

Overview of Implantable Devices

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LEARNING OBJECTIVES

- ✦ Define chronic pain
 - ✦ Describe the prevalence and cost of chronic pain
 - ✦ Review nociceptive, neuropathic, and mixed pain types
 - ✦ Discuss implantable pain therapies for chronic pain
- ✦ Review examples of chronic pain conditions treated with spinal cord stimulation (SCS) and targeted drug delivery (TDD)
 - ✦ Discuss the importance of patient selection including selecting appropriate patients, the role of the psychologist, and setting appropriate expectations

WHAT IS ACUTE PAIN?

★ Commonly defined as the normal, predicted physiologic response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, and acute illness¹

★ Characteristics^{1,2}: ★ Abrupt onset

★ Short-lived

★ Follows injury or near injury to tissue ★ Specific biological cause

WHAT IS CHRONIC PAIN?

Historical definitions of chronic pain include the following concepts

“It is not the duration of pain that distinguishes acute from chronic pain, but more importantly, the inability of the body to restore its physiological functions to normal homeostatic levels”

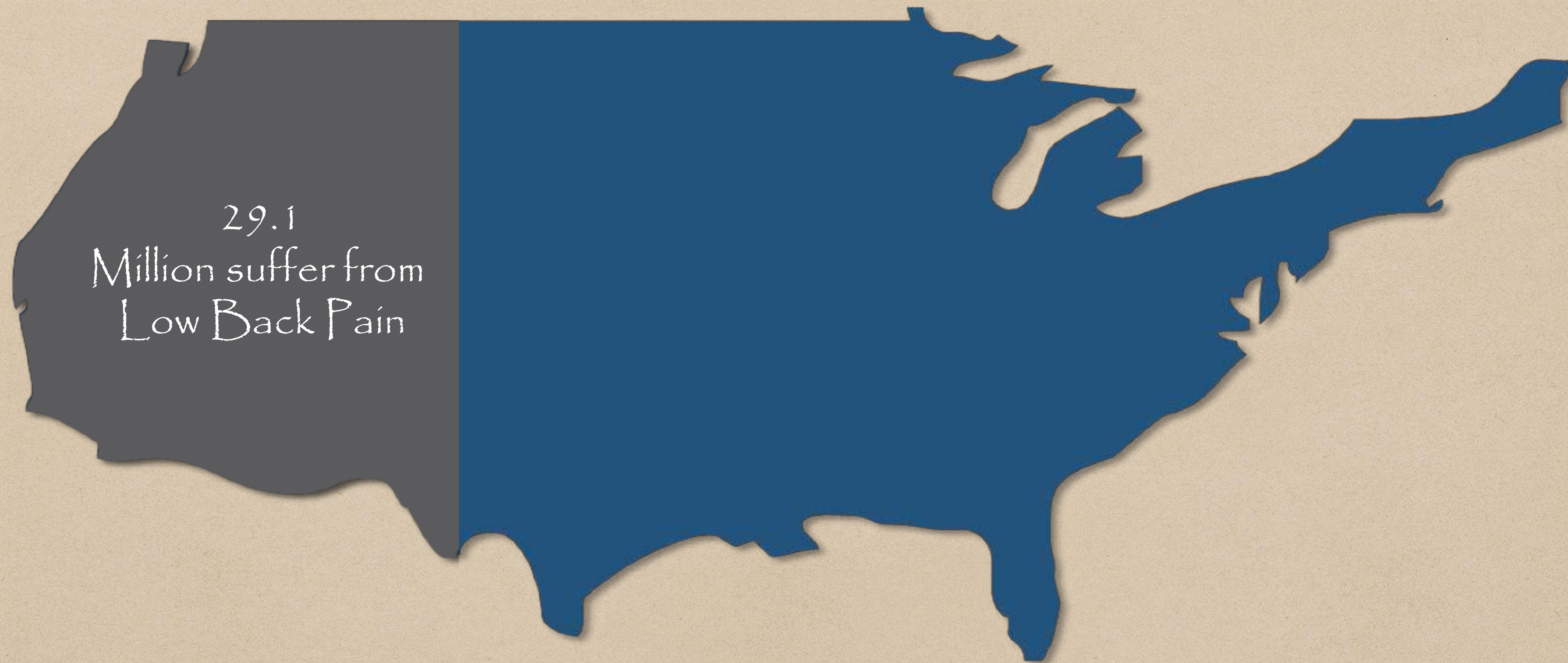
Chronic pain may be commonly triggered by disease or injury
Stress, environmental, and affective factors may contribute to the pain experience

Chronic pain continues when treatment stops

HOW PREVALENT IS CHRONIC PAIN?



HOW PREVALENT IS CHRONIC PAIN?



WHAT IS THE ANNUAL COST OF CHRONIC PAIN?



Institute of Medicine Report from the Committee on Advancing Pain Research, Care, and Education: Relieving Pain in America, A Blueprint for Transforming Prevention, Care, Education and Research. The National Academies Press, 2011.

Stewart WF, Ricci JA, Chee E, Morganstein D. Lost productivity work time costs from health conditions in the United States: results from the American Productivity Audit. JAMA 2003;290(18):2443-2554.

WHAT IS THE COST OF CHRONIC PAIN?

Costs of chronic pain may include:

- ✦ Ongoing medical expenses
- ✦ Lost income
- ✦ Lost productivity
- ✦ Compensation payments
- ✦ Legal expenses

IMPLANTABLE PAIN THERAPIES

★ Neurostimulation

★ Delivery of electrical stimulation to the spinal cord to inhibit or mask the sensation of pain

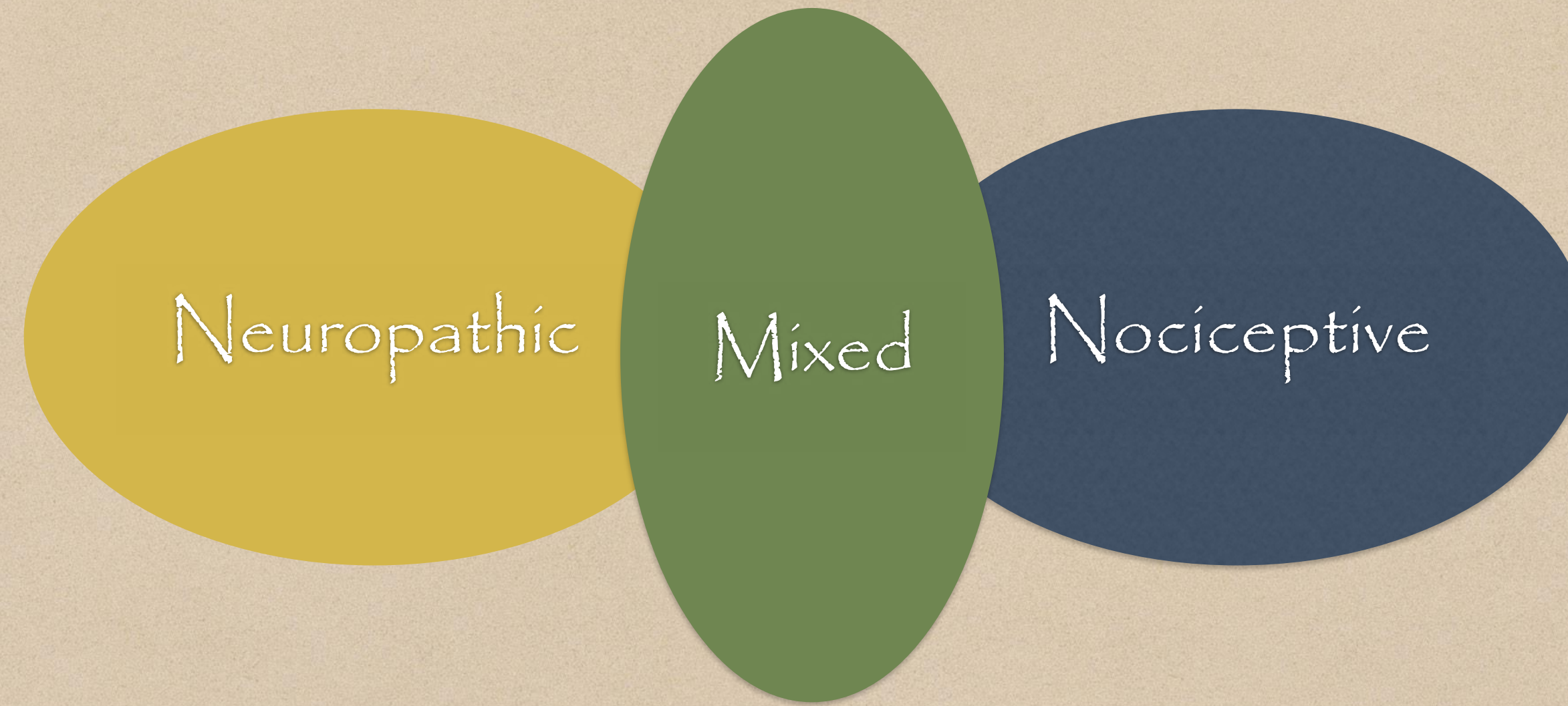
Spinal Cord Stimulation
Dorsal Root Ganglion Stimulation
Peripheral Nerve Stimulation

★ Targeted Drug Delivery

★ Delivery of precise doses of prescribed medication directly into the cerebrospinal fluid (CSF) to modulate the transmission of pain signals

Microdosing
Macro dosing

PAIN TYPES



NEUROPATHIC PAIN

- ✦ Associated with injury to the peripheral nervous system or the spinal cord
- ✦ Perceived as shooting, shock-like pain with severe burning or aching sensations

- ✦ May have tingling, numbness, or itching
- ✦ Severe cases have a ripping or tearing sensation

Examples

- ✦ Complex Regional Pain Syndrome
- ✦ Radicular leg pain
- ✦ Epidural fibrosis

NOCICEPTIVE PAIN

✦ Activated in response to tissue damage or inflammation arising from receptors sensitive to noxious stimuli

✦ Somatic: Well localized, constant, dull, aching, throbbing ✦ Visceral: Dull, vague and hard to localize

Examples

- ✦ Compression fractures
- ✦ Mechanical low back pain
- ✦ Cancer pain

MIXED NOCICEPTIVE AND NEUROPATHIC PAIN

✦ Mixed pain is a complex condition with neuropathic and nociceptive characteristics

✦ Pain perception depends on the condition

Examples

✦ Failed Back Surgery Syndrome ✦ Some forms of cancer pain

EXAMPLES OF CHRONIC PAIN TREATED WITH SCS OR TDD

Medical Condition	Spinal Cord Stimulation	Dorsal Root Ganglion Stim	Peripheral Stimulation	Intrathecal Pump
Failed Back Surgical Syndrome	✓			✓
Degenerative Disc Disease	✓			
Spinal Stenosis	✓			✓
Radiculopathies	✓			
Complex Regional Pain Syndromes	✓	✓		
Cancer Pain				✓
Peripheral Neuropathy (Alcoholic, Diabetic, Idiopathic)	✓	✓		
Abdominal and Pelvic Pain		✓		
Peripheral Neuralgias		✓	✓	

PATIENT SELECTION

★ Appropriate patient selection is critical for:

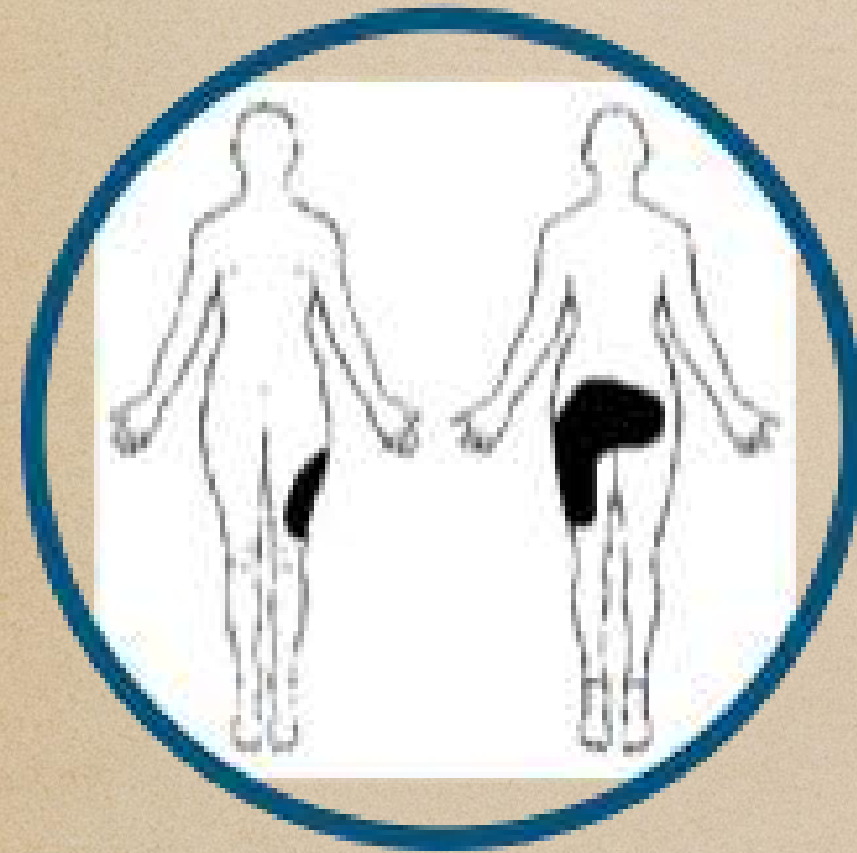
- ★ Patient safety
- ★ Therapy efficacy
- ★ Patient satisfaction
- ★ Pain relief

★ Patient selection consists of:

- ★ History and Physical Exam
- ★ Psychological Evaluation
- ★ Documented individualized patient goals for therapy
- ★ Patient and caregiver education

PAIN INTERVIEW AND PHYSICAL EXAM

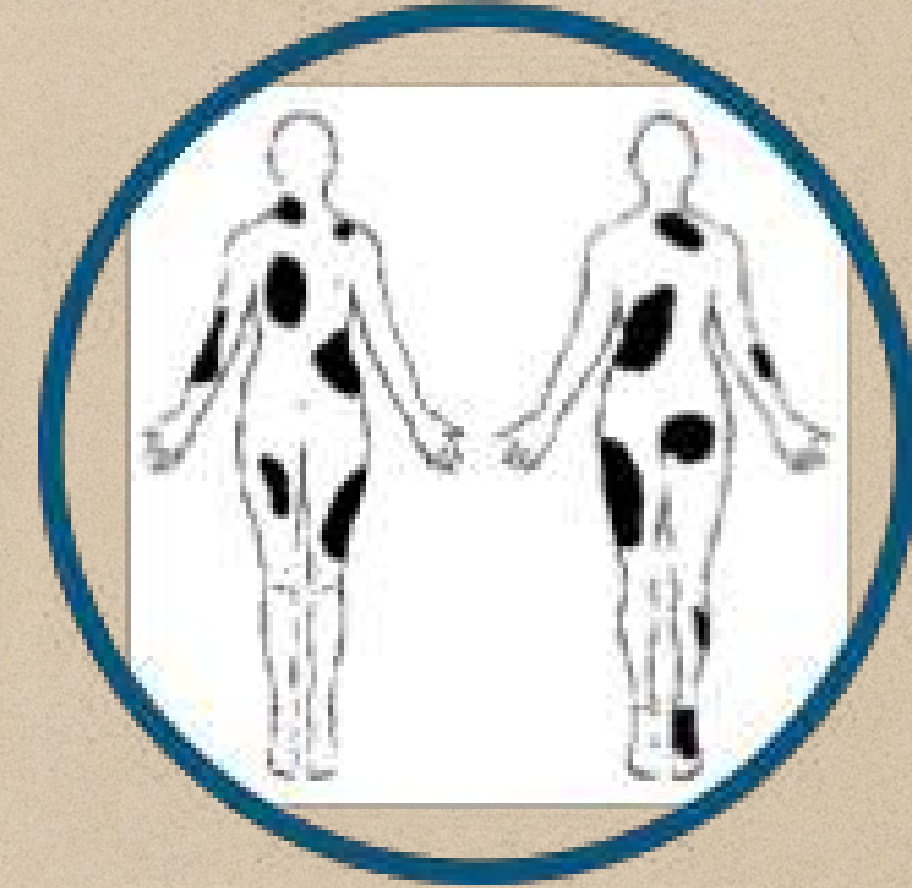
Determine pain pattern and intensity



Simple pain pattern

Complex pain pattern

Multifocal
Bilateral
Referred
Radiating



Determine how pain affects quality of life

Situations or conditions that ease or exacerbate pain

DOCUMENT THERAPY GOALS AND EXPECTATIONS

Express realistic expectations about what change may occur with improved function
Be able and willing to participate in a comprehensive treatment plan



Sufficient pain relief
Increased function
Decreased or elimination of systemic analgesics
Reduced side effects
Improved function or improved Activities of Daily Living
Increased range of motion, ambulation
With Targeted Drug Delivery for cancer patients, adequate pain relief may be only goal

THE PSYCHOLOGICAL EVALUATION

Helps reveal complex factors that contribute to pain

Establishes a baseline against which to measure improvement

Helps select the right treatment for managing the pain and related symptoms (e.g., fatigue, depression)

May increase the probability of a successful outcome by providing treatments that may resolve psychological risk factors

Identifies and treats psychological co-morbidities prior to therapy

Evaluates patient willingness, understanding, and competency to actively participate in their therapy

Provides insight into patient response during screening trial

- ✦ *Medicare and some other insurance carriers require a psychological evaluation for spinal and neural stimulation therapy*
- ✦ *Pre-authorization may be mandated by some insurers*

INTRODUCING THE THERAPY TO THE PATIENT

- ✦ Discussion may take more than one visit
- ✦ Include patient's family and caregiver in discussion
- ✦ Give patient, caregiver, and family time to review patient video and brochure
- ✦ Answer questions about the therapy
- ✦ Make sure patient, family, and caregiver have realistic expectations about potential results
- ✦ Establish and document specific therapy goals to compare against results
- ✦ Stress that the goal of the therapy is not to eliminate pain but to meet established goals

PATIENT SELECTION & TRIAL

The overall goal for patient selection is to choose those patients most likely to experience therapeutic success while reducing the possibility of risks, complications and adverse events.

SUMMARY

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