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**Treatment Options for Low Back Disorders:  
Systematic Review**

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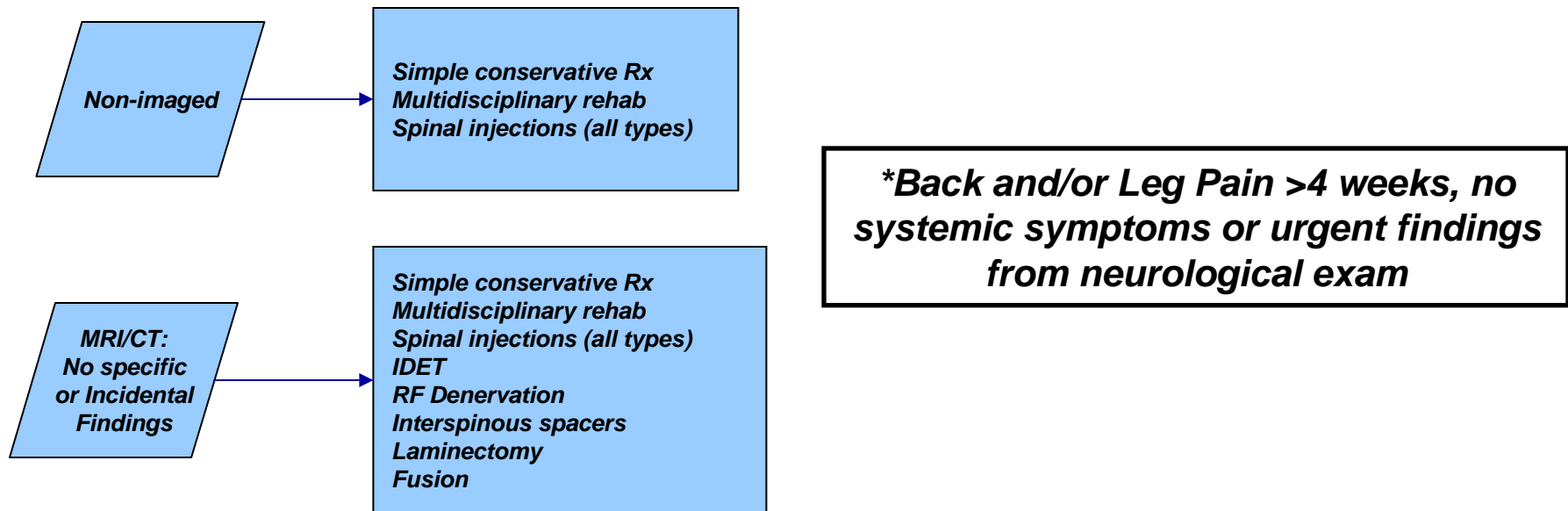
# Key Issues

- Revise patient categories?
- Where to use existing reviews vs. de novo abstraction
- “Lump” vs. “split” types of intervention?
- Use RCTs/SRs for effectiveness, other studies only for long-term outcomes and harms?

# Systematic Review Scope

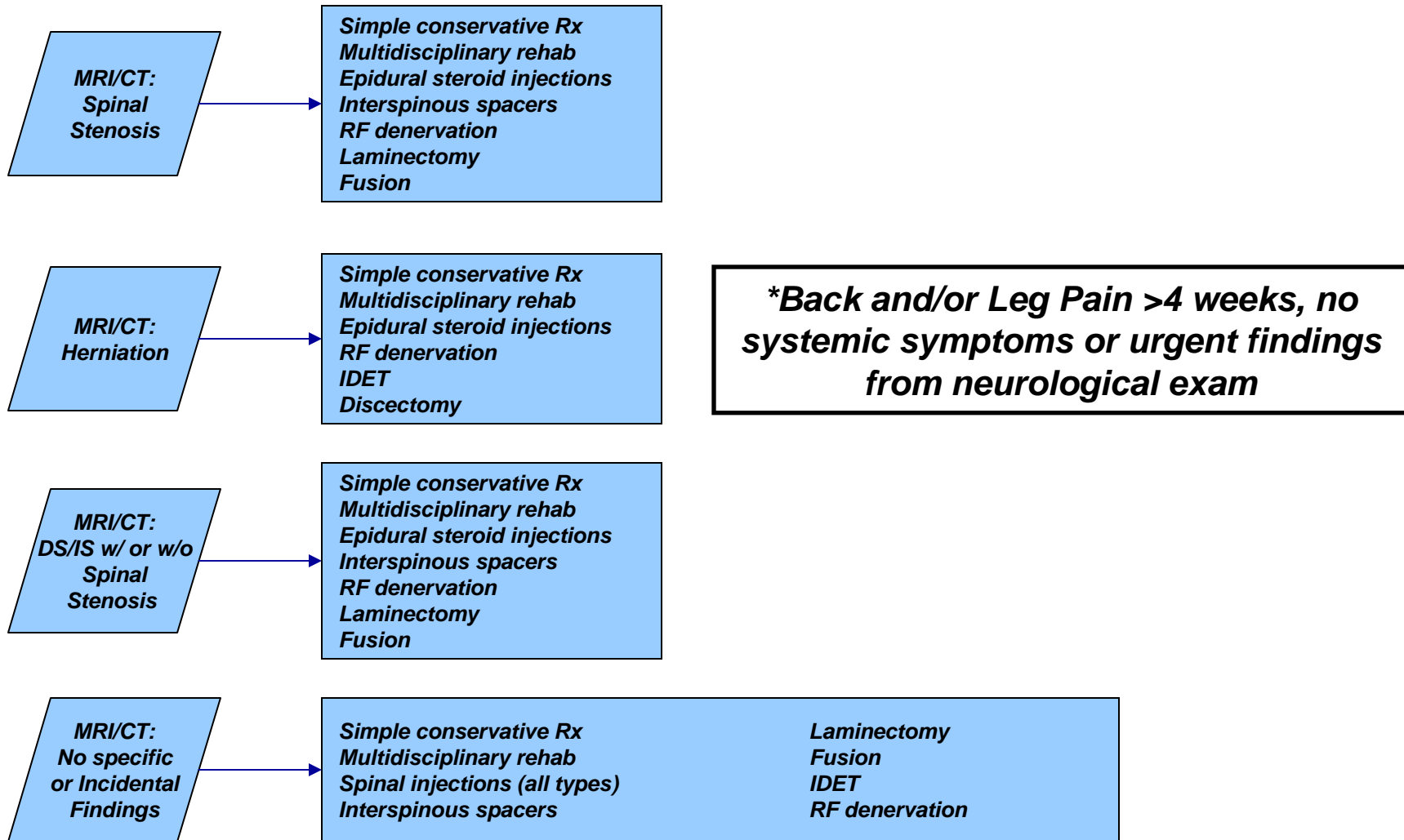
- To compare clinical effectiveness of multiple treatment options for low back disorders
  - Multidisciplinary rehabilitation
  - Minimally-invasive therapy
    - Epidural steroids and other spinal injections
    - RF denervation
    - Intradiscal electrothermal therapy
  - Surgery
    - Micro- and open discectomy
    - Interspinous spacers
    - Laminectomy
    - Instrumented and non-instrumented fusion

# Low Back Disorders\* Proposed Patient Categories and Treatments for Comparison: Non-Radicular Pain



RF: Radiofrequency; IDET: Intradiscal electrothermal therapy

# Low Back Disorders\* Proposed Patient Categories and Treatments for Comparison: Radicular Pain



RF: Radiofrequency; IDET: Intradiscal electrothermal therapy; DS: Degenerative spondylolisthesis; IS: Isthmic spondylolisthesis

# Review Strategy

- Use RCTs/SRs to obtain evidence on:
  - Effectiveness
  - Harms (given adequate follow-up)
- Use observational studies to obtain evidence on:
  - Harms (beyond 1-2 yr timeframe of most RCTs)
  - Stability of clinical benefit
  - Patterns of care (e.g., retreatment)
- For populations without RCT evidence:
  - Observational study findings on effectiveness will be summarized in ICER report

# Review Logistics

- Timeframe: January 2000 – November 2010
- Initial abstraction focused on RCTs and SRs only
  - Observational studies to follow
- Initial decision NOT to abstract studies focusing only on topics of recent high-quality systematic reviews:
  - Laminectomy
  - Fusion
  - Conservative management

## Review Logistics (cont'd)

- Subsequent decision to use recent systematic review as basis for spinal injection evidence\*
  - Other interventions?



# Major Exclusions

- Acute back pain, LBP arising from systemic disease, serious neurologic causes, or pregnancy
- Diagnostic spinal injections
- RCTs without active or sham/placebo control
- Sample size:
  - RCTs: <25 patients per arm
  - Observational studies:  $n < 50$
- <3 months of follow-up

# Outcomes Assessed

- Probability of “successful outcome”
- Functional status:
  - Roland-Morris or Oswestry indices
- Pain:
  - Visual analog scales
  - Likert scales
  - Numeric rating scales
  - Brief Pain Inventory (BPI)
- Return to work (e.g., # sick days, % return to work)

# Outcomes Assessed (cont'd)

- Health-related QoL
  - SF-36
  - EQ-5D
- Harms:
  - Peri-procedure mortality
  - Procedure-related major and minor complications
  - Repeat procedures

# Results of Initial Abstraction (Starting on Page 16)

# Multidisciplinary Rehab

- Attempt to categorize components of multidisciplinary programs
- Template for evaluating comparative effectiveness of program types

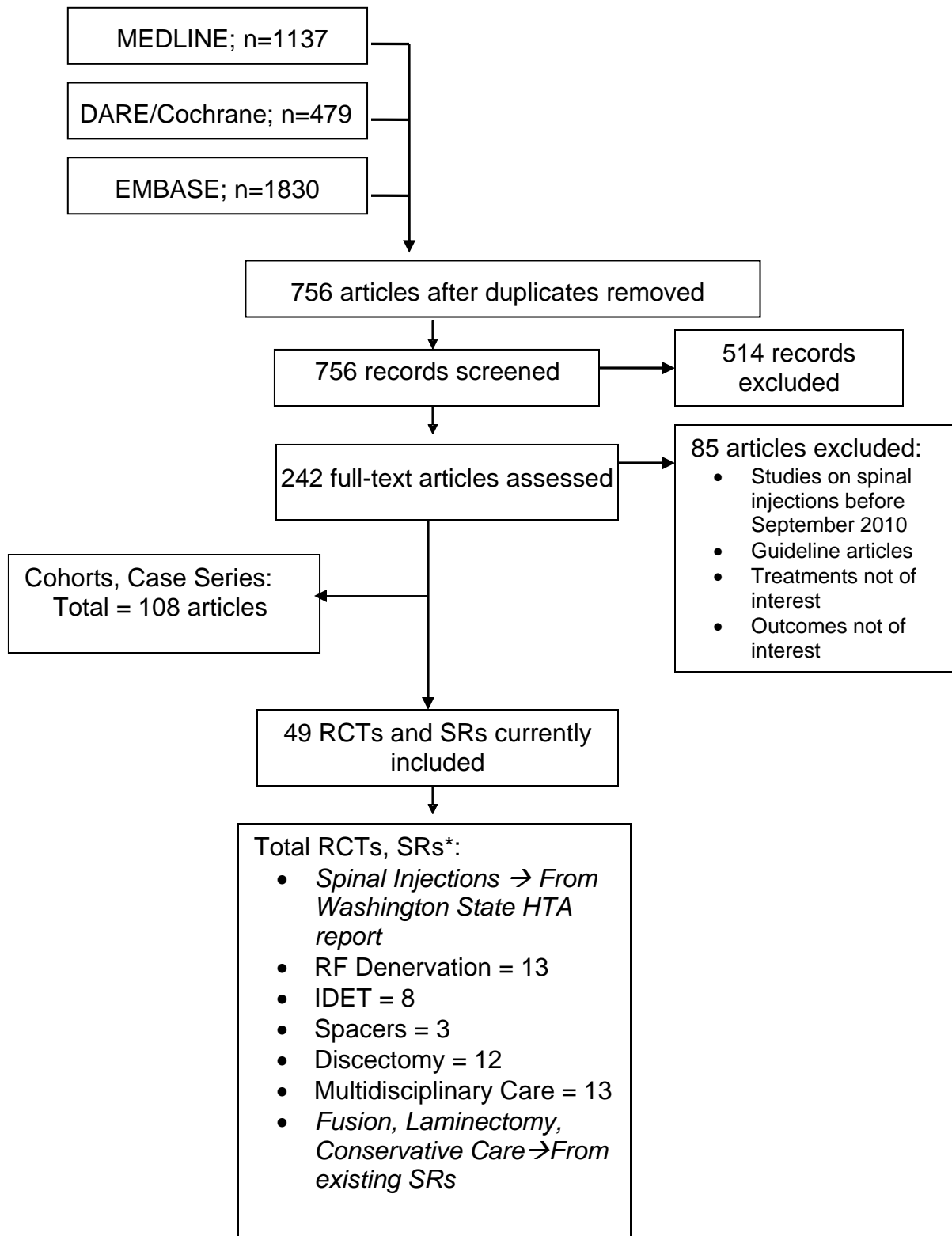
# Multidisciplinary Rehab RCTs

Author, Year	Vs.	Worksite Program	Strength Training	Function Training	Aerobic Exercise	Teaching	PT/OT	CBT	Program Intensity (hrs)
Anema 2007	Usual care	√	√ (PT)	√ (PT)		√ (PT)			26
Dufour 2010	Personal trainer		√ (PT)		√ (PT)	√ (PT)	√		75
Lang 2003	MD care		√ (TR)	√ (TR)	√ (TR)	√ (MD)	√	√ (Psy)	80
Fritz 2005	Exercise alone			√ (PT)			√		5 sessions
Lambeek 2010	Usual care	√	√ (PT)	√ (PT)		√ (PT)	√		26
Kaapa 2006	PT	√ (OT)	√ (PT)	√ (PT)	√ (PT)	√ (PT)		√ (Psy)	70
van der Roer 2008	PT		√ (PT)			√ (PT)			30 sessions
Vollen-Hutten 2004	Usual care	√ (OT)			√ (PT)		√		63
Roche 2007	PT		√ (PT)	√ (PT)	√ (PT)	√ (MD)	√	√ (Psy)	150

# Multidisciplinary Rehab

- Key findings from additional 4 systematic reviews:
  - Most effective programs are more intensive (>100 hours), have biopsychosocial component, and have functional restoration as primary goal
  - Long-term studies suggest positive impact on return to work and QoL
  - Other reviews identify worksite assessment as key component

**Figure 1. PRISMA flow chart showing results of literature search**





**Table. Matrix of identified RCTs and systematic reviews, by intervention and patient population of interest.**

INTERVENTION	PATIENT POPULATION						
	Non-Radicular Pain		Radicular Pain				Mixed Pain
	Non-imaged	Imaged: NS/INC findings	Imaged: Stenosis	Imaged: Herniation	Imaged: DS/IS w/ & w/o Stenosis	Imaged: NS/INC findings	NS, Mixed Pain Types & Imaging
Multi-disciplinary rehabilitation	1 RCT	1 RCT					7 RCTs 4 SRs
Epidural steroid injections		<i>From Washington State HTA Report</i>	<i>From Washington State HTA Report</i>	<i>From Washington State HTA Report</i>	<i>From Washington State HTA Report</i>		<i>From Washington State HTA Report</i>
Other steroid injections							<i>From Washington State HTA Report</i>
Medial branch block injections							<i>From Washington State HTA Report</i>
Other injections		<i>From Washington State HTA Report</i>					
Interspinous spacers			1 RCT		1 RCT		1 SR
IDET		1 SR		2 SR			2 RCTs 3 SRs
RF Denervation				1 SR			9 RCTs 3 SRs
Discectomy				7 RCTs 4 SRs			1 SR
Laminectomy			<i>From Chou et al., Spine 2009; 34:1094-1109</i>		<i>From Chou et al., Spine 2009; 34:1094-1109</i>		
Spinal fusion		<i>From Chou et al., Spine 2009; 34:1094-1109</i>					<i>From Chou et al., Spine 2009; 34:1094-1109</i>
Simple conservative care							<i>From Chou, Huffman, Ann Intern Med 2007;147:492-504 and 505-514</i>

NS: Nonspecific

INC: Incidental

DS: Degenerative spondylolisthesis

IS: Isthmic spondylolisthesis

IDET: Intradiscal electrothermal therapy

RF: Radiofrequency