

Building Consensus: Development of Best Practice Guidelines on Wrong Level Surgery in Spinal Deformity

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Abstract

Study Design: Consensus-building using the Delphi and nominal group technique.

Objective: To establish best practice guidelines using formal techniques of consensus building among a group of experienced spinal deformity surgeons to avert wrong-level spinal deformity surgery.

Summary of Background Data: Numerous previous studies have demonstrated that wrong-level spinal deformity occurs at a substantial rate, with more than half of all spine surgeons reporting direct or indirect experience operating on the wrong levels. Nevertheless, currently, guidelines to avert wrong-level spinal deformity surgery have not been developed.

Methods: The Delphi process and nominal group technique were used to formally derive consensus among 16 fellowship-trained spine surgeons. Surgeons were surveyed for current practices, presented with the results of a systematic review, and asked to vote anonymously for or against item inclusion during three iterative rounds. Agreement of 80% or higher was considered consensus. Items near consensus (70% to 80% agreement) were probed in detail using the nominal group technique in a facilitated group meeting.

Results: Participants had a mean of 13.4 years of practice (range: 2–32 years) and 103.1 (range: 50–250) annual spinal deformity surgeries, with a combined total of 24,200 procedures. Consensus was reached for the creation of best practice guidelines (BPGs) consisting of 17 interventions to avert wrong-level surgery. A final checklist consisting of preoperative and intraoperative methods, including standardized vertebral-level counting and optimal imaging criteria, was supported by 100% of participants.

Conclusion: We developed consensus-based best practice guidelines for the prevention of wrong-vertebral-level surgery. This can serve as a tool to reduce the variability in preoperative and intraoperative practices and guide research regarding the effectiveness of such interventions on the incidence of wrong-level surgery.

Level of Evidence: Level V.

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Keywords: Best practice guidelines; Wrong level surgery; Spinal deformity; Delphi process

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Introduction

Wrong-level surgery is an acknowledged, unfortunate reality in spinal surgery which can lead to devastating consequences for patients. Although wrong-site surgery has been extensively studied, there remains a paucity of literature in the specific area of wrong-level surgery in spinal deformity. Despite the National Quality Forum's efforts to address and eliminate wrong-level surgery, wrong-level surgery continues to occur with alarming frequency [1].

In a survey of 415 surgeons from the American Association of Neurological Surgeons, a staggering 50% reported one or more wrong-level surgeries, including 10% who performed four or more during their career [2]. The current literature estimates a procedural incidence of wrong-level surgery ranging from 0.003% to 2.12% [1-10]. However, this is likely under-reported given the lack of prospective studies [4,11].

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), American Academy of Orthopaedic Surgeons (AAOS), and North American Spine Society (NASS) have issued guidelines in an attempt to reduce the risk of incorrect procedures (wrong site, procedure, or person) [12-15]. Although preoperative verification, site marking, and time-out protocols in the operating room assist with the reduction of such errors [12-16], they may not have had the intended goal of making wrong-level spinal surgery a “never event.”

Prior studies have identified numerous risk factors for wrong-level surgery, including failure to recognize aberrant anatomy, vertebral miscounting, failure to relocalize after exposure, suboptimal intraoperative radiographs, and lack of communication [1,17]. Despite these identified risk factors, many of which are preventable [1], there remains considerable variation in preoperative and intraoperative methods to correctly identify vertebral levels.

The purpose of this initiative was to develop formal consensus-based best practice guidelines (BPGs) to help minimize wrong-level surgery in spine deformity using a systematic literature review and experience of fellowship-trained spine surgeons using the Delphi and Nominal Group Technique.

Materials and Methods

Consensus participants

Eighteen spine surgeons with various levels of experience from four academic institutions in the Spinal Deformity Club of New York were asked to join in this effort, and 16 agreed to participate. Surgeons were selected based on clinical experience, relevant research, and leadership positions in various spine organizations and study groups. The study was approved by the Columbia University Institutional Review Board (Protocol AAAR1745).

Overview of the Delphi and nominal group technique

This initiative closely followed the methodology utilized for the published BPGs on the prevention of surgical site infections in high-risk pediatric spine surgery [18] and intraoperative neuromonitoring in spinal deformity surgery [19]. Consensus building was established using the Delphi technique and nominal group technique.

Briefly, the Delphi method is a validated methodology of developing formal consensus via iterative rounds consisting of consensus statements or recommendations [20-24]. Throughout the process, statements are revised based on participant feedback and collaborative discussions [20,23]. Furthermore, the nominal group technique is a form of small group discussion that consists of three main

Table 1
Survey of current practices and scope of consensus.

Scope of consensus and current practices
1. What should be the scope of these best practice statement on correct level surgery (all spinal surgeries, spinal deformity, cervicothoracic spinal deformity, thoracolumbar spinal deformity)?
2. Does every member of your department or institution use a shared standard for vertebral counting?
3. Do you believe a standardized vertebral level counting method is needed?
4. What do you believe is the optimal method for vertebral level counting?
5. Does every member of your department have a standardized technique for obtaining quality intraoperative radiographs?
6. Do you believe a mechanism to standardize the technique and quality of intraoperative radiographs is needed?
7. What do you believe are the most common preoperative errors leading to wrong-level surgeries?
8. What do you believe are the most common intraoperative errors leading to wrong-level surgeries?
9. What criteria or elements do you believe are important for optimal radiographs or fluoroscopy?
10. Have you ever observed or participated in a surgery where the incorrect vertebral level was identified, but the issue was rectified prior to any intervention?
11. Have you observed or participated in a surgery where the incorrect vertebral level was identified and operated on?
12. Has anyone at your department/institution observed or participated in a surgery where the incorrect vertebral level was identified, but the issue was rectified prior to any intervention?
13. Has anyone at your department/institution observed or participated in a surgery where the incorrect vertebral level was identified and operated on?

components: (1) a moderator who facilitates the discussion process; (2) carefully prepared nonleading questions that elicit responses from all participants; and (3) task-oriented participants with expertise in a given field who generate, discuss, and prioritize the suggestions of all members [25,26]. The technique prevents a single participant from dominating or influencing the decision process [25].

Survey of current practices

A 13-item online survey (Qualtrics Platform) was administered to the participating spine surgeons in December 2016 (Table 1). Surgeons were asked about the mean number of annual spine deformity procedures completed per year, years in practice, and first- or secondhand experience with observation or participation in wrong-level surgery. Furthermore, surgeons who participated in wrong-level surgery were asked to describe the procedure and identify errors that lead to the outcome. Surgeons were also asked to identify the scope of this consensus project, in addition to current preoperative and intraoperative practices including vertebral-level counting and optimal intraoperative radiographic criteria.

Delphi and nominal group technique round 1

The primary authors created an electronic survey to evaluate current practices by spine deformity surgeons. A systematic review of the literature was conducted to

identify risk factors and prevention strategies associated with wrong-level surgery in all spine deformity. Published guidelines were used to grade the level of evidence [27,28].

Results of the systematic literature review and current practice survey were provided to participants in the first online round (Qualtrics platform) completed in January 2017. A secondary survey consisting of 24 consensus statements created by the primary authors was distributed to all participants as shown in Table 2.

Inclusion or exclusion of each intervention is dependent on participants' responses to a 4-point Likert scale that

Table 2
Consensus round 1.

Initial intervention recommendations
1. A standardized technique of vertebral naming and counting should be adopted for all pre- and intraoperative radiographs to minimize the possibility of naming error
2. The Spinal Deformity Study Group (SDSG) method should be the standard technique for vertebral level counting (Table 2)
3. Per the SDSG method, the Atlas (C1) should be used as the standard for cervical level counting
4. A preoperative multidisciplinary conference or meeting is the optimal time to discuss aberrant anatomy and vertebral level selection with the clinical or surgical team
5. The operative plan, including the plan for specific instrumentation/ fusion levels, should be clearly documented in the preoperative note
6. In cases where preoperative imaging is suboptimal, repeat preoperative radiographs should be considered
7. Radiology should be consulted for decision making in vertebral level counting in cases of ambiguity
8. The operative plan should be communicated to the OR team before or during time-out, including any changes from the preoperative plan
9. Vertebral levels should be estimated prior to incision with skin markings and pre-incision radiographs
10. Localization should occur after exposure with a marker at the level of a pedicle
11. Radiographs should be both prior to incision and after exposure
12. In the situation of any ambiguity following intraoperative imaging, another surgeon (attending/fellow) should be consulted first
13. In the situation of any ambiguity following intraoperative imaging, another radiologist should be consulted first
14. During imaging: <ol style="list-style-type: none"> All extraneous hardware and/or retractors should be removed The point of interest should be at the center of the image A known anatomical landmark should be included as reviewed and compared with the preoperative imaging that has been marked in ink according to the Spinal Deformity Study Group method The opaque marker should be at the level of the pedicle within two vertebrae of the lowest instrumented vertebra (LIV) An opaque marker at the level of the skin should be used An opaque marker at the level of the skin should NOT be used Three-dimensional orthogonal views of the marked vertebral body end should be obtained
15. If uncertainty regarding the vertebral level arises because of poor intraoperative imaging, further effort to optimize and/or repeat anteroposterior or lateral radiographs should be made
16. A grading system should be developed and used to assess the quality of intraoperative imaging to ensure attention to optimal imaging criteria
17. Radiography should be considered the gold standard for intraoperative imaging
18. Fluoroscopy should be considered the gold standard for intraoperative imaging

Table 3

Consensus round 2: revisions to select interventions.

Revised statements for Delphi round 2

1. The *Axis (C2)* should be used as a standard for cervical level counting
2. A *preoperative conference or meeting (indications conference)* is the optimal time to discuss aberrant anatomy and vertebral level selection with the clinical or surgical team
3. An *opaque marker at the level of the skin should generally NOT be relied upon* for instrumentation/fusion level determination
4. The opaque marker should be at the level of the pedicle *proximal to the LIV*
5. In the situation of any ambiguity, *another surgeon or radiologist* should be consulted

Revisions are shown in italics.

consists of 4 options (strongly agree, agree, disagree, or strongly disagree). Consensus is attained when a specific item attains at least 80% agreement or disagreement. Near consensus is defined as 70% to 79% agreement or disagreement, whereas indeterminate is less than 70%.

Delphi and nominal group technique round 2

The results from the first round were presented in a face-to-face meeting at the Spine Safety Summit in February 2017. Interventions that attained near-consensus or indeterminate status were modified to improve consensus by incorporating participant feedback (Table 3). An Audience Response System (Turning Point Solutions) was used to ensure anonymity during voting.

The final recommendations were organized into a checklist format including preoperative and intraoperative methods. Finally, participants were asked to respond with “yes or no” (1) to support the final best practice guidelines and checklist created by this consensus-building process and (2) implement the recommendation in their daily practice.

Results*Characteristics of participants*

The participant rate in the survey of current practices was 100%, with a total of 16 fellowship-trained spine surgeons from 4 academic institutions completing the survey. The participants had a mean of 13.4 years of practice (range: 2–32 years) and performed a mean of 103.1 (range: 50–250) spinal deformity surgeries annually. The approximate number of total spine deformity surgeries performed by the participants during their career was 24,200.

Overall, 87.5% (14/16) personally observed or participated in a wrong-vertebral-level surgery during their residency training, fellowship, or practice. Moreover, 100% (16/16) were aware of a surgeon at their department or institution who observed or participated in a wrong-vertebral-level surgery.

Survey of current practices

The majority of surgeons indicated that heretofore no standardized method for vertebral-level counting (15/16) or standardized technique for obtaining quality intraoperative radiographs (14/16) at their department or institution. Additionally, there was consensus that a standardized technique should be adopted for both vertebral counting and intraoperative radiographs.

The preoperative errors leading to wrong-vertebral-level surgery as cited by participants included failure to count or name vertebra in a reliable and reproducible manner, poor quality or insufficient preoperative imaging, and lack of attention to potential anatomical variants on preoperative images.

Furthermore, intraoperative errors cited by participants included use of confusing and unreliable marking when counting, such as marking at level of skin or superficial to the level of the pedicle, and failure to adequately visualize the level due to large body habitus.

Delphi and nominal group technique

Following presentation of the current practice survey, results of a systematic literature review, and participant feedback, the first consensus round produced 11 interventions attaining consensus (Table 4).

Interventions that were near but not at consensus (70% to 79%) included (1) adoption of the Spinal Deformity Study Group (SDSG) method [29] for cervical level counting (counting down from the atlas or C1); (2) a preoperative multidisciplinary conference is the optimal time for discussion regarding aberrant anatomy and vertebral-level selection; and (3) in the situation of poor intraoperative imaging radiology should be consulted if ambiguity remains following consultation of a surgeon.

Indeterminate consensus (<70%) was reached for the following interventions: For preoperative methods, radiology should be consulted for decision making in vertebral-level counting in cases of ambiguity. For intraoperative methods, (1) vertebral levels should be estimated prior to incision with skin markings and pre-incision radiographs; (2) radiographs should be taken both prior to incision and after exposure; and (3) an opaque marker anywhere on the spine should be used. Additionally, indeterminate consensus was attained for utilizing a grading system to assess the quality of intraoperative imaging to ensure attention to the intraoperative imaging criteria which reached consensus. Last, determination of a gold standard for intraoperative imaging (radiography or fluoroscopy) did not reach consensus, attaining 62.5% and 37.5% agreement, respectively.

During the live meeting, interventions that did not initially attain consensus were modified to elicit improved consensus. New items recommended by participants were also discussed. In total, the second round led to consensus for six additional interventions (Table 4).

Table 4
Recommendations reaching consensus.

Intervention	Consensus (%)		
	Total	Strongly agree	Agree
1. A standardized technique of vertebral naming and counting should be adopted for all pre- and intraoperative radiographs to minimize the possibility of naming error*	82	63	19
2. The Spinal Deformity Study Group (SDSG) method should be the standard technique for vertebral level counting (Table 4)*	81	56	25
3. The Axis (C2) should be used as a standard for cervical level counting†	100	69	31
4. A preoperative conference or meeting (indications conference) is the optimal time to discuss aberrant anatomy and vertebral level selection with the clinical or surgical team†	100	67	33
5. The operative plan, including the plan for specific instrumentation/fusion levels, should be clearly documented in the preoperative note*	100	63	37
6. In cases where preoperative imaging is suboptimal, repeat preoperative radiographs should be considered*	100	75	25
7. The operative plan should be communicated to the OR team before or during time-out, including any changes from the preoperative plan*	100	75	25
8. An opaque marker at the level of the skin should generally NOT be relied upon for instrumentation/fusion level determination†	100	100	0
9. Localization should occur after exposure with a radiopaque marker at the pedicle level*	88	50	38
10. During imaging,			
a. All extraneous hardware and/or retractors should be removed*	100	56	44
b. The point of interest should be at the center of the image*	81	50	31
c. A known anatomical landmark should be included as reviewed and compared with the preoperative imaging, which has been marked in ink according to the spinal deformity study group method*	94	44	50
d. The opaque marker should be at the level of the pedicle proximal to the LIV†	100	85	15
e. Three-dimensional orthogonal views of the marked vertebral body end should be obtained*	88	50	38
16. Consider a radiographic time-out to obtain a team-consensus regarding the vertebral levels†	100	83	17
17. If uncertainty regarding the vertebral level arises due to poor intraoperative imaging, further effort to optimize and/or repeat AP or lateral radiographs should be made*	82	63	19
18. In the situation of any ambiguity, another surgeon or radiologist should be consulted†	88	44	44

* These interventions reached consensus after the first round of voting.

† These interventions reached consensus after the second or third round of voting.

Table 5
Recommendations NOT reaching consensus.

Recommendation	Responses (%)				
	Summary	Strongly Agree	Agree	Disagree	Strongly Disagree
1. Vertebral levels should be estimated prior to incision with skin markings and pre-incision radiographs	63% agree	31.3	31.3	31.3	6
2. Radiographs should be both prior to incision and after exposure	57% agree	13	44	37	6
3. A grading system should be developed and used to assess the quality of intraoperative imaging to ensure attention to optimal imaging criteria	63% agree	19	44	37	0
4. X-ray should be considered the gold standard for intraoperative imaging	56% disagree	19	25	50	6
5. Fluoroscopy should be considered the gold standard for intraoperative imaging	63% agree	13	50	37	0

However, five interventions ultimately did not reach consensus (Table 5).

Following the completion of the final round, the BPGs were summarized utilizing a checklist (Fig.) organized

into preoperative and intraoperative interventions. All participants (100%) agreed to support the publication of the BPGs and implement the protocol at their respective institutions.

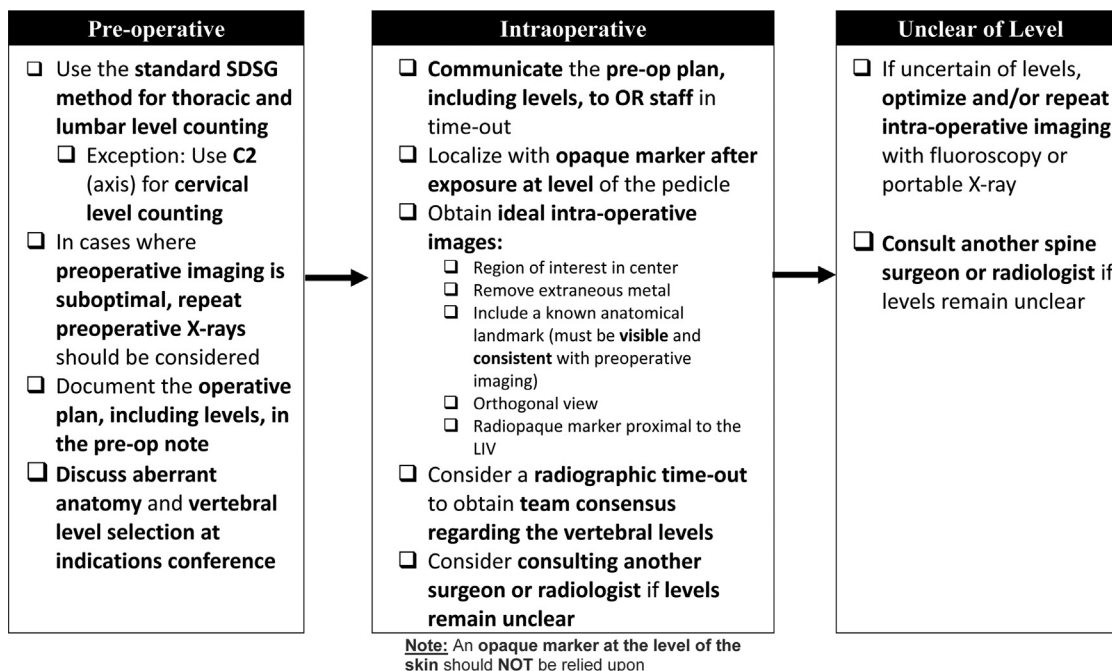


Fig. Final best practice guidelines checklist.

Discussion

Wrong-level surgery, a type of wrong-site surgery, falls under the Joint Commission's classification of a "sentinel event," which indicates serious physical or psychological injury, or risk thereof, has been rendered to the patient [30,31]. The term "risk thereof" refers to any process variation for which a recurrence would carry a significant chance of a serious adverse outcome [31]. Additionally, the Centers of Medicare and Medicaid Services considers wrong-site surgery a "never-event" [32]. Unfortunately, orthopedic surgery is among the specialties with the highest risk of wrong-site surgery [30]. This is of particular interest to spine deformity surgeons as identification of the correct spinal level can be more challenging than identification of the laterality of the procedure [33].

Since 2004, institutions accredited by the Joint Commission are obligated to verify the patient and procedure preoperatively, mark the intended surgical site, and call a time-out in the operating room prior to each procedure [34–36]. Spine deformity surgeons may voluntarily include additional items such as confirmation of appropriate implant availability and imaging modalities. Despite implementation of the evidence-based Universal Protocol [4,37], North American Spine Society (NASS), and American Academy of Orthopaedic Surgeons (AAOS) surgical site guidelines, wrong-level spine surgery continues to occur [1–10]. The number of *reported* wrong site, wrong patient, or wrong procedures has *increased* by 34.4% (from 90 to 121) since the introduction of the Universal Protocol in 2004 [34]. It is unclear whether the actual incidence of such events has

increased or a greater number of such procedures is being reported.

Despite the magnitude of this issue, there is no consensus on the definition of wrong-level surgery [37]. First, this requires a fundamental delineation as to whether the definition should be "error-based" or "harm-based." An error-based definition would imply only an unintentional deviation from the operative plan, whereas a harm-based definition would imply some harm to the patient, including unnecessary need for return to the operating room or failure to address the targeted surgical pathology. Although harm can occur without malpractice, the legal system has established a dedicated litigation process to determine whether harm is truly incurred following an operative error. Based on the tenants of medical malpractice in the United States, four legal elements must be proven to show that injury has resulted (1) duty to the patient; (2) breach of duty; (3) injury caused by the breach; and (4) resulting damages [38]. The adoption of a harm-based definition may yield a potentially complex and controversial definition because the above components must be taken into consideration.

After discussion of these issues, the consensus of our working group was that an error-based definition is most appropriate for spinal deformity surgery. More specifically, 100% of participating surgeons in this Delphi and nominal group technique process voted to adopt the following definition: "Wrong level surgery occurs anytime there is an *unintentional* deviation in instrumented vertebral levels from the preoperative plan. As such, although wrong-level surgery does indicate that an error in execution has

Table 6
Spinal deformity study group manual vertebral counting method.

SDSG guidelines
1. Start at the first vertebra with ribs and call that T1.
2. Continue labeling vertebrae until the last one with ribs is identified (it could be T11, T12, or T13).
3. If there are 11 definite ribs with 6 vertebrae below, and it is not clear if the 12th vertebra has a rib, call it T12 to maintain the 12 thoracic and 5 lumbar numbering.
4. In all other cases, the first vertebra below the last thoracic vertebra (last vertebra with ribs) is considered L1.

occurred, it does *not* necessarily imply that harm has been rendered to the patient.” In considering the reality that unintentional addition of a proximal instrumentation and fusion level to an exemplary intended T3–L3 spinal construct is likely not associated with any harm at all to a patient, this error-based definition seems most appropriate.

Participants reached consensus via iterative rounds during this Delphi process using the nominal group technique, supplemented by a systematic literature review and survey of current practices. The shared clinical and surgical experience, practice strategies, and face-to-face discussions allowed for the utilization of “collective knowledge” [20] in this nominal group to guide this consensus-driven process.

The Delphi and nominal group technique process increased consensus for both preoperative and intraoperative practices to avert wrong-level surgery. In the initial survey, 11 items achieved consensus; however, following additional discussions, 6 additional items reached consensus. The 17 interventions that comprise these BPGs serve as the first national formally derived consensus-based strategy to avert wrong-level surgery in spine deformity surgery. Of note, consensus was not reached for five recommendations, indicating collective equipoise which may provide an opportunity for further efforts and exploration.

Participants reached consensus for four preoperative interventions (Table 6). Consensus to utilize a standardized technique of vertebral counting was reached, followed by agreement to adopt the SDSG method with the exception of using C2 (axis) for cervical level counting. Prior to this initiative, only 50% of participants used a method partially or fully consistent with the SDSG, and a total of six different methods were reported. Furthermore, consensus was reached for the use of a preoperative meeting, commonly referred to as indications conference, to discuss aberrant anatomy and level selection. Implementation of these techniques is supported by the literature, as it allows for recognition of aberrant anatomy, avoidance of miscounting and radiographic misinterpretation, anticipation of difficult anatomy, and promotion of communication [35,39–42].

Additionally, 11 intraoperative techniques reached consensus, including radiopaque marker use [43,44], localization after exposure [15,42,45,46], and optimal imaging

criteria (Table 4) [42,47]. Most importantly, a recommendation addressing operative culture room was also included, as this has been found to be a risk factor in multiple industries including medicine, construction, and aviation [48–52]. Despite the seniority of an attending surgeon, commanding pilot, or construction manager, implementation of a culture that empowers junior staff to voice their concerns, or provide input regarding potential execution errors, can significantly impact outcomes [53,54]. Accordingly, 100% of participants agreed that a radiographic time-out to obtain a team-consensus regarding the vertebral levels should be considered. This would include eliciting input from other surgeon(s), including residents.

Participants did not reach consensus for a grading system to assess the quality of intraoperative imaging (indeterminate <70% agreement). Although agreement was reached regarding the optimal criteria for intraoperative imaging, it was the opinion of the participants that such a system would not alter the surgeon’s next steps given that consensus was reached regarding the next steps in situations of ambiguity. Additionally, no agreement regarding the gold standard for intraoperative imaging, such as radiograph or fluoroscopy, was reached.

There are several limitations that must be considered when implementing these BPGs. First, the lack of high-quality evidence assessing the interventions necessary to reduce wrong-level surgery necessitates the incorporation of consensus-based expert opinion. A BPG, by definition, relies on formally derived consensus opinions of experts informed but not solely reliant on the available clinical evidence. Furthermore, the systematic literature review that established the initial voting items and discussions in the Delphi and nominal group technique process included publications extending beyond the scope of spinal deformity. Although it is the authors’ hope that many of these interventions would be useful for other types of spine surgery (other than deformity), these guidelines were developed specifically for spinal deformity surgery. Lastly, several recommendations may appear nonspecific; however, they have been specifically formulated to provide the surgeon with autonomy in determining next steps. For instance, consulting another surgeon or radiologist if any ambiguity arises regarding vertebral levels, or considering a radiologic time-out to obtain to consensus regarding vertebral levels, is left to the surgeon.

In conclusion, we established a set of BPGs using formal techniques of consensus building among a group of experienced spine deformity surgeons in an attempt to prevent wrong-level surgery. A checklist consisting of the 17 consensus items was developed (Fig.) to assist with this initiative. All participants have agreed to support the final BPGs and implement them in their practice. The authors urge spine deformity surgeons to implement these BPGs to help standardize preoperative and intraoperative practices and avert wrong-level surgery, which may lead to adverse patient consequences.

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