
The medico-legal and ethical considerations associated with intraoperative neurophysiological monitoring in the USA: overview and proposed guidelines for legal and risk management professionals

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Abstract: Intraoperative neurophysiological monitoring, known by the acronym IONM, is a method for monitoring and recording the inner neurological activity of a patient undergoing surgery. When using conventional means of monitoring, neurological damage during surgery may go undetected. IONM prevents this by indicating what is going on within a patient, often in real time, enabling surgeons to change course during surgery. Although IONM offers benefits, its use should not be undertaken without regard to the legal and regulatory issues involved. These include contractual, malpractice, and products liability concerns. In the USA, where healthcare providers are seen as 'deep pockets', these issues must be approached with due care. Healthcare risk-management professionals should take precautions that ensure IONM use will be efficacious and utilised in a manner that minimises the risks inherent in the introduction of new technologies into heavily litigated fields. This paper provides professionals with legal strategies for accomplishing this task.

Keywords: intraoperative neurophysiological monitoring; IONM; healthcare; litigation; risk management, USA.

Reference to this paper should be made as follows: Wiggins, M., Sherman, J. and Pierson, S. (2013) 'The medico-legal and ethical considerations associated with intraoperative neurophysiological monitoring in the USA: overview and proposed guidelines for legal and risk management professionals', *Int. J. Liability and Scientific Enquiry*, Vol. 6, Nos. 1/2/3, pp.42–63.

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1 Introduction

Healthcare is risky – about as risky, by at least one study's reckoning, as bungee jumping and mountain climbing.¹ The perils involved with healthcare are anything but trivial, a recent National Safety Council study estimated that in the USA, as many as 120,000 deaths result annually from medical error (Wu, 2007). In a milieu where professionals are charged with managing risks cut along the same lines as hanging from sheer cliffs and leaping from bridges, where deaths from medical mistakes hit six figures annually in the USA alone, the need for medical administrators, healthcare providers and affiliated legal professionals to set rational risk management policy is clear.

Over the years, medical professionals have developed numerous methods for limiting these extreme risks. One of the most promising of the last century has been intraoperative neurophysiological monitoring, known by the acronym 'IONM' or 'IOM'.² IONM involves the use of neurophysiological recordings to detect, monitor, archive and interpret the changes in a patient's nervous system that are brought about by invasive surgery (Møller, 2011). The notion underpinning IONM is that if the changes in a patient's system can be monitored moment by moment by the surgical team, it becomes possible for the team to identify procedures that are doing damage to the patient's

neurological system.³ With this essential data in hand, the medical team in theory has the opportunity to discontinue a procedure that is doing damage to the patient.⁴

In theory, IONM should be a panacea for the medical professional: greater access to information, heightened ability for surgeons to identify and correct problems even before they occur, safer surgeries, improved patient outcomes, less medical malpractice exposure – a risk manager's dream. The reality, however, is more complex. Certain unintended consequences may make the use of IONM a more ambiguous prospect from a risk management, legal and regulatory perspective, as this paper will identify.

2 Overview of IONM

2.1 The theory underpinning IONM

A number of injuries to a patient's nervous system can occur as a direct and proximate result of surgery. For example, a scalpel may cut into essential nerves or the spinal cord. According to advocates of IONM, the feedback that it provides minimises the risk of internal injuries to a patient; if neurological changes are monitored, damage can be detected as it is occurring, a change of course can be undertaken, and the actions that are causing the damage can be discontinued – thus, injuries will be prevented.⁵ Advocates of IONM point out that without the data it provides, surgeons must rely upon relatively primitive means of monitoring, such as the observation of basic vital signs (e.g., blood pressure, body temperature, pulse and respiration rates) or naked eye observation of the patient's condition. The difficulty with these rudimentary monitoring techniques is they may give the surgical team only belated indications of neurological injury or, in many cases, no indication at all.

2.2 The technical aspects of IONM

The procedure for IONM is technically complex, but conceptually straightforward. A patient is hooked up to a number of devices that monitor changes in, for example, a patient's brain, muscles, spinal cord or central nervous system (Advanced Monitoring Services, <http://www.advancedmonitoringservices.com/ionm>). The data is then processed through a computer system and fed to the surgical team, often on a continuous, real-time basis, and recorded for contemporaneous and subsequent analysis.⁶ This is accomplished by means of specific nerve analysis and interpretation by a neurophysiologist. The neurophysiologist is responsible for monitoring the data in support of the surgical team, but ultimately for the safety of the patient.

There are a number of methods, or multimodalities, utilised in IONM. A partial list includes electroencephalography, commonly known as EEG, which involves the recording of electrical activity on a patient's scalp (Liu et al., 2002). This technique has been demonstrated to provide a reasonably accurate indication of electrical activity in the brain.⁷ Another method is electromyography, also known as EMG, in which electrical activity is recorded along the muscles. Changes in muscular electrical activity indirectly indicate changes in nerve activity, and such monitoring can ensure that the nerves near the area of surgery have not been damaged by the surgeon's scalpel and have

maintained their integrity (Liem et al., 2010). A third method is so-called somatosensory evoked potentials, also known as SEPs. Evoked potentials are electrical signals produced by the nervous system in response to electrical stimulation produced by an IONM system. Electrodes are placed on scalp, spine, neck, shoulders, wrist and other nerves close to the site of the surgery (Legatt, 2002). The electrodes record data in the form of electrical waves. The recording of this data allows the surgical team to monitor the spinal cord and nerves in the limbs while a computer in the IONM system records the manner in which brain and spinal cord are responding to the electrical stimulus (NeuroCareCenter, Inc., 2002). This too, provides indications of neurological damage developing during surgery.⁸

2.3 A brief history of IONM and a summary of its explosive growth as a diagnostic tool

IONM techniques, while apparently quite modern, are in fact nothing new. The use of IONM dates to the first half of the twentieth century. Perhaps the earliest form of neurological monitoring, beginning in the 1930s and 1940s – and still in use today – was direct stimulation of the cerebral cortex, the outer layer of the brain, to determine regions involved in directing motor and sensory functions (Nuwer, 2010). Doctors Foerster and Altenberger used a basic form of EEG in monitoring neurological responses during surgery as early as 1935 (Liem et al., 2010). SEPs had their genesis in the late 1940s,⁹ and the use of IONM in spinal cord surgery was developed in the 1970s (Tamaki and Kubota, 2007).

While IONM as a surgical aid is venerable, its use on a wide scale is a relatively recent phenomenon, dating primarily to the last quarter of a century (O'Brien, 2008). A case study of one US hospital network, the University of Michigan Health System, documented the growth of IONM from a single usage in 1984 to 73 in 1990, 152 in 2000, and 228 in 2003, the final year of the study (Edwards et al., 2004). If currently expressed attitudes are a reliable indication of future trends, IONM will only continue to grow in popularity. A recent international study of neurosurgeons' attitudes towards IONM indicated that a dominant majority, 76%, regard IONM as a "very important diagnostic tool for identifying risky surgical manoeuvres", while only 6% considered IONM to be of 'no importance' as a diagnostic tool (Cabraja et al., 2009).

Considering IONM's lengthy history, recent explosive growth, and perceived value by many surgeons, it is certainly more than a passing fancy and likely to continue growing in prominence. Logically, as IONM usage increases, so do the relative benefits and hazards thereof. Thus, IONM has become an issue with which healthcare administrators promulgating policy, surgeons and affiliated healthcare professions implementing it, and attorneys overseeing or consulting on it must grapple.

2.4 The latest evidence for the effectiveness of IONM

The primary goals of IONM have been generally identified as:

- 1 to alert surgical teams to neurological damage as it is occurring
- 2 to reduce the incidence of long-term neurological damage born by surgery.

The evidence for IONM's effectiveness in accomplishing the first goal, indicating potential neurological threats during surgery, is strong. Research in 1987 undertaken by Dr. Joseph Cunningham sought to establish whether the alerts provided by an IONM system during surgery were predictive of neurological damage; the results were a resounding 'Yes' (Cunningham et al., 1987). Dr. Cunningham found a strong correlation between IONM warnings and neurological damage: when an IONM system alerted the surgical team that neurological changes were occurring during surgery, paraparesis (partial paralysis of the legs), paraplegia, or quadriplegia occurred 31% of the time, whereas when the IONM system did not indicate any neurological changes during surgery, not a single such adverse event occurred.¹⁰ A second study headed by Dr. Sutter and published in the *European Spine Journal*, had similar results (Sutter et al., 2007). A total of 109 patients who had IONM-aided surgery were studied; of 84 surgeries in which the IONM system indicated no neurological change, not one patient developed paraparesis, paraplegia, or quadriplegia, while of the 25 patients in which the IONM system provided an alert, 4, or 16% suffered adverse results.¹¹ A third study involved 49 IONM-aided surgical patients and again, where the IONM system did not alert the surgical team to neurological damage, not a single patient suffered from long term paralysis, while a full 40% of patients for whom such an alert was given did (Weinzierl et al., 2007). A very recent study by Dr. Marc Nuwer of the UCLA Medical Centre took a bird's eye view of the research on IONM by analysing twelve studies conducted over the last few decades, including, inter alia, the Cunningham study cited above (Nuwer et al., 2012). In his research, Dr. Nuwer noted that not one study of the twelve failed to demonstrate the efficacy of IONM in identifying signs of neurological damage during surgery.¹² These studies are not isolated, the medical literature includes several other studies supporting the proposition that IONM is quite useful in providing accurate warnings.¹³

If IONM predicts bad surgical outcomes, goal one identified above, it would logically seem to follow that it should also be useful in accomplishing goal two, the preventing of them. But this second proposition has been controversial. Prima facie it seems self-evident, that if a system alerts you to a developing problem, it should aid in preventing that problem, analogous to the overheating temperature gauge on an automobile, pulling to the side of the road to avoid a blown engine. However, many medical experts have questioned this maxim as applied to IONM and its use in human subjects. As a point of fact, even most IONM advocates acknowledge that there is a paucity of human research unequivocally supporting IONM's effectiveness in preventing neurological injuries; as has been put by one neurology expert, this is "a largely missing piece of the puzzle".¹⁴

Dr. Nuwer, in his 2012 study referenced above, acknowledges this lack of significant human-based evidence, but points out that six studies on animals established an IONM system as effective not only in providing alerts, but in preventing long term neurological damage so long as the surgical team responded to the alert and changed course in surgery.¹⁵ He then makes the assumption that the animal-based research could be extrapolated to human subjects: "On this basis, it seems reasonable to assume that such interventions might improve outcomes in humans as well".¹⁶ As to those who contend that intervention after IONM alerts should not be assumed effective at preventing long-term human neurological injuries because there are no randomised human-based trials for outcome that establish this particular point, Dr. Nuwer contends that since the likelihood of any such research ever being conducted is almost zero,¹⁷ we should take

animal-based studies, described by some experts as ‘overwhelming data’, as the best available evidence for their effectiveness in humans.¹⁸

However, this analogy is not seen as inevitable by many experts.¹⁹ For example, some question whether IONM warnings in surgery come early enough to permit timely surgical intervention in human subjects, others question whether false positives or other technical failures might negate the positive effects (Wiedamayer et al., 2004), others question the use of IONM from the perspective of the applicable cost-benefit analysis,²⁰ while others point to the law of unintended consequences, e.g., that surgeons ‘protected’ by IONM might develop a false sense of security and attempt riskier procedures, perversely resulting in worse patient outcomes than with unaided surgery.²¹

Although there is not a huge body of evidence supporting proposition number two, there is scientific evidence supporting it. At least two studies provide evidence of IONM’s effectiveness in improving long term patient health. On study, headed by Dr. F. Sala of the Institute of Neurosciences at the University of Miguel Hernández in Spain, compared the long term neurological health of 50 patients without the benefit of IONM with 50 patients with IONM; it was found that the motor scores in patient follow-up were found to be significantly better in those who had IONM (Sala et al., 2006). In a second study led by Dr. Wiedemayer of the Department of Neurosurgery at the University of Essen in Germany, a 52% rate of preventing neurological deficits was found if the surgical team responded during surgery to an IONM alert (Wiedemayer et al., 2002).

In sum, judging by the weight of the evidence, including, inter alia:

- 1 studies unequivocally establishing the effectiveness of IONM in providing alerts to neurological damage
- 2 the existence of several animal studies indicating a direct link between long term neurological health and IONM alerts
- 3 the handful of human-based studies demonstrating at least preliminary evidence of long-term neurological benefits from IONM
- 4 the lack of evidence demonstrating bona fide harmful effects from the use of IONM, the arguments favouring the use of IONM are strong.

Finally, one must consider the sheer logic underpinning IONM’s claims to potentially benefit a patient’s long term neurological health prospects, i.e., all else being equal, is it not better for surgeons to have access to *more* information than *less*? There is also the argument from the scientific method and the near inevitability of scientific advances given accurate data being made available to those of a scientific bent. The argument goes that even assuming arguendo each of the contentions forwarded by critics, i.e., that IONM alerts at present fail to improve a patient’s long term neurological health, would not surgeons²² armed with additional, real time data about a patient undergoing invasive surgery, be expected over time to develop techniques that would convert IONM data into short-term and long-term health benefits? This logic of this proposition would appear to be relatively strong. On the whole, therefore, it is tacitly the opinion of thousands of surgeons and healthcare providers who currently use IONM, as well as the opinion of the authors of this article, that it is reasonable under present circumstances to promote the use of IONM in surgery.

3 Overview of the litigation landscape in the USA

IONM usage and technologies are growing rapidly and the efficacy of the procedure is supported by much research, but in all things, one must consider the cost. When a developing technology (such as IONM) used in conjunction with an inherently dangerous procedure (such as neurosurgery) intersects with an upward trend of litigiousness in a society (such as the USA in the 21st century), the results can reach something of a critical mass. As IONM grows in prominence in the USA, potential risk management issues need to be accounted for by healthcare providers and administrators. The various legal factors created or exacerbated by the use of IONM must be considered. One of these is the litigiousness of the US milieu in which the IONM is thriving.

The USA is by many accounts the most litigious nation in the world. By the majority of major measures, the USA came out on top in a recent survey of litigiousness. Professors Rasmusen and Ramseyer, of Indiana University and Harvard respectively, undertook a study of one year, 2006 – by no means a noteworthy year for litigation in the USA – in which there were almost 18.4 million suits identified as filed in US state and federal courts (Rasmusen and Ramseyer, 2010). While this only describes US litigation in terms of total volume, the litigation rate as a percentage of population also places the USA at the top of litigation measures. The USA ranks highest in litigation rates per capita, the 2006 *Rasmusen-Ramseyer Study* demonstrated that there were approximately 5.8 suits filed in the USA per 100 people.²³ This can be compared with other industrialised nations: about 1.5 in Canada and Australia, 1.8 in Japan, 2.4 in France, and 3.3 in England.²⁴

The reason for this litigious culture is difficult to define with precision and is likely the result of a mix of factors, statutory and cultural, but at least three can be suggested as plausible factors that have turned many US attorneys into de facto entrepreneurs. The culture of easy lawsuits has been encouraged by three hallmarks of the US legal system:

- 1 the popularity of contingent fee agreements (often known as ‘conditional fees’ in the UK)
- 2 class action lawsuits
- 3 the relative lack of accountability for those filing weak, borderline frivolous suits.

In the first half of the twentieth century, the legal system in the US tacitly accepted the status of ‘attorney as entrepreneur’ by approving contingent fee agreements (Coffee, 2007). Of course, under such arrangements attorneys receive a flat percentage of the jury verdict or settlement (American Bar Association, http://www.americanbar.org/groups/public_education/resources/law_issues_for_consumers/lawyerfees_contingent.html). At worst from counsel’s perspective, the attorney will be out the costs of pursuing the litigation, at best the attorney receiving a flat percentage, often one-third, but often upwards of 40%, of the total plaintiff’s award.²⁵ This system has produced attorney’s cuts in the USA into the hundreds of millions. The class action, approved under US Federal Rules of Civil Procedure, enables attorneys to join large numbers of plaintiffs with common claims together in a suit.²⁶ The payoff to attorneys can be tremendous by dint of the sheer volume of those who can be joined into an action. Advertisements by law firms fishing for large class action claims, seeking those who’ve had a given medical procedure performed or who have taken a certain drug, are ubiquitous in US direct mail, print media and on the airwaves. Finally, the US legal

system has rejected the so-called ‘English Rule’, in which the loser pays the winner’s legal fees. In the absence of concerns that a losing suit would involve significant costs for plaintiffs, the economic factors encouraging litigation are skewed indeed. As a senior fellow at the Manhattan Institute put it, US judges and juries appear to be “committed to running a generous sort of charity” (Huber, 2012). Healthcare risk management professionals must undoubtedly take the milieu in which they operate, for good or ill, into account in setting policy.

4 Litigation issues specific to IONM – potential benefits and pitfalls of IONM

4.1 Neurosurgery in general – and IONM in particular – is a magnet for medical malpractice claims, thus IONM should thus be approached with due care

From the perspective of healthcare providers, the problem of litigiousness in the USA is particularly acute. In the USA, healthcare has become a magnet for the plaintiff’s bar. The emergence of new drugs, treatments and medical technologies can readily become a vehicle for malpractice litigation and class actions. This is demonstrated by another distinction drawn by the Rasmussen-Ramseyer (2010) study cited above. There is a stark contrast between the ways in which US courts tend to dispose of different types of legal claims. For example, the study showed that US courts do not handle traditional legal claims, such as contract disputes, all that much differently from courts in other countries. In other words, shaky contracts claims tend to be losers. But the litigation statistics also show that US courts notably fail to control claims in arenas such as products liability and medical malpractice – shaky claims in those fields are often given wide deference by the US courts.²⁷ Thus, the litigiousness that statistically makes the USA the most sue-crazy country in the world is not evenly spread among all categories of claims, it is concentrated in a handful of areas, healthcare being prominent among these.²⁸ As a result of this volatile mix of litigation triggers, it has been estimated that 99% of US physicians in high-risk specialties will have a malpractice claim filed against them by the age of 65 (Jena et al., 2011).

Practicing in a milieu of litigiousness should be sufficient to give all providers of healthcare pause. But the situation is more complex with neurosurgery, which is a particular target of medical malpractice claims. A recent study indicated that, of 26 different medical specialties surveyed, neurosurgeons were the most likely to be sued. On average, nearly 20% of all neurosurgeons face a malpractice claim each year.²⁹ And once in the courthouse, lawsuits against neurosurgeons are highly successful vis-à-vis other medical specialties; neurosurgery-based malpractice suits had the highest median payments by defendant surgeons to plaintiffs of all specialties studied in a recent survey.³⁰ Dr. Alan Scarrow studied malpractice claims in neurosurgery in the USA and concluded that the average cost for a physician to merely defend these claims was almost \$87,000, not including the costs associated with losing a verdict.³¹ Once a neurosurgery case winds down to a resolution, whether through some form of alternative dispute resolution or by a verdict, the costs are almost equally bracing: the average physician payment for cases tried was \$378,000³² and \$392,000 for cases settled.³³ This adds up to a total average cost approaching half a million dollars per claim.³⁴ And the expertise of

the surgeon had little statistical effect; these huge liabilities were incurred in spite of the fact that the vast majority of the neurosurgeons surveyed were defined as exceptionally well-qualified, e.g., 90% of the defendant physicians surveyed were board certified.³⁵

Thus, even the best of neurosurgeons attract an inordinate number of malpractice claims, and the litigation that such claims spawn tends to be of an expensive nature. These concerns can be added to the fact that the win ratio for neurosurgery malpractice defendants is also relatively low. In the malpractice claims studied by Dr. Scarrow, defendant neurosurgeons lost in approximately 40% of all cases.³⁶ While the converse – that over half of all neurosurgeons won – is undeniably true, it is not necessarily a cause for celebration. A 60% success rate for defendants is by no means high vis-à-vis other documented success rates for malpractice defendants in general, which, per a recent study, hovered around 73% (Peters, 2007).

With these sobering statistics in mind, it is incumbent upon healthcare providers, prior to adopting any new medical technology – such as IONM – that could affect this dynamic positively or negatively, to factor litigation issues into their decision-making processes.

4.2 New technologies by their very nature can become a particular attraction for litigation

The culture of lawyer as entrepreneur is driven by a lawyer's awareness of an opportunity, in economic terms, a 'rent' that entrepreneurial lawyers 'seek'. As publicity for something increases, so does the awareness of the opportunities that trigger litigation. When neurosurgery is accompanied by IONM, it potentially increases legal exposure. Why is this? It is because, in part, IONM is a relatively new technology. While this is not technically true (IONM, as aforementioned, is venerable), it may as well be for the purposes of the plaintiff's bar, because IONM has only recently begun to become popular, and register on the national consciousness. As a technology first becomes prominent, it quite naturally catches the attention both of prospective plaintiffs and plaintiff's attorneys. This can in theory result in a proliferation of lawsuits. As the Japanese proverb goes, "The nail that sticks up gets hammered down".³⁷

Another issue from the perspective of attracting litigation for IONM is that as a relatively new technology, IONM as yet not well-regulated and although its growth has been enormous in recent decades, it is as yet a relatively new technology in terms of common usage. Thus, following of established standards, i.e., industry custom, that could provide some safe harbour for surgeons as a defence, is not yet available to a substantial degree with IONM. There is to date no formal educational path that provides a specialty degree in IONM (O'Brien, 2008). Further, there is no state licensing framework for IONM.³⁸ To date, there has been no appellate case law on the issue of licensure and its application to IONM, thus the field is as yet unsettled for those setting risk-aversion strategies and policies.³⁹

4.3 Neurosurgery aided by IONM is by nature complex, potentially more likely to involve systemic failure – but mitigated by potential benefits of documentary evidence

A genuine concern with IONM from a risk management perspective lies in the maxim that the more complex a system is, the more likely it is to fail. It is axiomatic that

failure in any system used by a professional increases both the likelihood of litigation being instituted and of its success. IONM devices are necessarily complex systems, and with the attendant computer componentry and electronics, as well as the trained specialist required to monitor the systems, enormously so. Thus, as additional complexities are introduced into the surgery – even if they be complexities that in practice make the surgery less dangerous, such as IONM – there are more ‘moving parts’ that can fail. As noted above, failures of any nature make litigation more likely. Failure in an IONM system, be it electronic, mechanical or human error, can spawn medical malpractice suits or litigation brought under a theory of products liability. More moving parts not only means more that can go wrong, but also more that must be defended in court or during the pre-trial discovery process. This increases the costs of litigation, as the surgical team will not only have to defend against malpractice claims for their performance, but also potentially products liability claims for the performance of the IONM system.

Technological errors in healthcare are a largely unreported, but growing phenomenon in healthcare. Such errors account for numerous so-called ‘adverse patient events’. This leads to an issue that must be considered in IONM. An IONM system transmits through computer technologies complex data that requires expert supervision, interpretation and accurate communication with the surgical team (Husain et al., 2008). If data is incorrectly interpreted or inaccurately translated, decisions could be made that are deleterious to the patient. As one expert puts it “No monitoring is better than bad monitoring” (Sala et al., 2002). In 2008, the US Joint Commission indirectly addressed the issue:

“As health information technology (HIT) and ‘converging technologies’ – the interrelationship between medical devices and HIT – are increasingly adopted by health care organisations, users must be mindful of the safety risks and preventable adverse events that these implementations can create or perpetuate...These unintended adverse events typically stem from human-machine interfaces..” (The US Joint Commission, 2008)

This is no small problem, the US Pharmacopeia MEDMARX database for 2006 contained over 176,000 medical error records.⁴⁰ Of these, 1.25% resulted in harm to the patient.⁴¹ Approximately one in four of the medical error records in the database identified computer technology, which is, of course, a key component of any IONM system, as at least partly responsible for the error.⁴²

On the positive side, the electronic trail that IONM creates can act as a deterrent to potential litigation, provided, of course, that the IONM record indicated no signs of surgery-caused neurological damage.⁴³ During the discovery process of US litigation, the parties can request copies of documents. IONM provides surgeons with documentary evidence of the condition of the patient’s neurological system during surgery. If IONM has been properly performed and data evidencing neurological damage is absent, plaintiffs will be hard pressed to prevail in a case. On the other hand, as one industry player puts it, “If monitoring is not performed, plaintiffs’ attorneys have recently been much more willing to argue that the failure to conduct IONM testing to ascertain if neurological compromise was occurring was a negligent action” (Synaptic Resources, <http://www.synapticresources.com/SR-Sales-Brochure.pdf>).

4.4 *IONM and the spector of the false positive/false negative*

A concern raised by medical professionals has been that IONM systems generate false positives⁴⁴ that would dissuade a neurosurgeon from continuing with a procedure that is beneficial to a patient, or, in the alternative, that false negatives⁴⁵ would give neurosurgeons a false sense of security that would encourage them to continue, with a procedure that is having deleterious effects on the neurological system of a patient. Prima facie, the incidence of false positives and false negatives would seem to pose serious concerns. Such concerns would most certainly be justifiable if IONM systems did in fact produce false data in either direction with anything approaching regularity. Fortunately for advocates of IONM, this does not appear to be the case. A recent study headed by Dr. Eager of the University of Virginia Medical Centre carefully catalogued incidences of false positives and negatives in IONM-aided surgeries (Eager et al., 2011). The huge study, which covered over 2,000 spinal surgeries, indicated only three incidences of false positives and three of false negatives, or .00145% of all surgeries for each.⁴⁶ To put it more directly, a grand total of less than one third of one percent of all the neurosurgeries studied were beset by a false readings, either positive or negative, from an IONM system. And even in those rare cases in which a false reading occurs, it is not a fait accompli that adverse events will occur.⁴⁷ Thus, the concerns over false positives or false negatives appear de minimis.

4.5 *IONM and the concept of 'good practice'*

'Good Practice', in medical parlance, in short stands for the notion that 'the interests of patients' should be put "above those of the physician, setting and maintaining standards of competence and integrity, and providing expert advice to society on matters of health" (National Alliance for Physician Competence, <http://gmpusa.org/Docs/GoodMedicalPractice-USA-V1-1.pdf>). Logically, good practice would necessitate the use of IONM if the medical team has evidence of a calculable risk that the patient could be harmed by a surgery, that such harm could be feasibly detected via IONM, and that actions could be taken by the surgical team to avoid it by dint of the detection (Smith et al., 2008).

An overview of medical malpractice cases indicated that failure to use pre-, peri- or postoperative monitoring was identified as a 'significant' legal risk factor in a number of cases.⁴⁸ A necessary implication of this is that the lack of monitoring often figures prominently in malpractice cases, an issue that would clearly be addressed – and in theory taken off the table – for the plaintiff's bar, by the appropriate use of IONM.

4.6 *General safety concerns and efficacy issues with IONM*

Procedures must be judged from cogent risk management perspectives. A handful of issues regarding IONM safety have been noted in academic literature and should be factored into the decision to use or not use IONM. First, the risk of seizures has been pointed out as a possible side effect, due to the electrical stimulation to the nervous systems that IONM systems produce (Kothbauer, 2008). However, a number of studies have demonstrated that there are no significant seizure risks associated with IONM.⁴⁹ The American Academy of Neurology claimed several IONM techniques, including EEG and

SEP, were safe and effective, to variable degrees, when used in the manner common to operating rooms.

One of the concerns about IONM is that while it does a good job of identifying impending issues, it does a poor job of giving a surgical team time sufficient to respond to them. From a medico-legal risk management perspective, this scenario might be the worst of all worlds: a paper trail indicating neurophysiological damage caused by the surgery – fodder for the plaintiff's bar – but no ready means of responding to the issues raised in time to correct them.⁵⁰ IONM can provide real time feedback, the technology provides for this, but as will be mentioned later in this paper, this efficacy concern is only addressed by having highly qualified and competent staff to provide it.⁵¹

4.7 What about the defence of that the surgical team offered the patient more than would otherwise be expected during surgery?

A 'common sense' defence to malpractice litigation directed at IONM must be considered. IONM, while beneficial, is not sine qua non for most surgical procedures. Thus, in offering IONM, the healthcare provider has provided the patient more than was technically required; the IONM protections were, in a manner of speaking, icing on the cake. Thus, it follows from this line of reasoning that a failure of the IONM system in some respect, be it an oversight of the attending IONM specialist or a failure of the IONM equipment itself, should not give rise to a justiciable controversy.⁵² The rationale behind this thinking is that if a patient is offered an extra benefit, that patient should not then be permitted to sue if the extra benefit fails to materialise and they receive in the bargain only the basics – i.e., the surgical procedure in which physicians still have their sense of sight and other bio inputs such as standard vital signs, to guide them as to neurological issues or damaging changes. This line of reasoning sounds logical and reasonable – but by the standards of US common law, it is neither. In the US courts, concepts of contract law would render such a defence ineffective. Under US contract law, once a patient signs the waivers or other contractual informed consent documentation required to accompany a surgical procedure, this would bind the healthcare provider to providing all services contracted for in a manner in keeping with the standards established for surgeons in a given jurisdiction for all services provided. A patient's signature on such informed consent documentation has been held to be necessary by US courts and the absence of it can make attending surgeons, or, in some jurisdictions, the hospitals where the surgery occurs, liable (Render, 1998). This includes, of course, IONM. Even if it be technically unnecessary, if it be offered, it is none the less a requirement that it be delivered in accord with the standards established for malpractice. Thus, the defence of 'better than expected' is not an airtight defence to claims that the add-ons, such as IONM, were delivered in a manner that constitutes malpractice.

5 IONM risk management recommendations

Neurosurgeons involved in the delivery of IONM should keep in mind the potential pitfalls associated with the use of it or of neurosurgery in general. While there are concerns, a number of prophylactic measures can be taken to minimise the risk of

litigation and to limit its success. This paper identifies five primary tactics that healthcare policy-makers can use to accomplish these goals.

5.1 *When in doubt, document*

It should be a maxim of the healthcare professional that in all possible circumstances, patient care should be accompanied by copious notes and documentation, from initial conversation to post-operative follow up. The nightmare scenario is for a crucial piece of evidence to be supported by nothing other than physician testimony in court. While in most cases, oral testimony is admissible under the Federal Rules of Evidence,⁵³ the bare fact of admissibility does not establish that such evidence would have equal status relative to documentary evidence in the opinion of the jury. In any event, one can only conclude by sheer logic that oral testimony *supplemented by documentary evidence* would have greater weight in court than the oral testimony *standing alone*. In some cases, of course, such as with the Statute of Frauds⁵⁴ or the rule regarding parol evidence,⁵⁵ oral testimony is wholly inadmissible.⁵⁶ The classic example of the latter doctrine, arguably the one more likely to have an effect on surgeons, would involve a conversation between surgeon and patient, in which the surgeon is explaining the terms of a waiver a patient is signing; evidence of such explanatory language rendered at the time of the waiver's signing, would be inadmissible in US courts under the parol evidence rule if it is being offered as an explanation of a contractual term contrary to the plain language thereof.⁵⁷ Legal doctrinal details aside, the want of documentation, given their relatively low cost in time and trouble and relatively great potential prophylactic effects, it is inexcusable to fail to document and file all surgeon-patient conversations, all information on the maintenance and upkeep of the IONM system, and any and all other details of the surgery.⁵⁸ As one US IONM industry player puts it, surgeons should go by the maxim: "If you didn't document it, you didn't do it" (Surgical Monitoring and Neurological Group, <http://neuromonitoring.wordpress.com/tag/electroencephalography>).

5.2 *Use well-qualified staff to monitor IONM data; obtain appropriate certifications and ensure that those of your team are up to date*

IONM technicians should be well-qualified and well-trained. The US Joint Commission⁵⁹ in its 2008 report on the use of technology in healthcare pointed out that lack of training was one of the factors contributing to the unsafe implementation of technologies in healthcare (The Joint Commission, 2008). As Dr. Stecker of Winthrop University Hospital in New York observed, highly trained personnel capable of providing real time feedback are imperative to a well-run process that maximises positive patient outcomes and minimises the risks of litigation (Stecker, 2012). Certifications can also be helpful in establishing that surgeons and surgical team members are operating in accordance with industry custom. This is not a failsafe defence against litigation, but it can prevent certain lawsuits and provide legal evidence that the surgical team using IONM was well-qualified and meeting industry standards. While IONM on the whole is not heavily regulated, there are available certifications. The most prominent is offered by American Board of Registration of Electroencephalographic and Evoked Potential Technologists (ABRET, <http://www.abret.org>, <http://abret.org/cnim/eligibility>), an industry group that offers the CNIM certification in which a technologist can become IONM-certified. The examination consists of over 400 questions, the requirements to sit for the examination

include that the candidate has monitored a minimum of 150 cases, at least 15 of which occurred in the previous 12 months and that candidates possess some form of bachelor's degree or current neurodiagnostic credential.⁶⁰ There has been a steady increase in popularity of the CNIM. The American Board of Neurophysiologic Monitoring (ABNM) offers an advanced certification in IONM, targeted towards those with advanced degrees. The requirements to sit for the exam are more stringent than the CNIM: an 'earned doctorate' in "physical science, life science or clinical allied health profession", documented 300 cases monitored, a minimum of 36 months IONM experience, and at least one graduate course each in neuroanatomy and neurophysiology (ABNM, <http://www.abnm.org>, <http://abnm.info/ppIII.htm>).

5.3 Use of IONM as 'defensive medicine'

Defensive medicine is the practice of utilising medical technologies not because they make healthcare safer – in the service of the patient – but because they ward off medical malpractice litigation or make it less effective – in the service of the physician. This turns the concept of 'good practice' on its head; it is understandably controversial. The US Congressional Office of Technology Assessment defined it as follows:

"Defensive medicine occurs when doctors order...procedures...primarily (but not necessarily or solely) to reduce their exposure to malpractice liability. When physicians do extra...procedures primarily to reduce malpractice liability, they are practicing positive defensive medicine". (Manner, 2008)

Though the controversy is real, the pragmatic use of certain procedures to act as a prophylactic against potential litigation is a fair consideration for those setting risk management policy. IONM is useful in this, as aforementioned, it provides a paper trial that, if clean, showing no evidence of neurological trauma, can act as a defence and deterrent to lawsuits making claims of neurological damages.

5.4 Understand the limits of IONM and beware unintended consequences: there is no failsafe technology

Another concern with the use of IONM devices from a risk management standpoint is the same as with any complex system, there is a danger that professionals will tend over time to place undue reliance upon it. The hubris that attends new technologies can often cause even the sober professional to treat the technology with too much deference. IONM is a supplement that has proven its effectiveness, but it is not the final word in safety, as with any technological aid, it cannot entirely replace human judgment or instinct, particularly that of the virtuoso. As it has been put by Professor Kopec of Brooklyn College: "As the dependency on technology in complex systems increases...so does the likelihood of accidents. Operators become less prone to intervene, speedy recovery from error(s) is less likely, and small failures can more easily grow into major catastrophes" (Kopec et al., 2003).

Eighteenth century Scottish poet Robert Burns wrote of how "the best-laid schemes of mice and men go often awry". And so it often goes with the best-laid schemes of healthcare professionals. In the case of IONM, there is a concern that early warnings of medical events may have unintended consequences. Professor Gary Gronseth of the University of Kansas Medical Centre states that "Unintended consequences from the use

of diagnostic tests can harm patients. For example, surgeons using IOM might attempt riskier procedures”.⁶¹ This is not a purely theoretical concern. The phenomenon of safeguards providing a sense of security that fails to make an activity safer or even making it less safe is well-documented. In an example from another field, a recent study revealed the at first glance paradoxical fact that traumatic head injuries in sports have actually increased simultaneous to technological advances in helmets designed protect the head from such injuries (Boettke, 2008). As US legal economist Gordon Tullock famously – and hilariously – observed, if we really want optimal automobile safety, we would be best served by mandating a dagger be mounted on the centre of all steering wheels.⁶² There is always the concern that surgeons will develop an undue sense of safety from any security device; to put it crisply, strong policy should be established regarding the use of IONM that will on a continual basis act to break surgical teams out of this pattern.

5.5 *Ceteris paribus, do the right thing*

There is a phrase in Latin, *ceteris paribus*, oft translated into English as “all else being equal”. The concept it connotes, roughly put, is that if all other matters were accounted for, and a question put starkly with no outside variables to consider, only the essentials, what course should one take? With the use of IONM, whether it should be used in neurosurgery, there are undeniably outside variables, such as potential litigation concerns. But the primary task at hand for the surgeon is to do that which best serves the interests of the patient and prevents harm to them.⁶³ The aforementioned concept of good practice could reasonably be interpreted as compelling the physician to be agnostic as to whether a given procedure places them at risk of legal action, so long as said procedure is undertaken to prevent harm to the patient. The physician is exhorted to put the needs of patients ahead of their own; if a surgical team has reason to believe that a patient will benefit from IONM, this should in theory be sufficient to justify its use. It should also be noted, however, that while the litigation concerns aforementioned are real, nonetheless, litigation is rare relative to the number of surgeries performed.

6 Conclusions

Technological innovations over the last century have revolutionised the healthcare industry. Doctors have used these innovations to provide information and insight into a patient’s condition that would have been unthinkable just a few decades ago. IONM has been one of the tools used by surgeons to produce real time information into a patient’s condition, and its usage rate in neurosurgery has spiked in the last two decades. However, the application of any technology to healthcare has proven to be a double-edged sword for attorneys and administrators charged with overseeing and managing risk for hospitals and healthcare systems. While patient outcomes have improved dramatically as a result of these improvements, paradoxically, simultaneous with this, so have the prevalence of lawsuits based on malpractice increased. The setting of carefully considered risk management policies in such a milieu is thus imperative.

Attorneys and other risk management personnel thus need to consider both sides of the issue with IONM: patient outcomes and the avoidance of costly litigation. Unfortunately, these two are sometimes in tension, occasionally even incompatible.

While the evidence for the beneficial effects of IONM is great, so is the potential for its use by the plaintiff's bar as a springboard for litigation. Anytime a technology is newly-prominent, it becomes an attraction for the plaintiff's bar. The greater the complexity of a technology, the greater the potential for mistakes in application or breakdowns in the components, and both of these provide grist for litigation. There is also the concern of unintended consequences with IONM, as with any technology or policy, for example, surgeons might become more prone to take risks in IONM-assisted surgery, leading perversely to increased risk – again, potential grist for litigation. IONM adds a product to the mix⁶⁴ that could theoretically open the door to products liability suits, with healthcare systems as named defendants – again, any additional complexity in theory increases the likelihood of litigation.

On the other hand, IONM has been demonstrated effective at improving patient outcomes, an obvious goal of any rational risk management policy. It is well-established as effective at identifying neurological injuries in progress – or the want thereof – and, although the data is somewhat less convincing, there is significant data to support the notion that long-term patient health is improved through the use of IONM. Healthier patients should in theory file fewer lawsuits with their associated costs. There is also the larger picture concept of doing the right thing in the face of all else. If IONM makes for healthier patients and a greater likelihood that surgeons and other researchers will be able to use the data it provides to improve surgical techniques over time – and IONM very arguably accomplishes, or is likely to accomplish, both of these goals – it would seem a *fait accompli* that the benefits of IONM outweigh the drawbacks. Taken on the whole, therefore, the adoption of IONM in neurosurgery is to be recommended, both from the standpoint of good healthcare and sound legal risk management.

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Notes

- 1 The Murff (2003) study identified a broad swath of activities and placed them within one of three categories: ‘dangerous’, ‘regulated’, and ‘ultra-safe’. The activities were measured along two metrics:
 - total lives lost per year
 - numbers of encounters per each fatality.

The first metric identifies the magnitude of the societal impact of the activity from the perspective of total loss of life, the second metric identifies the relative danger of the activity without regard to total magnitude. Healthcare ranked as number one for the first metric, with driving second, bungee jumping ranked as number one for the second metric, with healthcare and mountain climbing roughly tied for second. Taking these two facts into account, a reasonable weighted measure combining metrics one and two, could be interpreted as establishing that receiving healthcare is the most dangerous activity in the USA. By comparison, relatively commonplace activities such as commercial air travel, the use of nuclear power and riding the railroads were many magnitudes lower in risk.
- 2 This paper will refer to the practice by the acronym ‘IONM’.
- 3 Ibid.
- 4 Ibid.
- 5 Ibid.
- 6 Ibid.
- 7 Ibid.
- 8 Ibid.
- 9 Ibid.
- 10 Ibid.
- 11 Ibid.
- 12 Ibid.
- 13 For a partial sampling of pertinent research, see generally: Cabraja, M. et al. (2009) ‘Neurophysiological intraoperative monitoring in neurosurgery: aid or handicap? An international survey’, *Neurosurgical Focus*, Vol. 27, No. 4, p.E2; Fehlings, M. et al. (2010) ‘The evidence for intraoperative neurophysiological monitoring in spine surgery: does it make a difference?’, *Spine*, Supplement, Vol. 35, No. 9, pp.S37-S46; Quinones-Hinojosa, A. et al. (2004) ‘Neurophysiological monitoring for safe surgical tethered cord syndrome release in adults’, *Surgical Neurology*, August, Vol. 62, No. 2, pp.127–133.
- 14 Neurologist Dr John P. Ney’s response to Dr Nuwer’s defence of IONM as a tool for preventing long term injuries, as recorded in *Neurology*, see: http://www.neurology.org/content/78/8/585.full/reply#neurology_el_48499 (accessed 22 June 2012).
- 15 Ibid.
- 16 Ibid.
- 17 Id. The reason that such scientific studies are unlikely ever to have human subjects is, of course, because no ethical surgeon would take part in a study in which a control group of human patients received intervention after IONM alerts while a second group received no such intervention after an alert. A study along those lines would indeed enable the long term health results of IONM systems to be measured on human subjects, but such a study could only exist in a milieu worthy of the most heinous Nazi research! Dr Nuwer, in an interchange with IONM sceptics on the discussion section appended to his 2012 article in *Neurology* calls such proposed research “unrealistically idealistic, impractical, and unethical” that in any event “will never occur”. See: http://www.neurology.org/content/78/8/585.full/reply#neurology_el_48499 (accessed 22 June 2012).
- 18 Ibid.

- 19 As neurologist Dr. John P. Ney put it in an online response to the 2012 Nuwer study in *Neurology*: “animal studies and personal clinical experience are insufficient to support the claim that evidence of effectiveness is not needed”. See: http://www.neurology.org/content/78/8/585/reply#neurology_el_48499 (accessed 21 June 2012).
- 20 Ney, J. et al. (2012) ‘Cost-effectiveness of intraoperative neurophysiological monitoring for spinal surgeries: beginning steps’, *Clinical Neurophysiology* [online] <http://www.sciencedirect.com/science/article/pii/S1388245712001265> (accessed 22 June 2012). However, it should be noted that the opinion that there is no consensus that can be found in the literature holding that IONM does not meet the standards of a reasonable cost-benefit analysis; such a position is by no means monolithically shared by the medical community in general or neurosurgeons in particular. In the same forum that is attached to the Nuwer article in *Neurology* from which some of the opinions against IONM are cited in this article, the following opinion in favour of IONM from the perspective of cost-benefit analysis was written in response to the Nuwer article by Drs Stanley Skinner and David Rippe of Abbot Northwestern Hospital in Minneapolis: “[C]ost-effectiveness analyses suggest that the lifetime cost of one avoided paraplegic age 25 is about \$977,000. The avoidance of paraplegia in one patient age 50 may pay for about 250 monitored cases.” (Emphasis added) See: “IONM: The standard of evidence must be both credible and ethical”, http://www.neurology.org/content/78/8/585.full/reply#neurology_el_48499 (accessed 27 June, 2012).
- 21 Online response by professor Dr Gary Gronseth of the University of Kansas Medical Center to Dr Nuwer’s 2012 study published in *Neurology*, See: http://www.neurology.org/content/78/8/585.full/reply#neurology_el_48499, (accessed 22 June, 2012).
- 22 Who of course are, as a class, scientists, or at minimum as a group tending to be of a scientific bent. One would expect such a group as a whole to work towards both more efficient applications of IONM information and more effective uses thereof for the good of the patient, and for this information in time to find its way into the literature. Thus, it is the opinion of the authors of this article that insight into the well-being of a patient in the possession of such professionals should in time expected to lead to beneficial results for the patient, as doctors formally and informally work towards using it to improve surgical techniques. At a minimum, we contend that attempts should be made to factor the possibility of this phenomenon into cost-benefit analyses of IONM.
- 23 Ibid.
- 24 Ibid.
- 25 Ibid.
- 26 Federal Rules of Civil Procedure, Rule 23.
- 27 Ibid.
- 28 Ibid.
- 29 Ibid.
- 30 Ibid.
- 31 Scarrow et al. (2011), citing an average cost of defence of approximately \$87,000, was not a cherry-picked number only including cases that made it through pretrial, to the courthouse, and to a final jury or judge resolution. It includes those cases that fail to go to trial.
- 32 Ibid.
- 33 Ibid.
- 34 Id. These numbers were derived from the 2011 Scarrow Study cited. They were arrived at by simple mathematical calculation: Cases tried to a verdict: \$87,000 average cost of legal fees + \$378,000 average jury or judge verdict, for a total of \$465,000. Cases settled: \$87,000 average cost of legal fees + \$392,000 average settlement amount, for a total of \$479,000.
- 35 Ibid.
- 36 Ibid.
- 37 Rendered in Japanese as ‘Deru kugi wa utareru’.

38 Ibid.

39 Ibid.

40 Ibid.

41 Ibid.

42 Ibid.

43 It goes virtually without saying that plaintiff's attorneys, presented with evidence prior to filing or during discovery that indicated no electronic signs of neurological damage to the plaintiff during surgery were indicated by the IONM data, would have at least some disincentive to pursue a lawsuit. At the very least, it follows that they would be more likely to settle claims for less than would be the case were there no electronic record indicating a lack of perioperative (during surgery) neurological injury. This negative evidence effect is certainly not a failsafe guaranty against litigation, but logically it would tend to tilt the field in favour of the defendant neurosurgeon. One might liken this to the evidence raised by a defendant to a speeding ticket that the radar detector indicated no signs of speeding at the time the officer observed the vehicle claimed to be speeding. While no electronic device is perfect (e.g., a veritable litigation 'industry' has been built upon effective assaults upon the results of breathalyser tests) one can well envision a prosecutor's reluctance to pursue a case that was specifically unsupported by the electronic device that indicated such crimes.

44 A false positive is an alert generated by an IONM system that falsely indicates neurological damage is occurring as a result of invasive surgery.

45 A false negative, in contrast to the false positive, is when the IONM system fails to alert neurological damage is occurring as a result of invasive surgery.

46 Ibid.

47 Of course, while a reading that is in error is never desirable, as alluded to in the main body of this paper, for such an error to produce an adverse event for a patient, it would require that the surgeon either failed to commence (or discontinued) a beneficial surgical intervention as a result of a false negative or continued with a harmful surgical intervention that they would not otherwise have proceeded with in the event of a false negative. It must be noted, however, that a false negative failure of an IONM system would seem logically to pose no more pitfalls for a patient than a surgery unaided by IONM, i.e., the medical team would have no indications of neurological damage in either event. The only possible circumstance under which surgery with a false negative from an IONM system would logically seem to be inferior to surgery without IONM would be in those cases where the doctor unduly relied upon the IONM system and took risks that he or she would not have without IONM.

48 Ibid.

49 Ibid.

50 Of course, neurological damage can occur in a moment, a simple cut of a scalpel. Without moment-to-moment feedback from an IONM system, there is more of a threat of neurological damage occurring and being recorded without sufficient opportunity to reverse course to prevent or minimise it.

51 Of course, the specialist monitoring the IONM system is the key to this process.

52 'Justiciability', in US legal parlance, of course refers to a matter involving a legal theory capable of resolution and hearing in US courts; if a case or controversy is not justiciable, it means that no legal remedy can be pursued by a plaintiff, for the matter is not one resolvable by reference to the court system.

53 Federal Rules of Evidence, Rule 43.

54 The Statute of Frauds, a US law adopted from the English law of 1677, excludes certain types of testimony from the courtroom, including surety agreements, transfers of land, or any contract that, per its terms, cannot be completed within a year of its formation.

55 A hypothetical scenario could involve a surgeon explaining to a patient some of the provisions of a waiver the patient is considering preliminary to IONM-aided neurosurgery. Were the surgeon to verbally explain to the patient at the time of the signing of the waiver that IONM

poses certain risks, such as false positives or negatives, and the patient orally acknowledged these and affirmed their understanding of them, such evidence of the ‘understanding’ that the surgeon might wish to enter into evidence would be inadmissible were it not included in the written waiver.

- 56 This is not a matter of such testimony being given lesser weight by a court, it is a matter of it being given no weight whatsoever and excluded wholesale.
- 57 The rule states that testimony of oral agreements entered into before or contemporaneous with the signing of the contract, if they directly contradict the plain language of a contract that has the appearance of being whole, is inadmissible.
- 58 In fact, as is pointed out elsewhere in this article, one of the primary advantages of IONM is the documentary effect it has upon the process, i.e., in many instances providing negative evidence of a lack of neurological damage.
- 59 The Joint Commission is a non-governmental independent, non-profit US organisation responsible for certification and oversight of the healthcare professions.
- 60 Ibid.
- 61 Online response by professor Dr Gary Gronseth of the University of Kansas Medical Center to Dr Nuwer’s 2012 study published in *Neurology*, see: http://www.neurology.org/content/78/8/585.full/reply#neurology_el_48499 (accessed 22 June, 2012).
- 62 Professor Andrew McIntosh of the University of South Wales in Australia is a leader in this field. His research has primarily involved the Australian Football League, but he recently offered the opinion, cited in the November 11, 2009 Wall Street Journal, that the high prevalence of head injuries in the American game is largely due to the false sense of security given players by dint of being caged within helmets; they tend to hit each other with forces approaching 100%. He suggests as a remedy the turning back of technology over a century by playing the game helmetless “If they didn't have helmets on, they wouldn't do that (the extremely hard hits),” he says. “They know they'd injure themselves.”
- 63 This is simply a restatement of a key portion of the so-called Hippocratic Oath, the pertinent portion of which has been translated as “I will apply...measures for the benefit of the sick...I will keep them from harm...” The Oath was historically taken by those entering the practice of medicine, although it is no longer is a requirement of being admitted to practice in the USA. However, it is still administered, in various forms, by many schools of medicine upon commencement.
- 64 Of course, the IONM system, actually a series of ‘products’ linked electronically in addition to the attending specialist(s) charged with monitoring the equipment and passing along the data to the surgical team.