

## Public Comment Submission Form

### Instructions for Submitting Comments

**Due Date** Comments on Draft Standards are due by 5:00 p.m., EST, June 2, 2006

**How to Submit Comments** Please submit all comments via e-mail to: [scrp@ncqa.org](mailto:scrp@ncqa.org)  
Please use this comment form (MS Word Document) to submit all comments.

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<b>Organization Type: (e.g., physician practice, specialty society or board, health plan)</b>	Specialty society	<b>Phone Number:</b>	815.675.0021
<b>Measure</b>	<b>Issue*</b>	<b>Comment (examples)</b>	
General Program Comments		<p>There is a clear need to develop information that leads to the answers to some of the fundamental questions in spine care about efficacy and cost-effectiveness. NASS commends NCQA on this effort.</p> <p>Please accept this as an interim recommendation. This type of program will need to evolve as new information and higher levels of evidence become available. There needs to be a user-friendly mechanism in place which permits and encourages refinement.</p>	
General Program Comments		<p>Reliance on unpublished data from a study (SPORT) recognized by many to have significant design flaws resulting in bias against surgical intervention, despite good intent, is disturbing.</p>	
General Program Comments		<p>As proposed, the reporting requirements and suggested instruments pose a significant additional administrative burden on practitioners. How many measures will a physician be required to report on in each category? To "get credit" will each and EVERY category require reporting, or will there be a threshold above which practitioners will qualify for recognition? Where will the funds come from to</p>	

		gather and report all this data? Will public reporting of "passes" be on a measure by measure basis or once for the entire program?
General Program Comments		<p>A statement should be added stating that these measures do not encompass the full spectrum of what constitutes reasonable care.</p> <p>As an example, NASS uses a statement in our clinical guidelines that states, " This _____ should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution."</p> <p>Physicians should determine if patients meet numerator/denominator criteria. This should not be at the discretion of a third party. There should be a mechanism for exclusion from participation and data collection without penalty (e.g., Patient refuses a recommended treatment, insurance company insists on a test, new injury, etc.)</p>
Measure Development	Evidence Base, Scientific Soundness	<p>The measures proposed are heavily consensus-based, rather than evidence-based (for example, the quoted 2000-2001 NASS guidelines are not strictly evidence-based). When high quality data exists to support treatment, then that information should be used to encourage effective treatments and discourage those that are ineffective. Such data is identified in rigorous, evidence-based, clinical practice guidelines.</p> <p>As the proposed measures will be used and adapted by many health plans for various forms of performance measurement and reward, ultimately the proposed measures MUST be evidence-based and have a level of reliability and validity suitable to ensure that data is collected exactly the same way by providers and that comparisons are fair and goals have been achieved.</p>
Measure Implementation	Data Collection	<p>It is concerning that these assessments are intended to consist of retrospective chart review. Retrospective reviews are inherently limiting and subject to bias. Additionally, a lack of familiarity with individual documentation practices between practitioners may result in erroneous conclusions regarding the lack of documentation which, in fact, may be present.</p>
Measure Definitions	Population Definitions	<p><b>There is a recurrent inconsistency in the NCQA proposal between measures in defining which patients with back pain are being considered for</b></p>

		<p><b>assessment: acute vs. subacute/chronic. Evidence for acute low back pain doesn't necessarily apply to subacute/chronic low back pain.</b></p> <p><b>There is also a need to clearly distinguish protocols for radicular pain versus patients with back pain, and eliminate protocols regarding the treatment of radicular pain or radiculopathy as they are epidemiologically and clinically distinct from axial back pain.</b></p> <p><b>Separate protocols for back pain and radicular pain should be developed and clearly separate acute pain from subacute/chronic pain within these protocols.</b></p>
Initial Evaluation	Population Definition	Patient Population. Delete "and Subacute/Chronic (>6 weeks pain duration).
Initial Evaluation, Element A	Relevance, Evidence Base, Scientific Soundness	Delete "Indication of straight leg raise test" from Documentation Requirements, #2, bullet 1. SLR is not appropriate in the examination of LBP. SLR has traditionally been employed as a sign of nerve root tension resulting from impingement and is only applicable in patients with symptoms of radicular pain. (This is a concrete example of the criticism made in the box directly above).
Initial Evaluation, Element A	General Comment	Documentation Requirements, #2, bullet 2. This section is poorly worded. The constituents listed under "completion of neurologic exam" are not complete. Suggested wording: "Notation, at a minimum, of a focused neurological examination, including: quadriceps, gastrocnemius, extensor hallucis longus, anterior tibial motor strength, patellar and achilles deep tendon reflexes, and small and large fiber dermatomal sensory examination."
Initial Evaluation, Element A	General Comment	Documentation Requirements, #4.  Change "...physical examination for back pain" to "lower extremity neurological examination." As originally worded, demonstrates poor differentiation between radicular pain, radiculopathy and axial back pain.
Initial Evaluation, Element B	Clinical Specifications	Documentation Requirements, #2, bullet 2. Change "...symptoms..." to "past history or symptoms."  Documentation Requirements, #2, bullet 2, hyphen 6. Delete "previous back surgery" unless it can be supported in this context with more than one reference.  Documentation Requirements, #2, bullet 2, hyphen 12. Delete "heavy lift." This term is vague.

		<p>Documentation Requirements, #2, bullet 2, hyphen 18. Delete “Unexpected laxity of anal sphincter (loss of sphincter tone).” This is redundant with bowel incontinence and unlikely to exist in isolation without other significant acute neurological findings.</p> <p>Documentation Requirements, #2, bullet 2. Add “In the absence of history or symptoms suggesting red flag conditions, clear notation stating, “No predisposing factors suggesting fracture, tumor or infection present.”</p>
<p>Initial Evaluation, Element C</p>	<p>General Comment</p>	<p>Documentation Requirements, #3, bullet 4. Change to “...(e.g., imaging, diagnostic injections, etc.)”</p>
<p>Patient Assessment</p>	<p>Relevance, Validity</p>	<p>We support the use of validated outcome measures in clinical practice. As constructed, the program allows for usage of one of several accepted outcome instruments for pain, function and mental health status or a selection of elements from several pain scales, activities of daily function, or psychosocial variables. We agree that a choice of measurement tools should be available to the physician depending upon the type of practice situation. It is important to note that, in addition to the instruments listed, assessment can be conducted and recorded with other functional assessments that are appropriate as well (for example, tools that favor patient specified outcome).</p> <p>The instruments listed all stem from research studies and many are not practical in conventional practice. For example, who will score the instrument? Instruments such as the SCL-90 and SF-36 involve a complicated algorithm for scoring. In research studies, this is typically done by a research assistant or one of the investigators—not by the treating doctor. The protocol requires physicians to use instruments but does not indicate who will score them or indicate when this should take place.</p> <p>Pain: SF-36, ODI, RMDQ and SIP are not designed for pain. They measure other things. Intensity of pain could be measured using the VAS or NPRS.</p> <p>Functional Status: Instruments listed default to those used in research. Also, the indicative list of ADLs and mobility are ad hoc; they may not pertain to all patients.</p> <p>Mental Health: This measure should apply only to subacute/chronic pain. SF-36 is a poor measure of mental health. Other instruments listed are burdensome to apply and require specialized scoring. In conventional practice, the concern is</p>

		<p>only to identify if a patient has psychological problems in a binary manner—yes/no, not in a continuous manner—according to a score out of 100. Perhaps adoption of a simple, categorical checklist that indicates that members have attended to this domain and not ignored it. In addition, the measures have overlooked the entire issue of yellow flags and gone straight to psychometric testing. It is the yellow flag issues that are important in back pain, not the psychological traits. These yellow flags should be included as part of the checklist.</p>
<p>Appropriate Imaging for Acute Low Back Pain</p>	<p>Population Definition, Evidence Base, Clinical Specifications</p>	<p>Evidence supports consideration of selective nerve block with transforaminal epidural steroid injection in patients with suspected acute disc herniation/radiculopathy and primary complaints of radicular pain within the first 6 weeks of symptoms. Neuraxial imaging in this restricted patient population is appropriate. As currently structured, these patients would be counted as a failure.</p> <p>Current wording and structure of this section does not adequately discriminate between radicular and back pain. If describing strictly axial/somatic back pain, this measure makes sense. But it is unclear whether back pain is what is being described.</p> <p>When is it appropriate to obtain the first image for axial back pain?</p>
<p>Appropriateness of Repeat Imaging</p>	<p>Clinical Specifications, Relevance, Evidence Base</p>	<p>This should be re-named “Multiple Imaging.” This section is seriously flawed. The 12 month window is completely inappropriate. It is entirely possible that a patient with complaints of spinal pain lasting longer than 3 months will be sent for multiple imaging studies—especially in our litigious society. There should be a provision to exclude patients who proceed to surgical treatment within the 12 month time frame. These patients may justifiably need multiple complementary imaging studies and in some instances these may be mandated by their insurance carrier.</p> <p>Page 21. Intent. Change “progressive” to “worsening or significant change in.”</p>
<p>Patient Education/Decision Quality</p>	<p>Population Definition</p>	<p>Review of treatment options and risks/benefits. Needs clarification as to whether this is directed to acute and/or subacute/chronic. In acute phase, it applies only if surgery is performed. In subacute/chronic, it applies to all patients. With one exception, we generally agree with the measure. Patient encouragement and reassurance in the acute back pain setting doesn't seem to be included in this section.</p>

Patient Education/Decision Quality	General Comment, Evidence Base	Assessment of patient knowledge regarding options—under development. Is this a plan to test patients for retention of knowledge and understanding after a physician visit? The evidence suggests that better decisions are made when patients are better educated. Does re-education after poor test results result in improved decisions?
Medical Assistance with Smoking Cessation	Eligibility	Smoking cessation is important for general and spinal health. This measure, however, is not something a surgeon or spinal interventionalist would generally be involved in. It seems to be aimed at a primary care physician. Except in the case of a patient considering lumbar fusion, this measure should be dropped altogether. In patients considering spinal surgery, education about the association between smoking and compromised outcomes is important.
Advice for Normal Activities	Population Definition	Needs clarification as to whether this is directed to acute and/or subacute/chronic LBP. For axial LBP only—We agree with the importance of rapid return to activity and avoidance of prolonged bed rest in the <u>acute</u> situation. In the <u>chronic</u> situation, either the numerator should include patients who are documented to have attempted normal activities, but failed; or alternatively, for subacute/chronic pain, the measure should be dropped.  Patients with acute radicular pain or radiculopathy should be excluded early in this section.
Recommendation for Exercise	Population Definition, Evidence Base, Clinical Specifications	Needs clarification as to whether this is directed to acute and/or subacute/chronic. For the subacute/chronic population only, we agree that this should be documented as recommended or previously recommended and failed.  Therapeutic exercise. High intensity work hardening exercise programs are supported. McKenzie, stretching, passive exercise or physical therapy is not supported. NCQA needs to redefine what therapeutic exercise is.
Recommendation for Exercise	General Comment	Documentation Requirements. Replace “note” with “notation.” Replace “...the date on which a...” with “...when a...”
Appropriate Use of Epidural Steroid Injections	Evidence Base, Relevance	General text is fine.  Explanation, paragraph 1. Replace “Evidence...” with “Current evidence...”. Insert “(radicular pain)” after “dermatomal distribution.” Change “epidural steroids” to “transforaminal epidural steroids” in sentence 1. The evidence base for this particular assertion is quite clear.

		<p>Explanation, paragraph 2. Delete “invasive” and insert “any form of.” Change “acute low back pain without radiculopathy” to “acute, subacute or chronic low back pain without radicular pain or radiculopathy.”</p> <p>Please clearly define types of ESI—transforaminal, interlaminar, caudal, etc. and the use of image guidance to validate epidural placement of steroid.</p>
Appropriate Use of Epidural Steroid Injections	General Comment, Clinical Specifications	<p>Definition. Replace “dermatone” with “dermatome.”</p> <p>Change “on the nerve root” to “on or inflammation of the nerve root.”</p>
Surgical Alternatives	Population Definition	<p>There is a conflict between the “Description” section, which specifies within first 6 weeks and the “Patient Population,” which designates acute (6 weeks) <u>and</u> Subacute/Chronic (&gt;6 weeks). This section needs to allow for differentiation between surgical decompression, fusion and decompression plus fusion.</p> <p>Lack of distinction between axial and radicular pain is not tolerable in this section.</p> <p>Please define “acute.”</p>
Surgical Alternatives	General Comment	<p>Page 29.</p> <p>Numerator and denominator are reversed.</p>
Surgical Alternatives, Element B	Population Definition	<p>The “Explanation” section states that surgery is <i>usually</i> not considered in the first 6 weeks. However, there are patients with acute lumbar radiculopathy and severe pain from an HNP who, for very valid reasons, may refuse to wait 6 weeks to see if their symptoms will improve spontaneously. The current measures will count these patients as failures. Non-operative treatment trials are vague and leave the door open to misinterpretation and tacit support of unsubstantiated modalities. Specific, evidence supported non-operative treatment trials need to be clearly defined and listed. As written, the majority of non-operative treatments listed do not have strong evidence supporting efficacy in acute low back pain.</p> <p>Clearly define non-operative treatment as opposed to pre-surgical conservative care.</p>
Post-Surgical Outcomes, Element A	Relevance, Validity, Eligibility	<p>Measure Calculation. A valid performance measure should only include data points directly controlled by the physician under assessment. If a data point is under the control of two or more physicians, then those measures are suitable for general trending/quality assurance only and cannot be specifically assigned to one physician. (This</p>

		<p>comment may also carry through to other sections). With this consideration in mind, the following complications may not be attributable to the operating surgeon:</p> <p>List 1: More than one physician has a portion of the control of the following in most spinal surgeries. With this high incidence of crossover control, consider complete elimination of:</p> <ul style="list-style-type: none"> <li>• Damage to the trachea (e.g., sometimes from a difficult intubation by the anesthesiologist)</li> <li>• Damage to the esophagus (e.g., can be from an inadvertent esophageal intubation or passage of a naso-gastric tube by the anesthesiologist)</li> </ul> <p>List 2: Complications sometimes not controlled by the operating surgeon and should be removed from both the numerator and the denominator of the measure under specific conditions:</p> <ul style="list-style-type: none"> <li>• Infection             <ul style="list-style-type: none"> <li>○ When the anesthetic is an epidural or spinal administered by an anesthesiologist</li> <li>○ When an epidural catheter is used for post-op analgesia and controlled by an anesthesiologist</li> </ul> </li> <li>• Cerebrospinal Fluid Leakage             <ul style="list-style-type: none"> <li>○ When the anesthetic is an epidural or spinal</li> <li>○ When an epidural catheter is used for post-op analgesia and controlled by anesthesia</li> </ul> </li> </ul> <p>List 3: Complications should be removed as they have no relevance in the first 6 weeks post-op:</p> <ul style="list-style-type: none"> <li>• Pseudoarthrosis is not a valid diagnosis for a 3-6 month period of healing for a spinal fusion or one year for pseudoarthrosis with internal fixation as bone healing (as manifested by x-ray) is clearly slowed by internal fixation.</li> </ul>
<p>Post-Surgical Outcomes, Element A</p>	<p>Relevance, Validity</p>	<p>Re-hospitalization Within 6 Weeks of Surgery</p> <p>The rate of re-hospitalization within 6 weeks of surgery may provide insight into surgical skill sets and proper patient selection for surgical intervention. The individual physician rate of re-hospitalization will be highly dependent upon the severity and complexity of the spinal problem which is being treated and patient co-morbidities. Any provider-specific conclusions must be carefully risk</p>

		<p>adjusted and may be limited by small sample size. For example, a surgeon doing primarily revision spine surgery would be expected to have a higher re-hospitalization rate independent of the quality of care provided.</p> <p>This measure may be relatively easy to measure and report. There are, however, many other important post-surgical complications which are also important to track. They may provide more useful information upon which changes in practice and quality improvement can occur. For example, prolonged hospitalization, infection rate, CSF leak, hematoma, when only one surgeon is responsible for the care of the patient.</p>
Post-Surgical Outcomes, Element B	Clinical Specifications, Population Definition	<p>Re-hospitalization for Repeat Back Surgery Within 1 Year of Initial Surgery</p> <p>Need to clarify the definition of complication as it applies to re-hospitalization for "repeat back surgery." Is repeat disc surgery at a different level a complication or new problem? Is cervical surgery within one year of lumbar surgery a complication? Is progressive LBP following discectomy with complete relief of sciatica a complication or natural progression of disease? The authors quote a study by Osterman stating that the risk of multiple re-operations (presumably a bad thing) is reduced in patients if the first reoperation is a spinal fusion. Are they advocating for spinal fusion as the index procedure in all patients undergoing repeat spinal surgery?</p>
Treatment Re-evaluation and Patient Experience	Population Definition	<p>Needs clarification as to whether this is directed to acute and/or subacute/chronic. What does "within 6 to 12 weeks" mean? (A) Between 6-12 weeks; or (B) in less than 6-12 weeks, in less than 6 weeks, in less than 12 weeks? If it means 6 to 12 weeks, what happens to patients evaluated at 5 weeks or 13 weeks?</p>
Treatment Re-evaluation and Patient Experience	Population Definition, Clinical Specifications	<p>This is extremely cumbersome and needs to be streamlined. The measure needs to discriminate whether the patient is being seen for the same pain as the index evaluation? Or has the pain changed? For example, the patient may have originally presented with localizing back pain, but over the intervening 6 weeks the pain progressed to radiculopathy.</p>

\*Issue examples: population definition, eligibility, clinical specifications, evidence base, relevance, validity, scientific soundness, general comment.