



North American Spine Society

Training Recommendations for New Technology

General Principles

New drugs and devices are being introduced into the continuum of spine care more rapidly than ever before. As vigilant advocates for the safety of spine care patients, the North American Spine Society (NASS) believes it is essential for physicians to be educated in the indications, applications and techniques as well as the potential complications related to any new technology. To that end, NASS formed a Task Force on Training Recommendations for New Technologies in 2004. This Task Force represents a first time partnership between NASS and industry relative to the introduction of new medical technology. In the broadest sense, the goal of the Task Force is patient safety. In the narrowest view, it is to develop minimum training recommendations for new technologies. Task Force members represent relevant concerns of members of NASS (patient safety, education, resident and fellow activities, and clinical guidelines) as well as industry, specific to each technology being discussed.

It is in the best interests of patients, physicians, industry and third-party payers that adequate training be defined and implemented with each introduction of a new technology to the spine care armamentarium. NASS believes that certain general principles apply to the introduction of any new technology in addition to those principles specific to individual treatments. The general principles for consideration before undertaking a new technology include:

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- **Attention to the health and safety of the patient.**
- **Anticipation and planning for management of attendant risks of the treatment.**
- **Periodic assessment of outcomes to refine and expand indications for the procedure accordingly and to assess skill sets.**
- **Availability of a new technology.**

NASS is frequently approached by hospitals requesting recommendations for the implementation of new technologies (eg, what is adequate training?). NASS, as an organization, cannot implement or enforce any physician training recommendations, nor does it attempt to do so. Furthermore, it is recognized that individual hospitals are the final arbiters in establishing credentialing criteria for staff physicians engaging in the application of new technologies. Implementation and enforcement of any recommendations are at the discretion of individual hospital or hospital system credentialing and privileging committees. NASS is in a position, however, to make advisory recommendations regarding the training and/or experience that physicians implementing a new technology may need.

NASS uses the following criteria in determining the technologies for which it will develop training recommendations:

- Existing and/or new technologies that are debated or not yet well-established (eg, those with CPT tracking codes) may be considered.
- Technologies that are newly FDA-approved and/or have ongoing IDE studies.
- Technologies that are reviewed and addressed by NASS New Technology Assessment.

It is at the discretion of the Task Force to determine which technologies it wishes to address. Each specific technology addressed will be accompanied by distribution of these general recommendations.

NASS training recommendations should not be considered an endorsement of any technology or as evidence of efficacy. It is at the discretion of individual hospitals and physicians to determine if use of a new technology is appropriate in general

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and/or in a specific case. NASS training recommendations provide what NASS believes to be the minimum recommended training for any individual choosing to use a new technology for patient care. Recommendations are based on the state of the science at the time of issuance and NASS encourages future research for all new technologies. NASS plans to review recommendations biannually.

The American College of Surgeons (ACS)¹ has published a number of statements related to emerging surgical technologies. Their statements emphasize both qualifications needed for implementing a new technology and the importance of balanced evaluation of safety, efficacy and cost of new technologies—without impeding timely development or use.

NASS believes the ACS Guidelines, with appropriate modifications for spine care, represent reasonable expectations for the training of multidisciplinary physicians relative to any new patient care technology.

Recommendations

1. The physician must be a member in good standing of the department or service from which privileges are being requested.
2. Use of new technology in the clinical setting requires defined and appropriate education of physicians. This education includes:
 - Prerequisite in-depth knowledge of the relevant disease process and its management, gained through both formal training and clinical experience.
 - Acquisition of necessary technical skills and familiarity with indications through defined educational programs presenting balanced content in the technology. Qualifying programs should include didactic and practical elements, which must be successfully completed (not just attended) and documented either as part of fellowship training, a postresidency course of instruction or as a component of an approved residency program.
 - The physician must be qualified, experienced and knowledgeable in the management of the diseases for which the technology is applied:

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- Many skills are highly specialized and the mere acquisition of a skill is not the only criterion by which to measure qualifications.
- In spine care in general, patient selection is an essential element in the use of any treatment or technology. Furthermore, prompt recognition and management of complications can only be achieved when the physician is fully qualified in all aspects of treatment of the disease and/or equipped to make timely and appropriate referrals as needed.
- Physicians performing procedures should have knowledge of appropriate treatment options should the procedure/treatment fail and be accomplished in the required revision techniques.
- The qualifications of the physician who will apply the new technology should be reviewed by a local credentialing body whose members have experience and knowledge in the management of complex spine procedures. The practices of mentoring and proctoring are encouraged.

Other elements of appropriate training to be considered may include:

- Education containing a balanced presentation of pros and cons of a new technology as well as comparison to existing treatments.
- Sources of the content and funding of the education are transparent so that attendees may judge the potential bias of any given presentation.

Adapted with permission from 'Statement on Emerging Surgical Technologies and the Evaluation of Credentials,' American College of Surgeons, June 1994.

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¹ American College of Surgeons. [ST-18] Statement on Emerging Surgical Technologies and the Evaluation of Credentials. 1994. Available at: http://www.facs.org/fellows_info/statements/st-18.html. Accessed: July 20, 2004.

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North American Spine Society

Training Recommendations for New Technology: Lumbar Disc Arthroplasty

Lumbar Disc Arthroplasty (Artificial Disc Replacement)

All North American Spine Society (NASS) Training Recommendations for New Technology-General Principles apply, in addition to any recommendations that are procedure-specific. NASS training recommendations should not be considered an endorsement of any technology or as evidence of efficacy. Furthermore, it is recognized that individual hospitals are the final arbiters in establishing credentialing criteria for staff physicians engaging in the application of new technologies. Training elements/considerations specific to lumbar disc arthroplasty include:

- The risks inherent in an anterior transperitoneal or retroperitoneal approach—and particularly, a repeat anterior approach—are significant. It is recommended that surgeons be well-trained and have extensive anterior lumbar interbody fusion (ALIF) experience. If the spine surgeon does not perform his/her own anterior transperitoneal or retroperitoneal approaches, the approach surgeon used should have either significant experience with the anterior transperitoneal or retroperitoneal approach for ALIF or have completed additional instruction in this specific technique.
- Procedures should be performed in a clinical setting equipped to undertake a major anterior transperitoneal or retroperitoneal procedure with its attendant complexity. The clinical setting should be equipped to deal with potential intra-operative and postoperative complications.

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- Surgeons performing the procedure should have knowledge of appropriate treatment options if the procedure fails or needs to be aborted and should be accomplished in the possible salvage procedures including both re-do anterior as well as posterior spinal surgical procedures.
- Surgeon experience may be demonstrated by a combination of the following:
 - Anterior lumbar interbody fusion (ALIF) experience, performing on average one to two such procedures in each of the preceding 12 months.
 - Proficiency with fluoroscopy (essential to performance of the lumbar disc arthroplasty procedure).
 - Certification of completion of a lumbar disc arthroplasty course by the offering technology company.
 - A series of mentored operations commensurate with that surgeon's skill and experience with another surgeon accomplished in that disc arthroplasty procedure. (This recommendation would be considered fulfilled by a fellowship-trained spinal surgeon with extensive experience in disc arthroplasty during his/her training).

As is true in spine surgery in general, patient selection is very likely the most essential element in the application of lumbar disc arthroplasty. Considerations for any lumbar disc arthroplasty procedure include product labeling and sound physician judgment. Patient selection should take into consideration the pertinent medical literature and specific patient condition and characteristics.

In addition, it is important to consider and address patient expectations. Physicians should endeavor to replace unrealistic expectations with more reasonable ones. Hip and knee arthroplasty have become readily available, raising patient expectations for spine arthroplasty techniques and devices. Information regarding these procedures, which may not be peer-reviewed, is easily accessed via the Internet. In contrast to these created expectations, the actual indications for application of lumbar disc arthroplasty are relatively narrower.

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This bibliography is considered preliminary and is a sampling of the state of the science at the time of writing. It is provided for education and reference purposes only and is not intended to represent all of the information available on this topic or to imply endorsement of views therein expressed. Moreover, any or all of the conclusions reached by any or all of the authors may be rendered obsolete or may need to be modified in light of discoveries or other developments arising after the date of writing.

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