knowing which explanation is correct, given its failure to collect toxicology data from executed inmates, without testing the thiopental. The DOC should not simply hope and assume that this problem will not recur.

39. Auditing Process. The judge's order discusses an auditing process to correct the previous failure to institute any checks and balances before, during, or after the execution. I think this is an important step because I believe that people will be more motivated to perform executions in a considered, thoughtful, and humane manner if they know that they are being observed. Although the protocol provides that DOC officials will sign off on the chemical log after each execution, there are no on-the-scene checks and balances that can prevent mistakes from occurring during an execution. As I testified at trial, a system of "checks and balances" is critical to ensuring that no one person, whether through inadvertent error or bad faith, can thwart efforts to perform executions humanely.

40. In addition, the protocol states that the medical personnel will complete a "Chemical Log" indicating the quantities of chemicals used and discarded during the execution. As John Doe I testified, however, the document currently used by the DOC as a "Chemical Log" is not designed to allow personnel to record the quantities of chemicals discarded or actually used. Is the DOC going to prepare a new chemical log form? Or are they simply going to continue using the old one? Again, it appears that the DOC simply has not thoroughly considered the need for a means of accurately recording the amounts of chemicals used.

41. Lighting. The Court's order specified that the execution support room should be sufficiently lighted to allow the execution team to see clearly while they perform their tasks. Corrections officials stated that the level of lighting in the execution support room was designed to protect their legitimate interest in obscuring the identities of the execution team, and the interest in ensuring a humane execution by using sufficient lighting is somewhat in tension with the team's security interest. The new protocol states only that the lighting in the execution support room will be "sufficient" to "permit proper administration of the chemicals." It is therefore unclear to me whether and how the DOC plans to resolve the tension described above, and whether the DOC intends to increase the lighting in the support room. I think that the level of lighting should be set by an anesthesiologist, who, based on their clinical experience and practice, knows the level of illumination that is necessary for them to do their job.

42. In his decision, the judge indicated that the new protocol should "specify . . . how the anesthesiologist will certify that the inmate has achieved the appropriate anesthetic depth." I think this is a good suggestion, but the DOC appears not to be interested in following it. No provision is made for communicating to the executioners the medical personnel's conclusion as to whether the inmate is anesthetized. Failing to instruct team members as to how to communicate vital information to each other, and to institute procedures for ensuring that information is communicated accurately, increases the risk of miscues and errors.

III. The DOC's Failure to Recruit an Anesthesiologist

43. Another issue that warrants discussion is the DOC's approach to recruiting an anesthesiologist to participate in executions. My understanding of the judge's order was that the state was required to design a procedure incorporating an anesthesiologist by July 15, but was not required to find an anesthesiologist in this time period. Recruiting is necessarily a somewhat time-consuming process, and clearly the ethical dimensions of participation in executions will somewhat narrow the field of candidates. I would not expect that the State would be able to find an anesthesiologist within the three weeks between the order and the July 15 deadline. Rather, I thought the point of the judge's order was that the State would specify in the protocol that there would be a central role for an anesthesiologist, but that the DOC would not need to identify who would fill that role until an execution approached.

44. Despite the ethical issues that surround this, the reality is that there are many physicians, including anesthesiologists, who, at a personal level, are comfortable with participation in executions. This opinion is backed up by published literature. In an article entitled "Physicians' attitudes about involvement in lethal injection for capital punishment," attached hereto as Exhibit 4, Neil Farber and colleagues surveyed physicians in 2000 and found that 34% approved of eight actions related to the conduct of lethal injection, including actually injecting the drugs. (Arch.

Intern. Med. 2000 Oct. 23; 160(19):2912-6). In a related study, Farber and colleagues found that 25% of physicians would personally perform five or more actions intrinsic to the conduct of lethal injection. ("Physicians' willingness to participate in the process of lethal injection for capital punishment," Ann. Intern. Med. 2001 Nov. 20; 135(10):884-8, attached hereto as Exhibit 5.) Nineteen percent of responding physicians stated that they would personally administer the lethal drugs. While the survey did not specifically target anesthesiologists, I have no reason to believe that the attitude of anesthesiologists would depart markedly from the attitudes of physicians in general.

45. The survey data strongly suggest that, of the several tens of thousands of anesthesiologists in the United States, some significant minority would be willing to participate in executions in the manner envisioned by the court's order. Thus, it appears to me that the DOC has not meaningfully explored the possibility of recruiting an anesthesiologist. While I am not involved in the recruiting side of the medical profession, I do believe that simply sending out 298 letters of the type sent by the DOC would foreseeably fail to attract candidates.

IV. Conclusion

46. I am concerned that the DOC believes that its proposed protocol is adequate, and that it reasonably ensures that this important procedure is performed in a humane and dignified fashion. It appears that the DOC did not understand or appreciate the important issues that were being discussed during the hearing. Overall, the problem is that the DOC does not understand that if pancuronium and potassium are used, an anesthesiologist is necessary to assess anesthetic depth. The procedures proposed by the DOC do not come close to satisfying the standard of care that must be observed whenever a person is subjected to an excruciatingly painful procedure.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Mark Heath, M.D.

Dated: July 24, 2006

Practice Advisory for Intraoperative Awareness and Brain Function Monitoring

A Report by the American Society of Anesthesiologists Task Force on Intraoperative Awareness[*]

PRACTICE advisories are systematically developed reports that are intended to assist decision-making in areas of patient care. Advisories provide a synthesis and analysis of expert opinion, clinical feasibility data, open forum commentary, and consensus surveys. Advisories are not intended as standards, guidelines, or absolute requirements. They may be adopted, modified, or rejected according to clinical needs and constraints.

The use of practice advisories cannot guarantee any specific outcome. Practice advisories summarize the state of the literature and report opinions derived from a synthesis of task force members, expert consultants, open forums and public commentary. Practice advisories are not supported by scientific literature to the same degree as are standards or guidelines because sufficient numbers of adequately controlled studies are lacking. Practice advisories are subject to periodic revision as warranted by the evolution of medical knowledge, technology, and practice.

Methodology

A. Definitions

Intraoperative awareness under general anesthesia is a rare occurrence, with a reported incidence of 0.1-0.2%.[1-4] Significant psychological sequelae (e.g., post traumatic stress disorder) may occur following an episode of intraoperative awareness, and affected patients may remain severely disabled

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Supported by the American Society of Anesthesiologists under the direction of James F. Arens, M.D., Chair, Committee on Practice Parameters. A list of the references used to develop this Advisory is available by writing to the American Society of Anesthesiologists.

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for extended periods of time.[5] However, in some circumstances, intraoperative awareness may be unavoidable in order to achieve other critically important anesthetic goals.

The following terms or concepts discussed in this Advisory include: consciousness, general anesthesia, depth of anesthesia or depth of hypnosis, recall, amnesia, intraoperative awareness, and brain function monitors. Consistent definitions for these terms are not available in the literature. For purposes of this Advisory, these terms are operationally defined or identified as follows:

(1) Consciousness: Consciousness is a state in which a patient is able to process information from his or her surroundings. Consciousness is assessed by observing a patient's purposeful responses to various stimuli. Identifiers of purposeful responses include organized movements following voice commands or noxious/painful stimuli.[†] For example, opening of the eyes is one of several possible identifiers or markers of consciousness. Purposeful responses may be absent when paralysis is present as a consequence of neurological disease or the administration of a neuromuscular blocking drug.

(2) General anesthesia: General anesthesia is defined as a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation.[‡] The ability to maintain ventilatory function independently is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

(3) Depth of anesthesia: Depth of anesthesia or depth of hypnosis refers to a continuum of progressive central nervous system depression and decreased responsiveness to stimulation.

[†] Reflex withdrawal from a painful stimulus is NOT considered a purposeful response, as indicated by the "continuum of depth of sedation, definition of general anesthesia, and levels of sedation/analgesia;" American Society of Anesthesiologists, 2004.

[‡] American Society of Anesthesiologists: Continuum of depth of sedation, definition of general anesthesia, and levels of sedation/analgesia;" ASA Standards, Guidelines and Statements, 2004.

(4) Recall: For the purpose of this Advisory, recall is the patient's ability to retrieve stored memories. Recall is assessed by a patient's report of previous events, in particular, events that occurred during general anesthesia. *Explicit memory* is assessed by the patient's ability to recall specific events that took place during general anesthesia. *Implicit memory* is assessed by changes in performance or behavior without the ability to recall specific events that took place during general anesthesia that led to those changes.[6] A report of recall may be spontaneous or it may only be elicited in a structured interview or questionnaire. This Advisory does not address implicit memory.

(5) Amnesia: Amnesia is the absence of recall. Many anesthetic drugs produce amnesia at concentrations well below those necessary for suppression of consciousness. Anterograde amnesia is intended when a drug with amnestic properties is administered before induction of anesthesia. Retrograde amnesia is intended when a drug such as a benzodiazepine is administered after an event that may have caused or been associated with intraoperative consciousness in the hope that it will suppress memory formation and "rescue" from recall.

(6) Intraoperative awareness: Intraoperative awareness occurs when a patient becomes conscious during a procedure performed under general anesthesia and subsequently has recall of these events. For the purpose of this Advisory, recall is limited to explicit memory, and does not include the time before general anesthesia is fully induced or the time of emergence from general anesthesia, when arousal and return of consciousness are intended. Dreaming is not considered intraoperative awareness.

(7) Brain function monitors: Brain function monitors are devices that record or process brain electrical activity and convert these signals mathematically into a continuous measure typically scaled from 0 to 100. In addition to spontaneous cortical electrical activity (electroencephalogram, EEG), these devices may also record and process evoked cortical and

subcortical activity (auditory evoked potentials, or AEP) as well as electromyographic (EMG) activity from scalp muscles. For the purpose of this Advisory, only monitors purported to measure depth of anesthesia or hypnosis will be considered. Other, non-EEG/AEP/EMG devices are also available, but are not addressed by this Advisory.

B. Purposes of the Advisory

Intraoperative awareness under general anesthesia is an important clinical problem that clearly is within the foundation of training and continuing medical education in anesthesiology. The purposes of this Advisory are to identify risk factors that may be associated with intraoperative awareness, provide decision tools that may enable the clinician to reduce the frequency of unintended intraoperative awareness, stimulate the pursuit and evaluation of strategies that may prevent or reduce the frequency of intraoperative awareness, and provide guidance for the intraoperative use of brain function monitors as they relate to intraoperative awareness.

C. Focus

This Advisory focuses on the perioperative management of patients who are undergoing a procedure during which general anesthesia is administered. This Advisory is not intended for the perioperative management of minimal, moderate, or deep sedation in the OR or ICU; regional or local anesthesia without general anesthesia; monitored anesthesia care; tracheal intubation of patients or those undergoing resuscitation in emergency trauma after the administration of a neuromuscular block, or intentional intraoperative wake-up testing (e.g., for the purposes of assessing intraoperative neurologic function). In addition, this Advisory is not intended to address the perioperative management of pediatric patients.

D. Application

This Advisory is intended for use by anesthesiologists, other physicians who supervise the administration of general anesthesia, and all other individuals who administer general anesthesia.

The Advisory may also serve as a resource for other physicians and health care professionals who are involved in the perioperative management of patients receiving general anesthesia.

E. Task Force Members and Consultants

The American Society of Anesthesiologists (ASA) appointed this Task Force of 10 members to (1) review and assess the currently available scientific literature on intraoperative awareness, (2) obtain expert consensus and public opinion, and (3) develop a practice advisory. The Task Force is comprised of anesthesiologists from various geographic areas of the United States, an anesthesiologist from the Netherlands, and two methodologists from the ASA Committee on Practice Parameters.

The ASA appointed the 10 members to the Task Force because of their knowledge or expertise in the medical specialty of anesthesiology, and the development of practice parameters. The members include but are not limited to anesthesiologists with specialized knowledge or expertise in the area of neuroanesthesiology. Two of the 10 members disclosed receipt of funds from or a financial interest in a company developing or manufacturing brain function monitors, which companies have a direct financial interest in the expanded use of such monitors. Other members may have received funds from or have a financial interest in other companies, such as developers or manufacturers of anesthetics, that may be indirectly affected by the expanded use of brain function monitors. The Task Force did not request its members to disclose such interests because they were deemed too remote and speculative to present conflicts of interest.

The Task Force, in turn, sought input from consultants, many of whom who had particularized knowledge, expertise and/or interest in intraoperative awareness and brain function monitors. Such knowledge or expertise is based in part in some cases on research or investigational activities funded by a company developing or manufacturing brain function monitors. Fifty-four percent of the consultants disclosed receipt of funds from or a financial interest in a company developing or

manufacturing brain function monitors. Consultants also may have received funds from or have a financial interest in other companies that may be indirectly affected by the use of brain function monitors. The Task Force did not request its consultants to disclose such interests because they were deemed too remote and speculative to present conflicts of interest.

The Task Force used a six-step process. First, the members reached consensus on the criteria for evidence of effective perioperative interventions for the prevention of intraoperative awareness. Second, they evaluated original articles published in peer-reviewed journals relevant to this issue. Third, consultants who had expertise or interest in intraoperative awareness and who practiced or worked in diverse settings (e.g., scientists and/or physicians in academic and private practice) were asked to participate in opinion surveys on the effectiveness of various perioperative management strategies, and to review and comment on a draft of the Advisory developed by the Task Force. Fourth, additional opinions were solicited from a random sample of active members of the ASA. Fifth, the Task Force held open forums at three national and international anesthesia meetings to solicit input on the key concepts of this Advisory. Sixth, all available information was used to build consensus within the Task Force on the Advisory.

The draft document was made available for review on the ASA website, and commentary was invited via e-mail announcement to all ASA members. All submitted comments were considered by the Task Force in preparing the final draft.

F. Availability and Strength of Evidence

Practice advisories are developed by a protocol similar to that of an ASA evidence-based practice guideline, including a systematic search and evaluation of the literature. However, practice advisories lack the support of a sufficient number of adequately controlled studies to permit aggregate analyses of data with rigorous statistical techniques such as meta-analysis. Nonetheless, literature-based evidence from case reports and other descriptive studies are considered during the

development of the Advisory. This literature often permits the identification of recurring patterns of clinical practice.

As with a practice guideline, formal survey information is collected from consultants and members of the ASA. The following terms describe survey responses for any specified issue. Responses are solicited on a 5-point scale; ranging from 1 (strongly disagree) to 5 (strongly agree) with a score of 3 being equivocal. Survey responses are summarized based on median values as follows:

Strongly Agree:	Median score of 5 (At least 50% of the responses are 5)
Agree:	Median score of 4 (At least 50% of the responses are 4 or 4 and 5)
Equivocal:	Median score of 3 (At least 50% of the responses are 3, or no other response category or combination of similar categories contain at least 50% of the responses)
Disagree:	Median score of 2 (At least 50% of responses are 2 or 1 and 2)
Strongly Disagree:	Median score of 1 (At least 50% of responses are 1)

Additional information is obtained from open forum presentations and other invited and public sources. The advisory statements contained in this document represent a distillation of the current spectrum of clinical opinion and literature-based findings.[§]

Advisories

I. Preoperative Evaluation

A preoperative evaluation includes (1) obtaining a focused history (i.e., medical records, laboratory reports, patient or patient and family interview), (2) conducting a physical examination, (3) identifying patients at risk for intraoperative awareness (e.g., planned anesthetics, type of surgery), and (4) informing selected patients of the possibility of intraoperative awareness.

Descriptive studies and case reports suggest that certain patient characteristics may be associated with intraoperative awareness, including age, gender, ASA status, and drug resistance or tolerance.[4,7-

[§] Refer to appendix 1 for a summary of the advisories.

[11] Descriptive studies and case reports suggest that certain procedures (e.g., cesarean section, cardiac surgery, trauma surgery) [4,8,12-29] as well as anesthetic techniques (e.g., rapid-sequence induction, reduced anesthetic doses with or without the presence of paralysis)[2,3,9,13,16,21, 23,30-33] may be associated with an increased risk of intraoperative awareness. No studies were found that examined the clinical impact of informing the patient prior to surgery of the possibility of intraoperative awareness.

The consultants and ASA members agree that a preoperative evaluation may be helpful in identifying patients at risk for intraoperative awareness.[**] In addition, they agree that a focused preoperative evaluation to identify patients at risk of intraoperative awareness should include review of a patient's medical record, a thorough physical examination, and a patient or patient and family interview. They agree that patient characteristics that may place a patient at risk for intraoperative awareness include: substance use or abuse, limited hemodynamic reserve, and ASA status of 4 or 5. The consultants strongly agree and the ASA members agree that a history of intraoperative awareness may place a patient at risk. The consultants disagree and the ASA members are equivocal regarding whether all patients should be informed of the possibility of intraoperative awareness. The consultants strongly agree and the ASA members agree that only patients considered to be at elevated risk of intraoperative awareness should be informed of the possibility of intraoperative awareness. Finally the consultants and the ASA members disagree that informing the patient preoperatively of the risk of intraoperative awareness increases the *actual* risk of intraoperative awareness.

Advisory. The Task Force believes that some components of the preoperative evaluation may be useful in identifying a patient at increased risk for awareness. An evaluation should include, if possible, a review of a patient's medical records for previous occurrences of awareness or other potential risk factors, a patient interview to assess level of anxiety or previous experiences with anesthesia, and a physical examination. Potential risk factors to consider for patients undergoing

[**] Refer to appendix 2 for complete results of the consultant and ASA membership surveys.

general anesthesia include substance use or abuse (e.g., opioids, benzodiazepines, cocaine), a history of awareness, a history of difficult intubation or anticipated difficult intubation, chronic pain patients on high doses of opioids, cardiac surgery, Cesarean section, trauma and emergency surgery, reduced anesthetic doses in the presence of paralysis, planned use of muscle relaxants during the maintenance phase of general anesthesia, total intravenous anesthesia, the planned use of nitrous oxide-opioid anesthesia, ASA status of 4 or 5, and limited hemodynamic reserve. The consensus of the Task Force is that patients whom the individual clinician considers to be at substantially increased risk of intraoperative awareness should be informed of the possibility of intraoperative awareness when circumstances permit.

II. Preinduction Phase of Anesthesia

Issues concerned with the preinduction phase of anesthesia related to the prevention of intraoperative awareness include checking the functioning of anesthesia delivery systems, and the prophylactic administration of benzodiazepines.

Although checking the functioning of anesthesia delivery systems is standard practice, some cases of intraoperative awareness have resulted from too low concentrations of inspired volatile anesthetics or drug errors, including drug delivery errors.[8,34-39] One double-blind randomized clinical trial evaluated the efficacy of the prophylactic administration of midazolam as an anesthetic adjuvant during ambulatory procedures under total intravenous anesthesiaand reported a lower frequency of intraoperative awareness in the midazolam groups compared to the placebo group.[40] Two randomized clinical trials examined anterograde amnesia by providing pictures as stimuli after administration of midazolam but before induction of general anesthesia. Although these studies reported reduced recall in patients administered midazolam, the presence of consciousness during general anesthesia and subsequent intraoperative awareness was not examined.[41,42]

The consultants and ASA members strongly agree that the functioning of anesthesia delivery systems (e.g., vaporizers, infusion pumps, fresh gas flow, IV lines) should be checked to reduce the risk of intraoperative awareness. The consultants disagree, and the ASA members are equivocal that a benzodiazepine or scopolamine should be used as a component of the anesthetic to reduce the risk of intraoperative awareness for *all* patients. The consultants agree that a benzodiazepine or scopolamine should be used for patients requiring smaller dosages of anesthetics, patients undergoing cardiac surgery, and patients undergoing trauma surgery. They are equivocal regarding patients undergoing Cesarean section, emergency surgery, and with total intravenous anesthesia. The ASA members agree that a benzodiazepine or scopolamine should be used for patients requiring smaller dosages of anesthetics, patients undergoing cardiac surgery, emergency surgery, trauma surgery, and total intravenous anesthesia. They are equivocal regarding patients undergoing Cesarean section.

Advisory. Since intraoperative awareness may be caused by equipment malfunction or misuse, the Task Force believes that there should be adherence to a checklist protocol for anesthesia machines and equipment to assure that the desired anesthetic drugs and doses will be delivered. These procedures should be extended to include verification of the proper functioning of intravenous access, infusion pumps and their connections. The Task Force consensus is that the decision to administer a benzodiazepine prophylactically should be made on a case-by-case basis for selected patients (e.g., patients requiring smaller dosages of anesthetics). The Task Force cautions that delayed emergence may accompany the use of benzodiazepines.

III. Intraoperative Monitoring

Intraoperative awareness cannot be measured during the intraoperative phase of general anesthesia, since the recall component of awareness can only be determined postoperatively by obtaining information directly from the patient. Therefore, the primary issue regarding intraoperative

monitoring addressed by this Advisory is whether the use of clinical techniques, conventional monitoring systems, or brain function monitors reduce the occurrence of intraoperative awareness.

The majority of literature obtained during the search and review process did not directly address whether these techniques, systems, or monitors reduce the frequency of intraoperative awareness. However, many studies were found that report intraoperative measures or index values from monitoring activities. This literature, while not directly assessing the impact of an intervention on awareness, often reported patterns or values that occurred at identifiable times during the perioperative period with the intention of describing or predicting variations in the depth of anesthesia. Therefore, commonly reported findings from this literature are summarized below.

The literature for each intervention is presented in the following order: (1) randomized clinical trials, (2) nonrandomized comparative studies (e.g., quasi-experimental, prospective cohort studies), (3) correlational studies (e.g., correlations of index values with end-tidal concentrations of hypnotic drugs or with movement in response to noxious stimuli), (4) descriptive reports of monitor index values at particular times during a procedure; and (5) case reports of unusual or unintended benefits or harms occurring during a monitoring activity. Correlational studies often report a measure of association between two continuous variables (e.g., the correlation between index values and anesthetic drug concentrations). Other correlational measures include a prediction probability (Pk) value that provides a measure of how well a monitor or technique can differentiate between two different clinical states (e.g., response versus no response to verbal command).[43] A Pk value of 1.0 indicates perfect association between an index value and a clinical state, while a Pk value of 0.50 indicates a prediction probability equal to chance.

A. Clinical Techniques and Conventional Monitoring:

Among the clinical techniques utilized to assess intraoperative consciousness are checking for movement, response to commands, opened eyes, eyelash reflex, pupillary responses or diameters,

perspiration and tearing. Conventional monitoring systems include ASA standard monitoring[††] as well as the end-tidal anesthetic analyzer.

No clinical trials or other comparative studies were found that examine the effect of clinical techniques or conventional monitoring on the incidence of intraoperative awareness. Correlational studies reported Pk values ranging from 0.74 to 0.76 for the association between reflex or purposeful movement and indicators for depth of anesthesia.[44] One study reported a significant association between response to command and memory when continuous infusions of propofol were used as the induction anesthetic.[45] Pk values for mean arterial pressure (MAP) ranged from 0.68 to 0.94 for distinguishing a responsive state from an unresponsive state, and from 0.81 to 0.89 for distinguishing an anesthetized state from emergence following anesthesia (i.e., first response). Pk values for heart rate (HR) ranged from 0.50 to 0.82 for distinguishing a responsive state from an unresponsive state, and from 0.54 to 0.67 for emergence.[46-48] Wide ranges of mean MAP and HR values were reported during various intraoperative times. Studies reported ranges of mean MAP values as follows: before induction or baseline, 90 to 103 mmHg; at induction, 58.4 to 88 mmHg; during surgery, 78 to 102 mmHg; at emergence or end of surgery, 58.7 to 97 mmHg; and during postoperative recovery, 86 to 104mmHg. Mean HR ranges were reported as follows: before induction or baseline, 61 to 82 bpm; at induction, 55 to 67 bpm; during surgery, 74 to 82 bpm; at emergence or end of surgery, 59 to 92 bpm; and during postoperative recovery, 82 to 89 bpm.[49-56] Awareness has been reported to occur in the absence of tachycardia or hypertension.[8,23,24]

The consultants and ASA members agree that clinical techniques (e.g., checking for purposeful or reflex movement) are valuable and should be used to assess intraoperative consciousness. In addition, the consultants and ASA members agree that conventional monitoring systems (e.g, ECG,

[††] American Society of Anesthesiologists: Standards for basic anesthetic monitoring. *In* ASA Standards, Guidelines and Statements; American Society of Anesthesiologists Publication: October, 2004.

BP, HR, end-tidal anesthetic analyzer, capnography) are valuable and should be used to help assess intraoperative consciousness.

B. Brain Electrical Activity Monitoring:

Most of the devices designed to monitor brain electrical activity for the purpose of assessing anesthetic effect record electroencephalographic (EEG) activity from electrodes placed on the forehead. Systems can be subdivided into those that process spontaneous EEG and electromyographic (EMG) activity and those that acquire evoked responses to auditory stimuli (auditory evoked potential, AEP). After amplification and conversion of the analog EEG signal to the digital domain, various signal processing algorithms are applied to the frequency, amplitude, latency and/or phase relationship data derived from the raw EEG or AEP to generate a single number, often referred to as an "index" typically scaled between 100 and zero. This index represents the progression of clinical states of consciousness ('awake', 'sedated', 'light anesthesia', 'deep anesthesia'), with a value of 100 being associated with the awake state, and values of zero occurring with an isoelectric EEG (or absent middle latency AEP). These processing algorithms may either be published and in the public domain or proprietary. Detailed descriptions of the various approaches to EEG signal processing, including bispectral analysis may be found elsewhere.[57] Artifact recognition algorithms intended to avoid contaminated, and therefore spurious, 'index' values are an important component of the software in most monitors.

Although EMG activity from scalp muscles can be considered an artifact from the viewpoint of pure EEG analysis, it may be an important source of clinically relevant information. Sudden appearance of frontal (forehead) EMG activity suggests somatic response to noxious stimulation resulting from inadequate analgesia and may give warning of impending arousal. For this reason, some monitors separately provide information on the level of EMG activity.

1. Spontaneous EEG Activity Monitors.

Bispectral Index. Bispectral index (BIS) is a proprietary algorithm (Aspect Medical Systems) that converts a single channel of frontal EEG into an index of hypnotic level (bispectral index; BIS). BIS is available either as a separate device (BIS monitor; Aspect Medical Systems) or incorporated - under license from Aspect Medical Systems - in 'BIS modules' made by various anesthesia equipment manufacturers. To compute the BIS, several variables derived from the EEG time domain (burst-suppression analysis), frequency domain (power spectrum, bispectrum: interfrequency phase relationships) are combined into a single index of hypnotic level. BIS values are scaled from 0 to 100, with specific ranges (e.g., 40-60) reported to reflect a low probability of consciousness under general anesthesia. The weight factors for the various components in the multivariate model that generates the BIS were empirically derived from a prospectively collected database of over 1500 anesthetics. The BIS model accounts for the nonlinear stages of EEG activity by allowing different parameters to dominate the resulting BIS as the EEG changes its character with increasing plasma concentrations of various anesthetics, resulting in a linear decrease in BIS. As more data have become available and as methods and algorithms to suppress artifacts have been improved, revised iterations of the algorithm and optimized hardware have been released.

Several RCTs have compared outcomes with BIS-guided anesthetic administration versus standard clinical practice without BIS. In one RCT that enrolled 2500 patients at high risk of intraoperative awareness, explicit recall occurred in 0.17% of patients when BIS monitors were used and in 0.91% of patients managed by routine clinical practice ($p < 0.02$).[58] A small ($N = 30$) single-blinded RCT (i.e., the anesthesiologists were blinded to the recorded BIS values) compared BIS monitoring with clinical signs during cardiac surgery), and reported one episode of recall in the clinical signs group compared to no episodes in the BIS-monitored group ($p > 0.50$).[59] In other RCTs, times to awakening, first response, or eye opening and consumption of anesthetic

drugs were reduced with the use of BIS.[8,60-68]

One nonrandomized comparison of the use of BIS monitoring versus a cohort of historical controls (N = 12,771) found explicit recall occurring in 0.04% of the BIS monitored patients versus 0.18% of the historical controls ($p < 0.038$).[68] Another prospective nonrandomized cohort study (N = 19,575) designed to establish the incidence of awareness with recall during routine general anesthesia and to determine BIS values associated with intraoperative awareness events reported no statistically significant difference when BIS was used (0.18% of patients) compared to when BIS was not used (0.10% of patients). Other nonrandomized comparative studies reported higher index values upon arrival in the PACU, shorter recovery times, and lower anesthetic usage among patients monitored with BIS compared to patients not monitored with BIS.[70,71] Numerous correlational studies reported Pk values for BIS ranging from 0.72 to 1.00 for awake versus loss of response following induction with propofol (with or without opioids); and from 0.79 to 0.97 for anesthetized versus first response.[46-48,72-78] One study reported a Pk value of 0.86 for movement from electrical stimulation.[44] Wide ranges of mean BIS values have been reported during various intraoperative times. Ranges of mean BIS values were as follows: before induction or baseline, 80 to 98; at or after induction, 37 to 70; during surgery, 20 to 58; at emergence or end of surgery, 42 to 96; and during postoperative recovery, 64 to 96.[50,51,54-56,79-110] Several case reports indicate that intraoperative events unrelated to titration of anesthetic agents can produce rapid changes in BIS values, e.g., cerebral ischemia or hypoperfusion, gas embolism, unrecognized hemorrhage, inadvertent blockage of anesthesia drug delivery.[111-119] Other case reports suggest that routine intraoperative events (e.g., administration of depolarizing muscle relaxants, activation of electromagnetic equipment or devices, patient warming or planned hypothermia) may interfere with BIS functioning.[120-128] Two case reports were found that reported patients experiencing intraoperative awareness in spite of monitored values indicating an

adequate depth of anesthesia.[129,130] Finally, still other case reports suggested that certain patient conditions may affect BIS values.[131-133]

Entropy. Entropy (GE Healthcare Technologies) describes the irregularity, complexity, or unpredictability characteristics of a signal. A single sine wave represents a completely predictable signal (entropy = 0), whereas noise from a random number generator represents entropy = 1. The algorithm for calculation of entropy in the EEG signal (as incorporated in the Datex-Ohmeda S/5 entropy Module) is in the public domain and detailed descriptions have recently been published.[134]

Entropy is independent of absolute scales such as the amplitude or the frequency of the signal. The commercially available Datex-Ohmeda module calculates entropy over time windows of variable duration and reports two separate entropy values. State entropy (SE) is an index ranging from zero to 91 (awake), computed over the frequency range from 0.8 Hz to 32 Hz, reflecting the cortical state of the patient. Response Entropy (RE) is an index ranging from zero to 100 (awake) computed over a frequency range from 0.8 Hz to 47 Hz, containing the higher EMG-dominated frequencies, and will thus also respond to the increased EMG activity resulting from inadequate analgesia. No clinical trials or other comparative studies were found that examine the impact of entropy monitoring on the incidence of intraoperative awareness. One clinical trial reported reduced times to eye opening, response to command, and consumption of anesthetic drugs with the use of entropy monitoring.[135]

Correlational studies report the following Pk values for loss of consciousness: for RE, 0.83 to 0.97; for SE, 0.81 to 0.90.[45,136-137] For anesthetized versus first response, the following Pk values are reported: for RE, 0.85; and for SE, 0.82.[46] Ranges of mean RE and SE values were as follows: before induction or baseline, 98 (RE) and 89 to 91 (SE); during surgery, 34 to 52 (RE) and 50 to 63 (SE); and at emergence or end of surgery, 96 (RE) and 85 (SE).[52,135,138,139]

Narcotrend. The Narcotrend (MonitorTechnik) is derived from a system developed for the visual classification of the EEG patterns associated with various stages of sleep. After artifact exclusion and Fourier transformation, the original electronic algorithm classified the raw (frontal) EEG according to the following system: A (awake), B (sedated), C (light anesthesia), D (general anesthesia), E (general anesthesia with deep hypnosis), F (general anesthesia with increasing burst suppression). The system included a series of sub-classifications resulting in a total of 14 possible sub-stages: A, B0–2, C0–2, D0–2, E0–1, and F0–1.[140] In the most recent iteration of the Narcotrend software (version 4.0), the alphabet-based scale has been "translated" into a dimensionless index, the Narcotrend index, scaled from zero (deeply anesthetized) to 100 (awake), with the stated intention of producing a scale quantitatively similar to the BIS index.

No clinical trials or other comparative studies were found that examine the impact of Narcotrend monitoring on the incidence of intraoperative awareness. One RCT has compared the use of Narcotrend-controlled versus clinically controlled anesthetic administration and found a shorter recovery time in the Narcotrend group (i.e., opened eyes) after termination of anesthesia.[63] Pk values for Narcotrend ranged from 0.93 to 0.99 for awake versus loss of response following induction with propofol combined with an opioid, and from 0.94 to 0.99 for anesthetized versus first response.[47,48] Reported mean Narcotrend values are as follows: after induction (loss of response), 72 to 80; and at emergence or end of surgery (spontaneously opened eyes), 80.[73]

Patient State Analyzer. The Patient State Index, or PSI (Physiometrix) is derived from a 4-channel EEG. The derivation of the PSI is based on the observation that there are reversible spatial changes in power distribution of quantitative EEG at loss and return of consciousness. The Patient State Index (PSI) has a range of 0 to 100, with decreasing values indicating decreasing levels of consciousness or increasing levels of sedation, similar to BIS, Entropy and Narcotrend. The PSI algorithm was constructed using stepwise, discriminant analysis based on

multivariate combinations of quantitative EEG variables, derived after Fourier transformation of the raw EEG, and found to be sensitive to changes in the level of anesthesia.

No clinical trials or other comparative studies were found that examine the impact of PSI monitoring on the incidence of intraoperative awareness. One correlational study reported a Pk value of 0.70 for predicting response to command, with a sensitivity of 85.6% and specificity of 38.8%,[77] and another study reported a significant correlation of the PSI with unconsciousness.[141] Reported mean PSI values are as follows: before induction or baseline, 92; during surgery, 32; at emergence or end of surgery, 53; and during postoperative recovery, 81.[141]

SNAP index. The SNAPII (Everest Biomedical Instruments) calculates a "SNAP index" from a single channel of EEG. The index calculation is based on a spectral analysis of EEG activity in the 0-18 Hz and 80-420 Hz frequency ranges, and a burst suppression algorithm. There are no published data on the actual algorithm used to calculate the SNAP index, which is based on a composite of both low (0-40 Hz) and high (80-420 Hz) frequency components.

No clinical trials or other comparative studies were found that examine the impact of SNAP monitoring on the incidence of intraoperative awareness. One correlational study was found that reported a mean SNAP index of 71 to be predictive of a loss of consciousness in 95% of elective surgery patients.[142]

Danmeter Cerebral State Monitor/Cerebral State Index. The Danmeter CSM is a handheld device that analyzes a single channel EEG and presents a cerebral state 'index' scaled from 0-100. In addition, it also provides EEG suppression percentage and a measure of EMG activity (75-85 Hz).

No published literature was found that examined the impact of Danmeter CSM monitoring on the incidence of intraoperative awareness.

2. Evoked Brain Electrical Activity Monitors.

AEP Monitor/2 (Danmeter). Auditory evoked potentials (AEP) are the electrical responses of the brainstem, the auditory radiation and the auditory cortex to auditory sound stimuli (clicks) delivered via headphones. The effects of anesthetics on AEP have been studied since the early 1980s.[143-145] The brainstem response is relatively insensitive to anesthetics while early cortical responses, known as the middle-latency AEP (MLAEP) change predictably with increasing concentrations of both volatile and intravenous anesthetics. The typical AEP response to increasing anesthetic concentrations is increased latency and decreased amplitude of the various waveform components. These signals are extremely small (less than one microvolt) necessitating extraction from the spontaneous EEG using signal averaging techniques. Prior to recent innovations, signal averaging was relatively time consuming (several minutes per averaged waveform). More recent signal filtering advances have resulted in an instrument (A-Line) that can record and rapidly update a single channel of AEP from forehead electrodes. From a mathematical analysis of the AEP waveform, the device generates an 'AEP-index' that provides a correlate of anesthetic concentration. The AEP index, or AAI, is scaled from 0 to 100. In contrast to many EEG indices, the AAI corresponding with low probability of consciousness is less than 25, rather than the higher numeric thresholds associated with the other monitors. The device is FDA approved but is not currently marketed in North America.

RCTs that compared MLAEP monitoring (e.g., to titrate anesthetics) to standard clinical practice without MLAEP reported reduced times to eye opening or orientation.[63,64,146] A Pk value of 0.79 was reported for loss of eyelash reflex following induction with propofol and an opioid,[74] and Pk values of 0.63 and 0.66 were reported for responsiveness following discontinuation of remifentanil or sevoflurane, respectively.[147] One study reported a Pk value of 0.87 for movement,[148] and another study reported a Pk value of 0.99 for awareness after LMA insertion,[149] Descriptive studies reported ranges of mean values as follows: before induction or baseline, 73.5

to 85; at or after induction, 33.4 to 61; during surgery, 21.1 to 37.8; at emergence or end of surgery, 24.6 to 40; and during postoperative recovery, 89.7.[74,80,144,150-151]

C. Consultant and ASA Member Survey Findings.

Consultants who participated in this Advisory typically either had a particular knowledge or an expressed interest in intraoperative awareness and brain function monitors. The majority of these consultants disclosed receipt of funds from or a financial interest in a company developing or manufacturing brain function monitors. Consultants were not asked to disclose similar relationships with other companies that may be indirectly affected by the use of brain function monitors. ASA members were randomly selected from a list of active members of the society.

The consultants and ASA members disagree that a brain electrical activity monitor is valuable and should be used to reduce the risk of *intraoperative awareness* for *all* patients. The consultants and ASA members disagree that a brain electrical activity monitor is valuable and should be used to reduce the risk of intraoperative awareness for *no* patient. The consultants agree that a brain electrical activity monitor should be used for patients with conditions that may place them at risk, patients requiring smaller doses of general anesthetics, trauma surgery, Cesarean section, and total intravenous anesthesia. They are equivocal regarding the use of brain electrical activity monitoring for cardiac surgery and emergency surgery. The ASA members agree with the use of such monitors for patients with conditions that may place them at risk, patients requiring smaller doses of general anesthetics, and patients undergoing cardiac surgery. They are equivocal regarding the use of these monitors for patients undergoing Cesarean section, emergency surgery, trauma surgery, and total intravenous anesthesia.

The consultants and ASA members disagree that a brain electrical activity monitor is valuable and should be used to assess intraoperative *depth of anesthesia* for *all* patients. The consultants and ASA members disagree with the statement that “a brain electrical activity monitor is valuable and

should be used to assess intraoperative depth of anesthesia for *no* patient." The consultants agree that a brain electrical activity monitor should be used to assess intraoperative depth of anesthesia for selected patients. The ASA members agree with the use of brain electrical activity monitors for patients with conditions that may place them at risk and patients requiring smaller doses of general anesthetics. They are equivocal regarding the use of such monitors for patients undergoing cardiac surgery, Cesarean section, emergency surgery, trauma surgery, and total intravenous anesthesia.

Advisory. Intraoperative monitoring of depth of anesthesia, for the purpose of minimizing the occurrence of awareness, should rely on multiple modalities, including clinical techniques (e.g., checking for clinical signs such as purposeful or reflex movement) and conventional monitoring systems (e.g., ECG, BP, HR, end-tidal anesthetic analyzer, capnography). The use of neuromuscular blocking drugs may mask purposeful or reflex movements, and adds additional importance to the use of monitoring methods that assure the adequate delivery of anesthesia.

Brain function monitors are dedicated to the assessment of the effects of anesthetics on the brain, and provide information that correlates with some depth of anesthesia indicators, such as plasma concentrations of certain anesthetics (e.g., propofol). In general, the indices generated by these monitors vary in parallel with other established correlates of depth of anesthesia, although the values generated by individual devices in any given anesthetic state differ among the various monitoring technologies. In addition, the values generated by individual devices in the face of a given depth of anesthesia achieved by different combinations of anesthetic drugs (e.g., with or without opioids) will also differ. In other words, a specific numerical value may not correlate with a specific depth of anesthesia. Furthermore, the measured values do not have uniform sensitivity across different anesthetic drugs or types of patients. As with other monitors, common occurrences in the OR may introduce artifacts into the values derived by these monitors (e.g., electrocautery, lasers, warming devices).

The general clinical applicability of these monitors in the prevention of intraoperative awareness has not been established. While a single randomized clinical trial reported a decrease in the frequency of awareness in high-risk patients, there is insufficient evidence to justify a standard, guideline, or absolute requirement that these devices be used to reduce the occurrence of intraoperative awareness in high-risk patients undergoing general anesthesia. In addition, there is insufficient evidence to justify a standard, guideline, or absolute requirement that these devices be used to reduce the occurrence of intraoperative awareness for any other group of patients undergoing general anesthesia.

It is the consensus of the Task Force that brain function monitoring is not routinely indicated for patients undergoing general anesthesia, either to reduce the frequency of intraoperative awareness or to monitor depth of anesthesia. This consensus is based, in part, on the state of the literature and survey responses from the consultants and ASA membership, who generally disagree with the following statements: "Brain function monitors are valuable and should be used to reduce the risk of intraoperative awareness for all patients under general anesthesia," and "Brain function monitors are valuable and should be used when possible to assess intraoperative depth of anesthesia for all patients under general anesthesia" (see above and tables 1 and 2).

It is the consensus of the Task Force that the decision to use a brain function monitor should be made on a case-by-case basis by the individual practitioner for selected patients (e.g., light anesthesia). This consensus is based, in part, on the state of the literature and survey response patterns from consultants and ASA members regarding specific risk factors (see above and tables 1 and 2). The Task Force cautions that maintaining low brain function monitor values in an attempt to prevent intraoperative awareness may conflict with other important anesthesia goals (e.g., preservation of vital organ functions, minimizing the risks of aggravating existing co-morbidities [152]). It is the opinion of the Task Force that brain function monitors currently have the status of the many

other monitoring modalities that are currently used in selected situations at the discretion of individual clinicians.

IV. Intraoperative and Postoperative Interventions

Intraoperative and postoperative interventions include: (1) the intraoperative administration of benzodiazepines to patients who may have become conscious, (2) providing a postoperative structured interview to patients to define the nature of the episode after an episode of intraoperative awareness has been reported, (3) providing a postoperative questionnaire to patients to define the nature of the episode, and (4) offering postoperative counseling or psychological support.

No studies were found that evaluated the efficacy of the intraoperative administration of benzodiazepines to patients who have unexpectedly become conscious in reducing the occurrence of awareness. Two randomized clinical trials examined retrograde amnesia by providing pictures as stimuli to awake patients before administration of midazolam and induction of general anesthesia. The studies reported no evidence of retrograde amnesia.[41,42] However, these studies did not examine the effect of administering a benzodiazepine to patients after the apparent occurrence of consciousness during general anesthesia.

Although several studies have applied structured interviews and questionnaires to obtain additional information about reported incidences of intraoperative awareness,[4,11,26,28,153-157] no studies were found that demonstrated improvements in patient well-being or psychological state following such interactions. No studies were found that followed up on the efficacy of counseling or psychological support provided to patients who experienced a documented incidence of intraoperative awareness.

The consultants are equivocal and ASA members agree that benzodiazepines or scopolamine should be administered intraoperatively to prevent awareness after a patient has unexpectedly become conscious. The consultants strongly agree, and the ASA members agree that, once an episode of

intraoperative awareness has been reported, a structured interview should be conducted to define the nature of the episode. Both the consultants and ASA members are equivocal regarding whether a questionnaire should be given to define the nature of the episode. The consultants strongly agree, and the ASA members agree that, in documented cases of intraoperative awareness, patients should be offered counseling or psychological support. Finally, the consultants strongly agree, and the ASA members agree that, in documented cases of intraoperative awareness, an occurrence report concerning the event should be completed for the purpose of quality management.

Advisory. The Task Force consensus is that the decision to administer a benzodiazepine intraoperatively after a patient unexpectedly becomes conscious should be made on a case-by-case basis. . This consensus is based, in part, on the state of the literature and on responses from the Consultants and ASA members who generally agree with the following statement: "Benzodiazepines or scopolamine should be administered intraoperatively to prevent awareness after a patient has unexpectedly become conscious." However, the Task Force believes that evidence from the literature is not sufficient to provide guidance regarding this issue. Finally, the Task Force cautions that the use of scopolamine may result in unintended side-effects (e.g., emergence delirium).

Practitioners should speak with patients who report recall of intraoperative events to obtain details of the event and to discuss possible reasons for its occurrence.[⌗⌗] A questionnaire or structured interview may be used to obtain a detailed account of the patient's experience. Once an episode of intraoperative awareness has been reported, an occurrence report concerning the event should be completed for the purpose of quality management. Finally, the patient should be offered counseling or psychological support.

[⌗⌗] Refer to the ASA Director of Communications at 847-825-5586 for further information and guidance.

Appendix 1: Summary of Practice Advisory

Preoperative Evaluation

- Review patient medical records for potential risk factors
    - Substance use or abuse
    - Previous episode of intraoperative awareness
    - History of difficult intubation or anticipated difficult intubation
    - Chronic pain patients on high doses of opioids
    - ASA status 4-5
    - Limited hemodynamic reserve
- Interview patient
    - Assess level of anxiety
    - Obtain information regarding previous experiences with anesthesia
- Determine other potential risk factors
    - Cardiac surgery
    - Cesarean section
    - Trauma surgery
    - Emergency surgery
    - Reduced anesthetic doses in the presence of paralysis
    - Planned use of muscle relaxants during the maintenance phase of general anesthesia
    - Planned use of nitrous oxide-opioid anesthesia
- Patients whom the individual clinician considers to be at substantially increased risk of intraoperative awareness should be informed of the possibility of intraoperative awareness when circumstances permit

Preinduction Phase of Anesthesia

- Adhere to a checklist protocol for anesthesia machines and equipment to assure that the desired anesthetic drugs and doses will be delivered
- Verifiy the proper functioning of intravenous access, infusion pumps and their connections, including the presence of appropriate back-flow check valves
- The decision to administer a benzodiazepine prophylactically should be made on a case-by-case basis for selected patients (e.g., patients requiring smaller dosages of anesthetics)

Intraoperative Monitoring

- Use multiple modalities to monitor depth of anesthesia
    - Clinical techniques (i.e., checking for purposeful or reflex movement)
        - Neuromuscular blocking drugs may mask purposeful or reflex movement
    - Conventional monitoring systems (e.g., ECG, BP, HR, end-tidal anesthetic analyzer, capnography
    - Brain function monitoring
        - Not routinely indicated for general anesthesia patients
        - The decision to use a brain function monitor should be made on a case-by-case basis by the individual practitioner for selected patients (e.g., light anesthesia)

Intraoperative and Postoperative Management

- The decision to administer a benzodiazepine intraoperatively after a patient unexpectedly becomes conscious should be made on a case-by-case basis
- Speak with patients who report recall of intraoperative events to obtain details of the event and to discuss possible reasons for its occurrence
- A questionnaire or structured interview may be used to obtain a detailed account of the patient's experience
- Once an episode of intraoperative awareness has been reported, an occurrence report concerning the event should be completed for the purpose of quality management
- Offer counseling or psychological support to those patients who report an episode of intraoperative awareness

Appendix 2: Literature Review and Consensus-Based Evidence

For this Advisory, a literature review was used in combination with opinions obtained from experts and other sources (e.g., professional society members, open forums, web-based postings) to provide guidance to practitioners regarding intraoperative awareness. Both the literature review and opinion data were based on *evidence linkages*, consisting of directional statements about relationships between specific perioperative interventions and intraoperative awareness. The interventions for the evidence linkages are listed below:

Preoperative Evaluation

- Focused history (i.e., medical records, patient interview, physical exam)
- Patient characteristics associated with risk of awareness
- Procedures associated with higher risk of intraoperative awareness
- Anesthetic techniques may be associated with higher risk of intraoperative awareness
- Informing patients of the possiblity of intraoperative awareness

Preinduction Phase of Anesthesia

- Check anesthesia delivery systems to reduce errors
- Prophylactic administration of benzodiazepines as co-anesthetics

Intraoperative Monitoring

- Commonly used clinical techniques
- Conventional monitoring systems
- Brain function monitors
  - Spontaneous electrical activity (EEG/EMG)
    - Bispectral index (BIS)
    - Danmeter Cerebral State Monitor/Cerebral State Index
    - Entropy
    - Narcotrend
    - Patient state analyzer (PSA)
    - SNAP index
  - Evoked electrical activity (auditory evoked potential monitoring)
    - AEP Monitor/2

Intraoperative and Postoperative Interventions

- Intraoperative use of benzodiazepines for unexpected consciousness
- Structured interview of patients who report recall of intraoperative events
- Questionnaire administered to patients who report recall of intraoperative events
- Patient counseling for patients who report recall of intraoperative events

A. State of the Literature.

A study or report that appears in the published literature is included in the development of an advisory if the study: (1) is related to one of the specified linkage statements, (2) reports a finding or set of findings that can be tallied or measured (e.g., articles that contain only opinion are not included), and (3) is the product of an original investigation or report (i.e., review articles or follow-up studies that summarize previous findings are not included).

For the literature review, potentially relevant studies were identified via electronic and manual searches of the literature. The electronic search covered a 40-year period from 1966 through 2005. The manual search covered a 36-year period of time from 1970 through 2005. Over 1500 citations were initially identified, yielding a total of 711 non-overlapping articles that addressed topics related to the evidence linkages and met our criteria for inclusion. Following review of the articles, 389 studies did not provide direct evidence, and were subsequently eliminated. A total of 322 articles contained direct linkage-related evidence. No evidence linkage contained enough studies with well-defined experimental designs and statistical information to conduct a quantitative analysis (i.e., meta-analysis).

Interobserver agreement among Task Force members and two methodologists was established by interrater reliability testing. Agreement levels using a kappa (κ) statistic for two-rater agreement pairs were as follows: (1) type of study design, $\kappa = 0.60$ to 0.85; (2) type of analysis, $\kappa = 0.60$ to 0.93; (3) evidence linkage assignment, $\kappa = 0.77$ to 0.88; and (4) literature inclusion for database, $\kappa = 0.76$ to 1.00. Three-rater chance-corrected agreement values were: (1) study design, Sav = 0.82, Var (Sav) = 0.007; (2) type of analysis, Sav =0.73, Var (Sav) = 0.008; (3) linkage assignment, Sav = 0.69 Var (Sav) = 0.012; (4) literature database inclusion, Sav = 0.84, Var (Sav) = 0.014. These values represent moderate-to-high levels of agreement.

The primary focus of this Advisory was to examine studies with hypothesis-driven research designs, such as RCTs, that examined the effect of an intervention (such as a brain function monitor) on reducing the occurrence or frequency of intraoperative awareness. To date, only two randomized controlled trials were found that reported intraoperative awareness as the primary study endpoint.[55,56] Additional controlled trials will be necessary before data from published literature can be aggregated to provide a basis for quantitative evidence (i.e., meta-analysis).

Several other RCTs were reviewed that reported primary outcomes other than intraoperative awareness, including emergence time, consumption of anesthetic drugs and recovery characteristics. In addition, many other published studies applied non-hypothesis driven research designs to obtain non-causal or indirect data. For example, descriptive literature (i.e., reports of frequency or incidence) may provide an indication of the scope of the problem. Correlational or predictive data provides information regarding the direction and strength of association of values obtained from patient monitoring devices with other intraoperative measures such as blood concentrations of anesthetic drugs, time to loss of eyelash reflex, and time to awakening. Case reports are typically employed as a forum for reporting and recognizing unusual or unintended benefits or harms. Often, case reports, as well as descriptive or correlational data provide useful hypotheses-generating information that may stimulate additional causal examination of the topic of intraoperative awareness.

Future studies should focus on prospective methodologies, when possible, that utilize traditional hypothesis testing techniques. Use of the following methodological procedures for assessing the impact of interventions for intraoperative awareness is recommended: (1) comparison studies assessing the efficacy of one technique versus other techniques; (2) random assignment to treatment groups with blinding if appropriate; and (3) full reporting of sample size, effect size estimates, test scores, measures of variability, and p-values. The Task Force recognizes that conducting such

studies may be difficult and expensive, because intraoperative awareness is a very low incidence event. The required sample size for a RCT to test the impact of an intervention (e.g., brain function monitor) on the incidence of intraoperative awareness is invariably large. The Task Force also recognizes that, with low incidence data, a difference in the recording of one or two cases of intraoperative awareness can affect the statistical significance of study findings.

Limiting the study to patient subgroups thought to have a higher risk for intraoperative awareness (e.g., cardiac surgery, cesarean section, emergency trauma surgery) may allow for a smaller sample size and provide useful information regarding these subgroups. However, the Task Force recognizes that the generalizability of these findings to the larger population of general anesthesia patients may be limited.

B. Consensus-Based Evidence.

Consensus was obtained from multiple sources, including: (1) survey opinion from Consultants who were selected based on their knowledge or expertise in intraoperative awareness, (2) survey opinions from a randomly selected sample of active members of the American Society of Anesthesiologists, (3) testimony from attendees of three open forums held at national anesthesia meetings,[§§] (4) internet commentary, and (5) Task Force opinion and interpretation. The survey rate of return was 60% (N = 57/95) for Consultants, and 30% (N=151/500) for the ASA membership. Survey results are presented in the text of the document and in tables 1 and 2.

Ninety-one percent of the consultants and 72% of the ASA members indicated that they had personally used a brain function device in the past. Fifty-seven percent of the consultants indicated that they make use in their current practice of a brain function device either always (11.1%), frequently (20.4%), or sometimes (25.9%). Thirty-six percent of the ASA members

[§§] American Society of Anesthesiologists, Annual Meeting, October 25, 2004 in Las Vegas, NV; International Anesthesia Research Society, 79th Clinical and Scientific Congress, March 12, 2005 in Honolulu, HI; and Association of University Anesthesiologists 52nd Annual Meeting, May 6, 2005 in Baltimore, MD.

indicated that they make use in their current practice of a brain function device either always (6.0%), frequently (13.4%), or sometimes (16.8%).

The Consultants were also asked to indicate which, if any, of the evidence linkages would change their clinical practices if the Advisory was instituted (table 3). The rate of return was 18% (N = 17/95). The percent of responding Consultants expecting *no change* associated with each linkage were as follows: preoperative evaluation - 82%; informing patients of the possibility of intraoperative awareness - 65%; check anesthesia delivery systems - 94%; prophylactic use of benzodiazepines as co-anesthetics - 100%; use of clinical techniques to monitor for intraoperative awareness - 94%; use of conventional monitoring systems to monitor for intraoperative awareness - 100%; use of brain function monitors to monitor for intraoperative awareness - 59%; intraoperative use of benzodiazepines for uuunexpected consciousness - 100%; use of a structured interview for patients who report recall of intraoperative events - 41%; use of a questionnaire for patients who report recall of intraoperative events - 53% and counseling for patients who report recall of intraoperative events - 76%. Seventy-one percent of the respondents indicated that the Advisory would have *no effect* on the amount of time spent on a typical case. Four respondents (24%) indicated that there would be an increase in the amount of time they would spend on a typical case with the implementation of this Advisory. The amount of increased time anticipated by these respondents ranged from 1 to 20 minutes.

Table 1. Consultant Survey Responses [***]

		Percent Responding to Each Item				
Preoperative evaluation:	N	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
1. Helpful to identify pts at risk of intraoperative awareness	57	31.6	43.9*	7.0	10.5	7.0
2. A preop eval should include:						
Review of medical records	48	41.7	45.8*	4.2	6.3	2.1
A physical examination	47	21.3	34.0*	17.0	25.5	2.1
A patient/family interview	48	39.6	35.4*	14.6	8.3	2.1
3. Potential patient risk factors:						
Substance use or abuse	54	38.9	42.6*	5.6	13.0	0.0
Pt history of intraop awareness	55	52.7*	29.1	10.9	7.3	0.0
Limited hemodynamic reserve	54	38.9	40.7*	13.0	7.4	0.0
ASA status of 4 or 5	54	24.1	48.1*	20.4	7.1	0.0
4. Procedures/ anesthetic techniques that may place a patient at risk for intraop awareness:						
Cesarean section under GA, cardiac surgery, trauma, emergency surgery	57	75.4*	24.6	0.0	0.0	0.0
Planned use of reduced doses of anesthetics in the presence of paralysis	56	66.1*	25.0	5.4	1.8	1.8
Planned use of muscle relaxants for maintenance	57	26.4	45.6*	8.8	17.5	1.8
Planned use of total intravenous anesthesia	57	10.5	33.3	24.6*	21.1	10.5
Planned use of volatile anesthetics	57	3.5	5.3	12.3	57.9*	21.1
Planned use of nitrous oxide-narcotic anesthesia	57	29.8	35.1*	14.0	19.3	1.8
Preoperative or intraoperative use of beta-blockers under general anesthesia	57	5.3	35.1	26.3*	29.8	3.5
Rapid-sequence induction	57	5.3	29.8	19.3*	42.1	3.5
5. All pts should be informed of the possibility of intraop awareness	57	10.5	31.6	5.3	42.1*	10.5
6. Only patients considered to be at elevated risk of intraop awareness should be informed of the possibility of intraop awareness	40	17.5	60.0*	5.0	7.5	10.0

[***] N = the number of consultants who responded to each item. An astrisk beside a percentage score indicates the median.

	N	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
7. Informing the pt preoperatively of the risk of intraop awareness increases the actual risk of intraoperative awareness	53	3.8	5.7	30.2	35.8*	24.5
Preinduction activities:						
8. The functioning of anesthesia delivery systems should be checked preoperatively to reduce the risk of intraop awareness	57	77.2*	17.5	1.8	3.5	0.0
9. A benzodiazepine or scopolamine should be used as a component of the anesthetic to reduce the risk of intraop awareness:						
For all patients under GA	54	7.4	24.1	1.9	33.3*	33.3
For no patients under GA	54	3.7	3.7	3.7	46.3*	42.6
For pts with conditions that may place them at risk for intraop awareness	53	20.8	58.5*	7.5	7.5	5.7
For patients requiring smaller dosages of general anesthetics (“light anesthesia”)	53	17.0	43.4*	11.3	20.8	7.5
For patients undergoing cardiac surgery	54	22.2	44.4*	11.1	16.7	5.6
For patients undergoing Cesarean section under GA	54	7.4	29.6	20.4*	31.5	11.1
For patients undergoing emergency surgery under GA	53	15.1	30.2	20.8*	28.3	5.7
For patients undergoing trauma surgery under GA	54	16.7	35.2*	20.4	22.2	5.6
For patients undergoing total intravenous anesthesia	54	16.7	31.5	18.5*	24.1	9.3
Intraoperative Monitoring:						
10. Commonly used clinical techniques (e.g., checking for purposeful or reflex movement) are valuable and should be used to detect intraop consciousness	53	18.9	47.2*	5.7	18.9	9.4
11. Conventional monitoring systems are valuable and should be used to detect intraoperative consciousness	53	22.6	41.5*	5.7	24.5	5.7

	N	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
12. Brain function monitors are valuable and should be used to reduce the risk of intraoperative awareness:						
For all patients under GA	57	7.0	21.1	19.3	15.8*	36.8
For no patients under GA	56	3.6	7.1	14.3	35.7*	39.3
For pts with conditions that may place them at risk for intraop awareness	57	36.8	26.3*	14.0	14.0	8.8
For patients requiring smaller dosages of general anesthetics ("light anesthesia")	56	26.8	32.1*	14.3	19.6	7.1
For patients undergoing cardiac surgery	57	28.1	21.1	26.3*	14.0	10.5
For patients undergoing Cesarean section under GA	57	31.6	21.1*	21.1	17.5	8.8
For patients undergoing emergency surgery under GA	57	21.1	28.1	24.6*	17.5	8.8
For patients undergoing trauma surgery under GA	57	26.3	24.6*	24.6	15.8	8.8
For patients undergoing total intravenous anesthesia	56	16.1	39.3*	23.2	14.3	7.1
13. Brain function monitors are valuable and should be used when possible to assess intraoperative depth of anesthesia:						
For all patients under GA	56	12.5	21.4	10.7	14.3*	41.1
For no patients under GA	54	9.3	5.6	9.3	37.0*	38.9
For pts with conditions that may place them at risk for intraop awareness	56	33.9	30.4*	8.9	14.3	12.5
For patients requiring smaller dosages of general anesthetics ("light anesthesia")	56	28.6	35.7*	10.7	10.7	14.3
For patients undergoing cardiac surgery	56	26.8	28.6*	16.1	14.3	14.3
For patients undergoing Cesarean section under GA	56	28.6	32.1*	12.5	12.5	14.3

	N	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
For patients undergoing emergency surgery under GA	57	21.1	36.8*	10.5	17.5	14.0
For patients undergoing trauma surgery under GA	57	22.8	38.6*	10.5	14.0	14.0
For patients undergoing total intravenous anesthesia	57	26.3	35.1*	17.5	8.8	12.3
Intraoperative & Postoperative Interventions:						
14. Benzodiazepines or scopolamine should be administered intraoperatively to prevent awareness after a pt has unexpectedly become conscious	57	21.1	26.3	15.8*	21.1	15.8
15. Once an episode of intraoperative awareness has been reported, a structured interview should be conducted to define the nature of the episode	57	63.2*	31.5	1.8	0.0	0.0
16. Once an episode of intraop awareness has been reported, a questionnaire should be given to define the nature of the episode	57	10.5	19.3	36.8*	28.1	5.3
17. Once an episode of intraop awareness has been reported and documented, the pt should be offered counseling or psychological support	56	69.6*	25.0	5.4	0.0	0.0
18. Once an episode of intraop awareness has been reported, an occurrence report concerning the event should be completed for the purpose of quality management	57	54.4*	40.4	0.0	5.3	0.0

Table 2. ASA Member Survey Responses[†††]

		Percent Responding to Each Item				
Preoperative evaluation:	N	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
1. Helpful to identify pts at risk of intraoperative awareness	146	27.4	46.6*	14.4	10.3	1.4
2. A preop eval should include:						
Review of medical records	121	38.8	47.9*	7.4	5.0	0.8
A physical examination	118	23.7	37.3*	18.6	17.8	2.5
A patient/family interview	121	46.3	43.0*	6.6	3.3	0.8
3. Potential patient risk factors:						
Substance use or abuse	147	31.3	44.2*	16.3	6.8	1.4
Pt history of intraop awareness	146	45.2	31.5*	11.0	11.6	0.7
Limited hemodynamic reserve	145	46.3	38.6*	6.9	6.9	1.4
ASA status of 4 or 5	145	33.1	40.7*	11.0	13.1	2.1
4. Procedures/ anesthetic techniques that may place a patient at risk for intraop awareness:						
Cesarean section under GA, cardiac surgery, trauma, emergency surgery	151	70.2*	27.2	0.7	1.3	0.7
Planned use of reduced doses of anesthetics in the presence of paralysis	148	48.6	44.6*	4.1	2.7	0.0
Planned use of muscle relaxants for maintenance	147	21.1	34.7*	16.3	26.5	1.4
Planned use of total intravenous anesthesia	146	13.0	26.7	24.0*	32.2	4.1
Planned use of volatile anesthetics	148	0.7	10.1	10.1	63.5*	15.5
Planned use of nitrous oxide-narcotic anesthesia	147	11.6	46.9*	18.4	19.7	3.4
Preoperative or intraoperative use of beta-blockers under general anesthesia	148	4.7	31.1	23.0*	36.5	4.7
Rapid-sequence induction	148	3.4	31.1	18.9*	41.9	4.7
5. All pts should be informed of the possibility of intraop awareness	147	15.0	28.6	10.9*	40.1	5.4
6. Only patients considered to be at elevated risk of intraop awareness should be informed of the possibility of intraop awareness	112	17.0	49.1*	7.1	21.4	5.4

[†††] N = the number of members who responded to each item. An astrisk beside a percentage score indicates the median.

	N	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
7. Informing the pt preoperatively of the risk of intraop awareness increases the *actual* risk of intraoperative awareness	147	2.7	10.9	33.3	38.8*	14.3
Preinduction activities:						
8. The functioning of anesthesia delivery systems should be checked preoperatively to reduce the risk of intraop awareness	148	60.8*	37.8	0.7	0.7	0.0
9. A benzodiazepine or scopolamine should be used as a component of the anesthetic to reduce the risk of intraop awareness:						
For all patients under GA	150	15.3	34.0	6.0*	30.7	14.0
For no patients under GA	144	0.7	2.8	3.5	50.7*	42.4
For pts with conditions that may place them at risk for intraop awareness	148	37.8	56.1*	3.4	2.7	0.0
For patients requiring smaller dosages of general anesthetics ("light anesthesia")	150	31.3	60.7*	4.7	3.3	0.0
For patients undergoing cardiac surgery	147	39.5	48.3*	9.5	2.7	0.0
For patients undergoing Cesarean section under GA	151	13.2	23.2	27.8*	28.5	7.3
For patients undergoing emergency surgery under GA	151	21.1	42.4*	21.9	13.9	0.7
For patients undergoing trauma surgery under GA	150	24.0	44.7*	22.7	8.7	0.0
For patients undergoing total intravenous anesthesia	150	23.3	48.0*	14.0	12.7	2.0
Intraoperative Monitoring:						
10. Commonly used clinical techniques (e.g., checking for purposeful or reflex movement) are valuable and should be used to detect intraop consciousness	151	10.6	50.3*	21.2	13.9	4.0
11. Conventional monitoring systems are valuable and should be used to detect intraoperative consciousness	150	20.7	56.7*	9.3	10.7	2.7

	N	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
12. Brain function monitors are valuable and should be used to reduce the risk of intraoperative awareness:						
For all patients under GA	149	10.7	10.7	16.1	37.6*	24.8
For no patients under GA	146	2.7	3.4	24.7	44.5*	24.7
For pts with conditions that may place them at risk for intraop awareness	147	21.1	48.3*	19.0	10.2	1.4
For patients requiring smaller dosages of general anesthetics ("light anesthesia")	147	19.7	38.8*	24.5	13.6	3.4
For patients undergoing cardiac surgery	148	20.3	33.8*	30.4	12.2	3.4
For patients undergoing Cesarean section under GA	148	12.8	34.5	25.0*	23.0	4.7
For patients undergoing emergency surgery under GA	146	17.8	26.0	28.8*	24.0	3.4
For patients undergoing trauma surgery under GA	148	18.9	29.7	28.4*	19.6	3.4
For patients undergoing total intravenous anesthesia	148	13.5	35.1	25.7*	20.3	5.4
13. Brain function monitors are valuable and should be used when possible to assess intraoperative depth of anesthesia:						
For all patients under GA	150	12.0	9.3	16.0	30.7*	32.0
For no patients under GA	147	2.7	4.8	24.5	41.5*	26.5
For pts with conditions that may place them at risk for intraop awareness	148	20.3	43.2*	20.9	10.8	4.7
For patients requiring smaller dosages of general anesthetics ("light anesthesia")	149	20.1	37.6*	20.8	15.4	6.0
For patients undergoing cardiac surgery	149	20.1	27.5	28.2*	19.5	4.7
For patients undergoing Cesarean section under GA	149	13.4	30.2	22.8*	26.2	7.4
For patients undergoing emergency surgery under GA	149	14.8	26.8	24.8*	26.8	5.4
For patients undergoing trauma surgery under GA	149	16.1	28.9	25.5*	24.2	5.4
For patients undergoing total intravenous anesthesia	149	15.4	32.9	24.8*	20.1	6.7

	N	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
Intraoperative & Postoperative Interventions:						
14. Benzodiazepines or scopolamine should be administered intraoperatively to prevent awareness after a pt has unexpectedly become conscious	151	33.1	49.7*	9.9	7.3	0.0
15. Once an episode of intraoperative awareness has been reported, a structured interview should be conducted to define the nature of the episode	151	49.0	43.0*	7.3	0.7	0.0
16. Once an episode of intraop awareness has been reported, a questionnaire should be given to define the nature of the episode	151	19.9	21.9	38.4*	18.5	1.3
17. Once an episode of intraop awareness has been reported and documented, the pt should be offered counseling or psychological support	151	44.4	39.1*	14.6	1.3	0.7
18. Once an episode of intraop awareness has been reported, an occurrence report concerning the event should be completed for the purpose of quality management	151	47.7	41.1*	9.3	1.3	0.7

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