Developing and implementing patient-resource use diaries for a clinical trial assessing spinal stenosis interventions in the elderly

Bresnahan BW1,2, Rundell SD3, Comstock BA4, Sullivan SD2, Jarvik JG1,2, Nguyen H2, Bauer Z1, and Friedly JL4

Departments of Radiology1, Pharmacy2, Epidemiology3, Rehabilitation Medicine4, Center for Biostatistics5, University of Washington, Seattle, WA, USA

Background

• Lumbar spinal stenosis is common cause of low back pain in older adults
  • can cause substantial disability
  • impacts patients, providers, payers, and health systems

• In pain studies, patient-reported resource use data can complement electronic health record information

Setting

• Lumbar Epidural Steroid Injections for Spinal Stenosis (LESS) is a double-blind randomized controlled trial of epidural steroid injections

• LESS recruits up to 400 patients (≥50 years old) with low back and leg pain due to spinal stenosis

• Randomizes patients to epidural steroid injection with a local anesthetic vs. local anesthetic alone

Objectives

• Develop and implement patient-reported resource use questionnaires to assess utilization and time spent on back pain condition

• Focus on “out-of-system” data not in health systems’ electronic records

Methods

• Developed five patient-reported resource use diary sections
  1) Opioid prescriptions
  2) Over-the-counter medications
  3) Provider services (visits)
  4) Patient time caring for back
  5) Other back product purchases

• Assessed resource diaries for all LESS participants combined (to May 2012, week 1 only)
  • Number completing sections
  • Most frequently reported type of use for each section

Preliminary Results

Preliminary Descriptive Analysis

• Diary administration: four 3-week periods during 1 year

• Assessed resource diaries for all LESS participants combined (to May 2012, week 1 only)

Preliminary Descriptive Demographics (to May 2012)

• 192 participants completed ≥ 1 diary section for week 1
  • Age, mean (SD): 68.8 (10.6) yrs
  • Gender: 60% female
  • Race: 36% non-white

Discussion

• Patient-completed resource diaries collecting “out-of-system” use can complement electronic records which have “in-system” use

• Comprehensive data related to low back pain and resource utilization informs economic evaluations including multiple stakeholders

Preliminary Utilization Reporting

All participants combined (week 1)

Opioid prescriptions (n=169)
  1. Hydrocodone-acetaminophen (33.7%)
  2. Acetaminophen-codeine (15.4%)

OTC medications (n=81)
  1. Acetaminophen (27%)
  2. Ibuprofen (15.4%)
  3. Aspirin (11.5%)

Provider Services (n=139)
  1. Physical Therapy (7.2%)
  2. Massage (0.7%)

Time spent (back care) (n=140)
  0-2 hours: 70.7%
  2-5 hours: 19.3%
  >5 hours: 10%

Other products purchased (n=32)
  1. Braces: 6.3%
  2. Massage product: 3.1%

Presented at ISPOR, 17th Annual International Meeting (6/2012)