

## LOW BACK PAIN DATA COLLECTION PROTOCOL - Short Version

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The American Medical Group Association serves the needs of group practices committed to providing the highest quality, most cost-effective health care to their patients. AMGA is dedicated to the continuous improvement of the group practice of medicine. In order to promote and improve medical care by group practices, AMGA and over 60 of its members have agreed to participate in a project that will expand the use of patient outcomes measurement in routine medical care. The focus of this effort will be patients diagnosed as having diabetes, asthma, hypertension, and low back pain, and patients undergoing hip replacement, total knee replacement, or cataract surgery.

Objectives of the OMC include:

- Assess the health status of particular groups of patients and track changes in their clinical and functional status over time.
- Assess the effectiveness of treatment alternatives based on the effect on patients' overall health.
- Assess the feasibility of collecting outcomes data as part of routine medical care.
- Enhance continuous quality improvement efforts by using outcomes information to target areas needing improvement.
- Evaluate patient outcomes across systems of care.
- Provide better feedback for physicians and staff.
- Improve the quality of information available to patients to aid them in making decisions about their care.

### QUESTIONS OF INTEREST REGARDING LOW BACK PAIN

- What factors predict:
  - appropriate surgical candidates?
  - chronicity?
  - return to work?
- Which treatment option(s) produce the best result(s), based upon patient satisfaction, decreased pain and/or function at specific time intervals?
- Are there differences among the various provider types?

### THE SAMPLE

Each project site should attempt to obtain a cross section of low back pain patients 18 years of age and older seen at their clinic. Sampling methodology and inclusion criteria should be formally defined by each project site. A minimum sample of 200 patients per year should be targeted. As a data validity measure, each participating clinic must provide the total number of consecutive patients enrolled in the project **and** the total number of patients actually treated (non-surgically or surgically) for low back pain. All patients sampled for the project (enrolled or not enrolled) should be documented in a log that records the following information:

- Patient identification number
- First three letters of patients last name
- Sex
- Treatment date (non-surgical or surgical)
- Enrolled (yes/no)
- Reasons for non-enrollment (if any) (comment space)

## THE INSTRUMENTS

All project sites enrolling Low Back Pain will use the following data collection instruments:

1. *Patient Log*: This form will document information about all patients eligible for the study and dates of enrollment (or reasons for non-enrollment if not enrolled). The log will be an essential part of the patient tracking system, and will allow clinics to determine an accurate denominator (enrolled versus eligible patients).
2. *Face Sheet*: This form is for internal use only, and will not be submitted to the aggregate data pool. Intended to be used as part of a tickler system, it may be customized for each clinic, as long as it provides a system for assessing the quality of data capture.
3. *Personal Characteristics Form*: The demographic and comorbidity data on this form will be collected for basic data analysis. This form will be completed by the patient at the time of enrollment, and once per year thereafter.
4. *Health Status Questionnaire*: This form includes functional status and well-being questions, as well as depression screening questions. It will be completed at the baseline visit and once per year thereafter.
5. *Employment History and Work Status*: This form collects the patients employment history and current work status. It will be completed at the baseline visit and once per year thereafter.
6. *Patient Baseline Questionnaire—Non-Surgical and Surgical—Low Back Pain Form 6.1*: This form requests information from patients regarding pain and functional status in relation to their lower back. The form also queries the patient about his/her expectations, in terms of pain relief and increased functional status, after surgical or non-surgical treatment. Specific questions pertaining to surgical treatment are contained on Page 3 of Form 6.1. This form should be completed by the patient during his/her initial visit or visit prior to surgery.
7. *Physician Baseline Questionnaire—Non-Surgical and Surgical—Low Back Pain Form 6.2*: This history and clinical evaluation form must be completed by the physician/medical staff prior to surgical or non-surgical treatment. The form should be completed during the patients' initial visit or visit prior to surgery. Note: Diagnostic criteria and definitions for completing question #10 are attached.
8. *Patient Post-Operative Questionnaire—Surgical Care—Low Back Pain Form 6.3*: This form requests information from patients regarding pain and functional status after their low back surgery. In addition, the form queries the patient about their post-operative recovery and satisfaction with care they received. It should be filled out by the patient during the initial visit after surgery and during all subsequent visits thereafter.
9. *Physician Post-Operative Questionnaire—Surgical Care—Low Back Pain Form 6.4*: This clinical evaluation form must be completed by the physician/medical staff during the initial visit after surgery and during all subsequent visits thereafter.
10. *Facility Discharge Form—Low Back Pain Form 6.5*: This form requests information about the patient's post-operative care, complications, and discharge plan. It should be filled out by the physician/medical staff on the day of the surgical patients' discharge from the hospital.
11. *Physician Characteristics Form—Low Back Pain Form 6.6*: This form provides information about the education, training, and experience of the physician. This form must be completed by **each** physician participating in the study. The form should be completed once at project baseline and annually thereafter. **Please forward Physician Characteristics Forms to AMGA.**
12. *Patient Follow-Up Questionnaire—Non-Surgical Care—Low Back Pain Form 6.7*: This form requests information from patients regarding pain and functional status after their non-surgical low back pain treatment. It should be completed by the patient at each follow-up visit.
13. *Physician Follow-Up Questionnaire—Non-Surgical Care—Low Back Pain Form 6.8*: This clinical evaluation form must be completed by the physician/medical staff at each follow-up visit after non-surgical treatment. It should be completed by the physician/medical staff at each follow-up visit.
14. *Process Information Form*: This form is used to assess patient compliance in regard to data collection. It should be the **last** form to be filled out by the patient. It should be completed by the patient at the time of enrollment.
15. *Loss-To-Follow-Up Patient Log*: This form will document information about all patients who are eligible and participating in the project, but who are no longer participating in the project due to death, refusal to participate, relocation, etc. Reasons for loss-due-to-follow-up should be documented.

## DATA COLLECTION PROCEDURES

### Tracking System

Prior to project initiation, staff involved at the project site should develop systems and schedules for tracking patients, verifying eligibility, and assuring that data will be collected in a routine manner to assure data quality. Tracking systems should be documented through flow-charting or similar techniques.

### Forms to be Completed

- A. Baseline—Non-Surgical and Surgical Treatment (Initial visit/Pre-op visit)
  - 1. Patient: Personal Characteristics Form  
Health Status Questionnaire  
Patient Questionnaire—Low Back Pain Form 6.1  
Process Information Form  
Employment History and Work Status
  - 2. Physician: Physician Questionnaire—Low Back Pain Form 6.2
- B. Non-Surgical Treatment—Second study visit
  - 1. Patient: Patient Questionnaire—Low Back Pain Form 6.7
  - 2. Physician: Physician Questionnaire—Low Back Pain Form 6.8
- C. Surgical Treatment—Second study visit (First visit post-op)
  - 1. Patient: Patient Questionnaire—Low Back Pain Form 6.3
  - 2. Physician: Physician Questionnaire—Low Back Pain Form 6.4
- D. Non-Surgical and Surgical Treatment—Third study visit
  - 1. Patient (Non-Surgical): Patient Questionnaire—Low Back Pain Form 6.7  
Patient (Surgical): Patient Questionnaire—Low Back Pain Form 6.3
  - 2. Physician (Non-Surgical): Physician Questionnaire—Low Back Pain Form 6.8  
Physician (Surgical): Physician Questionnaire—Low Back Pain Form 6.4
- E. Non-Surgical and Surgical Treatment—Fourth study visit
  - 1. Patient (Non-Surgical): Personal Characteristics Form  
Health Status Questionnaire  
Patient Questionnaire—Low Back Pain Form 6.7  
Process Information Form  
Employment History and Work Status
  - Patient (Surgical): Personal Characteristics Form  
Health Status Questionnaire  
Patient Questionnaire—Low Back Pain Form 6.3  
Process Information Form  
Employment History and Work Status
  - 2. Physician (Non-Surgical): Physician Questionnaire—Low Back Pain 6.8  
Physician (Surgical): Physician Questionnaire—Low Back Pain Form 6.4

### Tracking Referral Patients:

After a patient’s baseline (initial/pre-op) visit, if the patient is referred to and visits another physician for non-surgical or surgical treatment **within 6 weeks** of his/her baseline visit, Low Back Pain Form 6.2 (Physician Baseline—Non-Surgical and Surgical Care) and Low Back Pain Form 6.6 (Physician Characteristics) **should be completed**. The patient **does not** need to complete a baseline patient questionnaire (Form 6.1). However, if a non-surgical patient is referred for surgical treatment, question 10 (page 3) of the baseline patient questionnaire (Form 6.1) **must be completed** by the patient. Project sites should devise a specific data collection methodology for collecting surgical expectation information contained on page 3. Such methodologies may include administering the surgical expectation questions to the patient **after** he/she has consulted with the physician at the baseline visit, mailing the page to the patient with a self-addressed, postage-paid envelope, etc.

If a patient visits the referral physician **beyond 6 weeks** of his/her baseline (initial/pre-op) visit, the patient **and** the physician should complete **all** forms that are required to be filled out at a baseline visit; i.e. the patient should enter the study as a **new** enrollee.

To better “track” the low back pain patient through his/her treatment experience, it is recommended that xerox copies of the data collection forms be kept with the patients’ medical record.

### Target Times for Data Collection (TO BE USED FOR DATA ANALYSIS ONLY)

Since treatment for low back pain does not follow specific treatment patterns and patient visits do not usually follow a strict regimen, specific data collection windows will not drive patient visits for this study. Specified window periods will be used for the purpose of data analysis only. Optimal data points that will be stressed in analysis of the data elements will be as follows:

<i>Target Time</i>	<i>Type of Care</i>	<i>Data Collection Window</i>
Baseline	Surgical and Non-Surgical	Visit prior to surgery/Initial visit
Second visit	Non-Surgical	4 to 8 weeks after baseline
Second visit	Surgical	4 to 8 weeks <b>post-op (after date of surgery)</b>
Third visit	Surgical and Non-Surgical	3 to 9 months
Fourth visit	Surgical and Non-Surgical	10 to 14 months

**NOTE: Upon data analysis, if a patient has multiple office visits within a window, data collected at the point closest to the targeted observation window will be submitted to the data pool.**

### Collecting Information from the patient—Forms 6.3 and 6.7

The description of the purpose of these questionnaires is very important. It should be described consistently by all persons distributing the questionnaires to patients. Project sites may wish to incorporate a cover letter into their patient questionnaires that provides the descriptions and purpose of the study and also provides instructions to the patient for correctly and accurately completing the patient questionnaire. If the patient requires assistance, the questions should be read rather than interpreted.

If the patient cannot stay long enough to complete the forms, the patient may be provided with a self-addressed, postage-paid envelope, in order for he/she to complete the forms at home.

In order to maintain data quality and integrity, if a patient does not return for his/her follow-up visit, every means should be attempted to obtain follow-up data. Follow-up data collection forms for the patient may be mailed and accompanied by a self-addressed, postage-paid envelope, data forms may be administered to the patient via conversation by phone, etc. If it is felt that the patient may be lost-due-to-follow-up, attempts should be made to support this reasoning. Local post offices may be contacted to assess whether a patient has moved and local and national death registries may be contacted to assess whether the patient has died during the follow-up period. Reasons for a patient no longer participating in the study should be documented in the Loss-To-Follow-Up Patient Log.

DIAGNOSTIC CRITERIA FOR QUESTION 10, FORM 6.2 LOW BACK PAIN DIAGNOSIS AND FOR QUESTION 7, FORM 6.8

- I. Mechanical back disease: Any symptom complex felt to be originating from the spine—either bony, discogenic, ligamentous or muscular (not caused by neoplastic, infectious or rheumatological process).
  - A. Non-specific: The pain will have mechanical qualities evident on clinical exam and history but no specific structure can be adequately identified as the source of disturbance.
    1. Acute: less than 3 months<sup>1</sup> (i.e. acute sprain, strain)
    2. Chronic: greater than 3 months (i.e. non specific low back pain)
  - B. Discogenic: There will be evidence on clinical and/or radiologic exam to indicate the disturbance can be attributed to disk structure(s).
    1. Disk herniation with radiculopathy
      - a. Acute
      - b. Chronic
    2. Disk herniation without radiculopathy
      - a. Acute
      - b. Chronic (i.e. degenerative disc and joint disease)
  - C. Spinal Stenosis: Neurogenic claudication. Must have appropriate exertional/positional symptoms. If imaging done, evidence for inadequate spinal lumen (various etiologies) should be present.
  - D. Spondylolisthesis: Radiologic evidence required. There should be clinical evidence that the spondylolisthesis/spondylolysis is causing symptoms or may be complicating another identified process.
    1. Degenerative spondylolisthesis/spondylolysis
    2. Non-degenerative spondylolisthesis/spondylolysis
  - E. Fracture : (i.e. osteoporotic compression fractures, etc.)
- II. Neoplasm : Abnormal formation of tissue, as a tumor or growth.
- III. Inflammatory spondyloarthropathy : (i.e. ankylosing spondylitis)
- IV. Other:(i.e.Pyiformis syndrome, Trochanteric bursitis, etc.)

<sup>1</sup>Richard Deyo, M.D., M.P.H., et.al.

GLOSSARY OF TERMS FOR DIAGNOSTIC CRITERIA FORM  
(reprinted from the Glossary of Spinal Terminology)

**Ankylosing spondylitis**

Definition: An inflammatory disease of the spine which leads to bony ankylosis of the vertebral articulations.

Synonym: Marie-Strumpell disease

**Degenerative disc disease**

Definition: That disorder in which disc degeneration produces clinical symptoms and signs.

**Mechanical Qualities**

Definition: Pain that has changed with the mechanics of the back, such as heavy lifting, twisting or some other movement that causes back pain.

**Neurogenic Claudication**

Definition: Lower extremity pain with walking coming from the back.

**Piriformis syndrome**

Definition: Pain in the buttock and down the limb due to the sciatic nerve irritation by a spasm or contracture in the piriformis muscle.

**Spinal stenosis**

Definition: Reduction in the size of the spinal canal or regions thereof to a pathological degree.

The classifications:

A. Congenital stenosis

Definition: Malformation present at birth

B. Developmental stenosis

Definition: Malformation of genetic origin

C. Acquired stenosis

Definition: Malformation developed after birth. It is lateral stenosis of the nerve canal (lateral recess entrapment).

**Spondylitis**

Definition: An inflammatory disease of the spine.

**Spondylolisthesis**

Definition: Anterior displacement of a vertebrae on the adjacent vertebrae below which occurs in one of five types:

A. Dysplastic: The orientation of the facets of the zygapophyseal joint is sufficiently horizontal to permit slipping, or the superior facet of the lower vertebrae is hypoplastic thus attaining displacement of the upper vertebrae.

B. Isthmic: Fibrous defects are presents in the pars interarticularis which permit forward displacement of the upper vertebrae and separation of the anterior aspects of that vertebrae from its neural arch.

C. Degenerative: Anterior displacement of a vertebrae arising from erosive degenerative changes in the zygapophyseal joints.

D. Traumatic: Anterior displacement of a vertebrae due to traumatic injury to its restraining structures.

E. Pathologic: Anterior displacement of a vertebrae because of elongation of the pedicles from a disease process in the bone.

**Spondylolysis**

Definition: A defect in the pars interarticularis.