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Delphi Consensus Report

Best Practices in Intraoperative Neuromonitoring in Spine Deformity Surgery: Development of an Intraoperative Checklist to Optimize Response

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Abstract

Study Design: Consensus-based creation of a checklist and guideline.

Objective: To develop a consensus-based checklist to guide surgeon responses to intraoperative neuromonitoring (IONM) changes in patients with a stable spine and to develop a consensus-based best practice guideline for IONM practice in the United States.

Summary of Background Data: Studies show that checklists enhance surgical team responses to crisis situations and improve patient outcomes. Currently, no widely accepted guidelines exist for the response to IONM changes in spine deformity surgery.

Methods: After a literature review of risk factors and recommendations for responding to IONM changes, 4 surveys were administered to 21 experienced spine surgeons and 1 neurologist experienced in IONM. Areas of equipoise were identified and the nominal group process was used to determine items to be included in the checklist. The authors reevaluated and modified the checklist at 3 face-to-face meetings over 12 months, including a period of clinical validation using a modified Delphi process. The group was also surveyed on current IONM practices at their institutions. This information and existing IONM position statements were used to create the IONM best practice guideline.

Results: Consensus was reached for the creation of 5 checklist headings containing 26 items to consider in the response to IONM changes. Consensus was reached on 5 statements for inclusion in the best practice guideline; the final guideline promotes a team approach and makes recommendations aimed at decreasing variability in neuromonitoring practices.

Conclusions: The final products represent the consensus of a group of expert spine surgeons. The checklist includes the most important and high-yield items to consider when responding to IONM changes in patients with a stable spine, whereas the IONM guideline represents the group consensus on items that should be considered best practice among IONM teams with the appropriate resources.

Level of Evidence: V

Keywords: Neuromonitoring; Spine deformity surgery; Surgical checklist

Introduction

Although fortunately quite rare, neurologic complications of spine deformity surgery are perhaps the most feared risk of these procedures [1,2]. Neurologic complications may occur through a variety of mechanisms, including direct trauma to the spinal cord, ischemia, and stretch during deformity correction [3]. Intraoperative neuromonitoring (IONM) using modalities such as somatosensory evoked potentials, motor evoked potentials, and descending neurogenic evoked potentials can detect these neurologic changes in a timely manner, allowing for intervention and reversal of neurologic deficits before they become permanent [3,4].

Multimodality monitoring is now commonplace in spinal deformity surgery [5]. The simultaneous use of somatosensory evoked potentials, motor evoked potentials, and descending neurogenic evoked potentials (for surgeries involving the thoracic spine) results in sensitivity and specificity for neurologic compromise reported to be nearly 100% [5-8]. Risk factors for changes in IONM include the presence of large degree of deformity, cardiopulmonary comorbidities, and labile intraoperative mean arterial pressures [3,9]. As the use of neuromonitoring allows for immediate action to be taken to reverse the course of neurologic dysfunction, the ability to detect and respond to these changes intraoperatively has resulted in a decline in the rate of new or worsening neurologic deficits in this population [10,11]. Although the aspirational

goal is to make complications of surgery a "never event," a more realistic goal is to consistently optimize responses to neuromonitoring changes so that permanent deficits occur as infrequently as possible [12]. Although several algorithms for the response to neuromonitoring changes have been created, none are widely accepted or used consistently in general practice for a variety of reasons [11,13].

Nevertheless, there is evidence from other areas of surgical intervention that checklists positively impact care. Evidence indicates that surgeon performance suffers under stress and time pressure, and that checklists are valuable aids in these situations [14,15]. Studies also show that the use of a cognitive aid, such as a checklist, correlates with improved management of operating room crises [16]. In a recent study assessing the use of checklists in crisis situations in the operating room, checklist use resulted in a sixfold reduction in failure of adherence to critical steps in management [15]. There is also evidence that skilled surgical teams of spine surgeons, anesthesiologists, and neuromonitoring experts perform significantly better than teams with more limited monitoring experience. A survey performed by Nuwer et al. found that the least experienced neuromonitoring team had a neurologic deficit rate that was twice as high as the rate of the most experienced team [17]. Similarly, neuromonitoring team members with higher levels of experience, certification, and education have demonstrated greater reliability in their monitoring interpretations [18]. This strengthens the call for a checklist that will help to optimize the response of the surgical team in their response to IONM changes [19]. Therefore, the goal of this project was to formally develop a consensus-based checklist relevant to pediatric and adult spine deformity surgery to improve the quality of patient care and to minimize the risk of neurologic deficit through optimization of clinical decision making during times of intraoperative stress and uncertainty. The group also sought to use the experience and expertise of the participants to develop a best practice guideline for IONM in spine deformity surgery in the United States.

Materials and Methods

Study preparation

The methodology and participants of the current initiative closely followed those that led to the development and publication of a best practice guideline for the prevention of surgical site infection after high-risk spinal deformity surgery [20]. Before initiating the current study, an extensive literature review was performed to identify other efforts to develop similar tools (algorithms, guidelines, checklists, etc) both in print and in use by members of our working group.

Consensus participants

Twenty-one spine surgeons with expertise in the area of spine deformity surgery across pediatric and adult populations from 14 hospitals in North America were asked to participate in this study. These surgeons all hold leadership positions among various orthopedic and academic organizations and study groups, and were selected because of their clinical experience and record of relevant research. In addition, attending physicians specializing in neurology (AM) and neurosurgery (RCA) and expert neurophysiologists

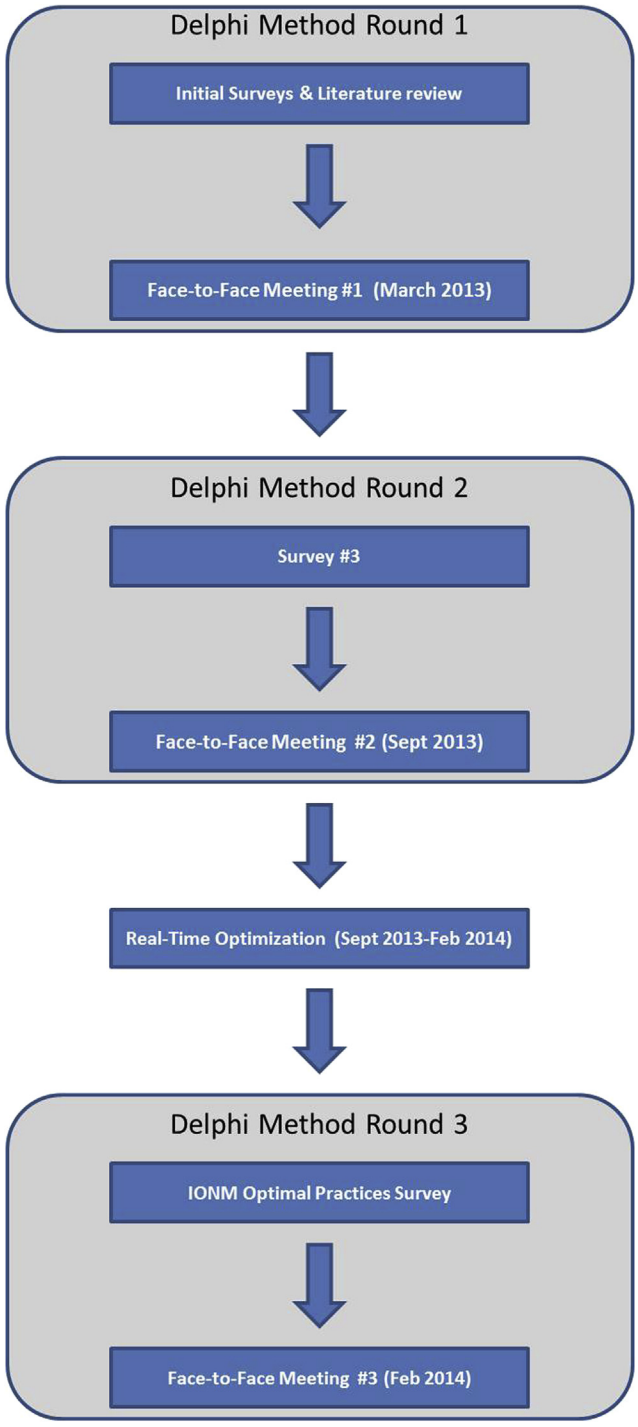

Fig. 1. Algorithm highlighting the key steps in the checklist creation process.

trained in IONM participated in the final optimization of the checklist.

Developing consensus using the Delphi technique

The Delphi method, a validated process for obtaining consensus of expert opinion through a series of structured questionnaires and discussions, was used to develop and modify the final checklist [21]. The timeline of multiple face-to-face meetings and survey polls (SurveyMonkey™) in which various aspects of the project were iteratively addressed is shown in Figure 1.

Initial surveys

An initial 4-item online survey was administered to participating surgeons to determine the number of separate checklists to be created. These questions addressed patient characteristics including the risk of neurologic deficit, degree of spine destabilization, and use of intraoperative traction. Additionally, participants were queried on whether growing rod instrumentation should be addressed in the checklist. A second survey with more specific questions was then sent to the group, which included questions regarding the structure and organization of the checklist, as well as potential content of the checklist.

Delphi method: Consensus Round 1

Results of the initial 2 surveys and the systematic literature review were presented to the participants at the first face-to-face meeting in March 2013. An outline of potential items to include in the checklist was also presented to the group based on the results of the second survey. Participants were then asked to discuss each potential item on the checklist. The nominal group technique was used to create consensus statements for each of the items, and a threshold of 80% agreement was used to determine group consensus [22].

Third survey

After the March 2013 meeting, a third survey was created by the primary authors and administered to the group. This survey addressed the inclusion of items that did not reach group consensus during the first meeting and proposed modifications to these items.

Delphi method: Consensus Round 2

Results from the third survey were presented to the participants in a second face-to-face meeting in September 2013, and a preliminary version of the IONM checklist was addressed. Participants were asked to discuss each item on the checklist, as well as the items that had not been initially agreed upon and had been modified on the basis of the results of the third survey. The checklist format was also discussed in order to maximize ease of use. After group discussion, the nominal group technique was again used to determine consensus on items for inclusion. All participants were surveyed for their willingness to participate in the real-time use and optimization of the checklist for a 6-month period after this meeting.

Real-time optimization of the checklist

All 20 participants agreed to a 6-month preliminary implementation of the IONM checklist after the second face-to-face meeting. Participants were asked to share their feedback on the checklist after each time that it was used during a neuromonitoring alert.

Development of an IONM best practice guideline

In an effort to develop a best practice guideline for IONM practices in the United States, the primary authors created a survey of current monitoring practices that was administered to the consensus group before the third face-to-face meeting. Respondents were asked to provide information regarding their use of specific monitoring modalities, warning criteria, and other information pertaining to the timing and technical aspects of neuromonitoring at their institution.

Delphi method: Consensus Round 3 and creation of the IONM best practice guideline

The real-time surgeon feedback on the checklist was shared with the participants at the third and final face-to-face meeting in January 2014. After group discussions about the surgeon feedback, consensus statements were created. Using the audience response system (ARS), consensus statements were anonymously voted on and the statements with $>80\%$ agreement were included in the checklist. A formal vote on adoption of the checklist by all consensus group participants followed.

Additionally, the results of the IONM best practices survey were presented to the group along with existing IONM position statements from the Scoliosis Research Society (SRS) and the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM). After group discussion, final consensus statements for the guideline were created and agreed upon using ARS.

Results

Initial surveys and Delphi method Round 1

After the literature review, the presentation of the initial surveys, and a thorough discussion of potential checklist items at the first meeting in March 2013, a preliminary version of the checklist with 27 items under 5 separate headings and 1 subheading was produced. At this point, the group also determined that the checklist should only be applicable to patients who have a ‘‘mechanically stable spine’’ intraoperatively, as patients who are undergoing procedures that would destabilize the spine (ie, 3-column

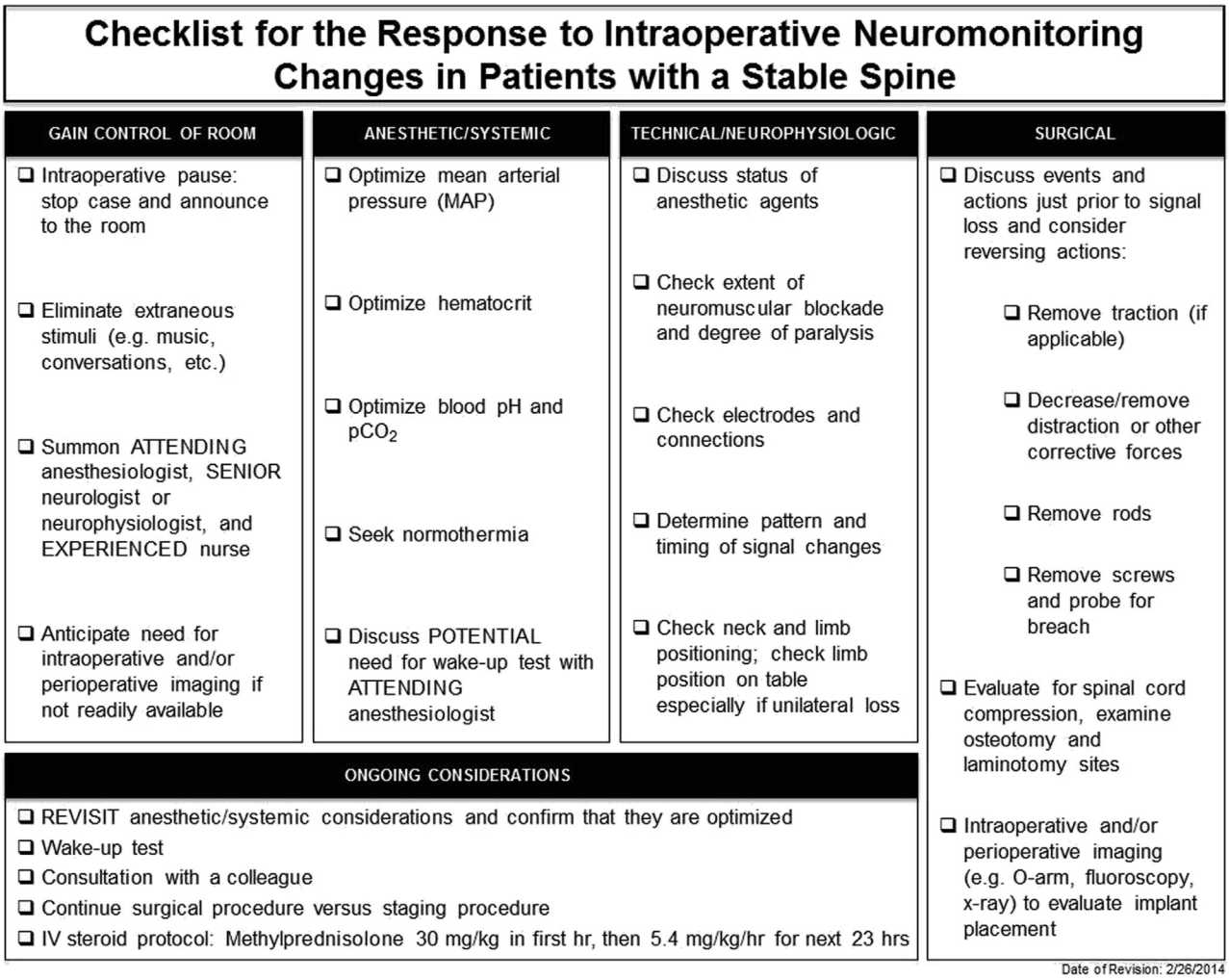

Fig. 2. Final checklist for the response to intraoperative neuromonitoring changes in patients with a stable spine.

osteotomy or vertebral column resection) would require a more nuanced response to IONM changes.

Third survey and Delphi method Round 2

After the results of the third survey and the discussion at the second face-to-face meeting, the participants reached consensus to maintain 10 of the items on the initial checklist as they had been written. Additionally, 4 of the 5 headings and the 1 subheading reached consensus for inclusion. The group then reached consensus to include 15 revised items that had previously been near consensus, 2 new items, and 1 new subheading. Two items did not reach consensus and were removed. One heading that did not reach consensus was revised.

Delphi method round 3

At the third and final face-to-face meeting, participants discussed their experiences with their use of the IONM checklist during neuromonitoring signal changes. Based on these discussions, 2 items were omitted and 1 was added. Additionally, 5 checklist items were modified and the format of the ongoing considerations section was modified. Each of these changes was approved through the use of

Table
Consensus-Based Best Practice Guideline for IONM Practices in the United States.

1. Intraoperative neuromonitoring is best performed with a team approach: surgeon, anesthesiologist, and qualified neuromonitoring personnel should all be involved in the identification and communication of neuromonitoring changes.
2. Somatosensory Evoked Potentials (SSEPs) should be used in all spine deformity cases.
3. Transcranial Motor Evoked Potentials (TcMEPs) and/or Descending Neurogenic Evoked Potentials (DNEPs) should be used in all spine deformity cases.
4. A 50% degradation in SSEP signal amplitude from baseline, and/or a sustained decrease in TcMEP signal amplitude, and/or a decrease in DNEP signal of $>60\%$ constitute "significant warning criteria" in spine deformity surgery.
5. A Wake-Up Test should always be CONSIDERED in spine deformity cases with persistent signal degradation or in all patients who cannot be monitored.

ARS, with consensus defined as 80% agreement. A formal vote on adoption of the checklist by all consensus group participants followed, resulting in 100% agreement in surgeon adoption of the stable spine checklist (Fig. 2, which is also present as a tear-out page at the end of this issue and can be found in the online version at http://dx.doi.org/10.1016/j.jspd.2014.05.003).

After final agreement on the checklist for patients with a stable spine, the results of the IONM best practices survey were presented to the group, and the SRS and AANEM position statements were reviewed. Consensus statements were created and modified through group discussion and ARS was used to finalize the IONM Best Practice Guideline (Table).

Discussion

Numerous forces have led to a sharp focus on opportunities to improve the quality and safety of health care. There is now widespread recognition that in order to deliver a product with very high reliability, systems and processes must be put in place to manage variability and the inevitable vagaries of human behavior and decision making. Drawing on experience from other fields involving high-risk and complex tasks such as aviation, space exploration, and the military, physicians have begun incorporating checklists into complex areas of health care delivery. To a large extent, these checklists serve to 1) allow a formal pause before response; 2) ensure that prerequisite personnel, equipment, and necessary preparations are in place; and 3) facilitate an optimal, orderly, coordinated, and thorough response to crisis situations [23,24].

Spine deformity surgery represents an area of ever-increasing complexity and sophistication. As techniques have evolved to more completely address greater degrees of deformity, so have the methods to detect impending neurologic change through IONM. In a recent study by the lead author, 13% of patients undergoing spinal deformity correction had IONM changes that led to an alert [3].

Confusion is often present between the use of checklists for process execution and clinical practice guidelines and pathways that take an algorithmic approach to clinical situations based on evidence-supported practices. Previous efforts have sought to provide structure to the response to neuromonitoring changes through the development of algorithms, which contain many important items to consider when responding to neuromonitoring changes, but are not displayed in an ideal format for a crisis situation, which requires a rapid and concise team response [12,25,26]. A checklist, on the other hand, is defined by the Flight Standards Information Management Systems as ‘‘a visual or oral aid that enables the user to overcome the limitations of short-term human memory [and] is designed for independent use so that the user does not have to reference a manual.’’ To achieve this standard, we followed the same principles during the selection of content and formatting for our checklist; simple and clear sentences, limited clutter, and inclusion of items that allow for corrections or modifications to be made in order to ensure patient safety [24].

Development of this checklist greatly benefited from the cumulative experience of assembled experts, and the use of the Delphi method and Nominal Group technique to formally derive consensus. Where available, decision making was strongly informed by the best available evidence in the literature. The initial literature review provided several items for discussion among the consensus group participants that ultimately were included in the current version of the checklist; for example, hypotension and significant curve correction have been reported as 2 very common causes of IONM changes, and certain anesthetic regimens with inhalational agents are commonly known to affect the interpretation of motor evoked potentials during spine surgery [3,27]. In areas where little or no evidence was available, the checklist relied on the expertise of the participants involved. For example, all participants agreed that the initial response to an IONM change should include an effort to ensure that conditions are optimal for effective communication among team members. The checklist also contains several prompts for items that could be easily overlooked during a crisis response, such as checking limb positioning and anticipating the need for future actions such as a wake-up test. Iterative modifications and communication allowed the emergence of a consensus-based product.

A similar approach was used to create a consensus-based best practice guideline for current IONM practices in the United States. Currently, IONM practice recommendations are available from the SRS and AANEM, but the group felt that there was an opportunity to extend the scale and impact of these recommendations. The SRS position statement suggests that the use of IONM during spine surgery is ‘‘not investigational’’ and that the use of multimodality monitoring is preferable to single modality monitoring [28]. The AANEM statement is primarily written for use by neuromonitoring technologists and neurophysiologists and addresses team-related and technical aspects of neuromonitoring [29]. In order to create the IONM Best Practice Guideline, the group collected input from several members of the neuromonitoring team, including monitoring technologists, neurologists, and spine surgeons. The existing position statements and experience from the current practices of the group were used to create the 5 final consensus statements.

One limitation of the checklist and guideline is that they are primarily consensus based, as the lack of literature in this area limited our ability to make evidence-based recommendations. In addition, the checklist focuses specifically on patients with a stable spine intraoperatively, as patients with a destabilized spine (ie, patients undergoing a vertebral column resection) require a modified checklist designed for the specific needs of that population. The author group chose to focus on the lower risk patients first, as they encompass the vast majority of spine deformity patients, and a checklist for destabilized patients will be developed in the future. It is also important to note that

although the checklist aims to improve team communication and streamline team responses to IONM changes, it is only one part of the equation for improving the safety of spine deformity surgery. Although there is an implicit assumption that institutions choosing to use this checklist will have defined expertise and processes to manage crisis situations, it is recommended that concepts of team training be incorporated into implementation of the checklist. A culture of open communication, teamwork, and motivation to improve the quality of care is essential for successful implementation of this type of checklist, and the checklist should be adapted to the realities of local resources and skill sets [30]. It is also important to remember that although the checklist is distilled from the collective experience of 21 high-volume surgeons, of course no guideline or checklist is meant to supplant clinical judgment or experience, and responses should always be considered on a case-by-case basis.

The use of surgical checklists is increasingly common as a result of their success in improving patient outcomes and patient safety. The result of our work is a consensus-based checklist for the response to IONM changes during spine deformity surgery in patients with a stable spine, as well as a best practice guideline for the use of IONM in spine deformity surgery. Widespread and successful implementation of these products has the potential to improve surgical outcomes and patient safety in the field of spine surgery.

Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.jspd.2014.05.003.

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