AGENDA

EVIDENCE-BASED GUIDELINES SUBCOMMITTEE (EbGS)

Clackamas Community College
Wilsonville Training Center, Room 211
29353 SW Town Center Loop E, Wilsonville, OR 97070
March 1, 2012 from 2:00pm - 5:00pm

(All agenda items are subject to change and times listed are approximate)

#	Time	Item	Presenter	Action Item
1	2:00 PM	Call to Order / Introductions	Cat Livingston	
2	2:05 PM	Orientation to goals of subcommittee	Cat Livingston Darren Coffman	
3	2:15 PM	Election of Chair and Vice-Chair		x
4	2:20 PM	Review process of development of guidelines and coverage guidance	Cat Livingston Darren Coffman	
5	2:40 PM	Prioritize topics for coverage guidance	Cat Livingston Alison Little	x
6	3:00 PM	Review draft coverage guidance on: 1) Elective induction of labor before 39 weeks 2) Cesarean section on maternal request 3) Evaluation and management of low back pain	Cat Livingston	x
7	3:45 PM	Review guidelines currently underway 1) Advanced Imaging for Low Back Pain 2) Percutaneous Interventions for Low Back Pain 3) Spinal Fusion	Alison Little	x
8	4:45 PM	Confirm next meeting April 5th	EbGS Chair	x
9	4:50 PM	Public Comment		
10	5:00 PM	Adjournment	EbGS Chair	

HERC TOPIC SELECTION CRITERIA

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Represents high public interest or policy urgency/diffusion concern

Coverage Guidance Development Process

DRAFT 022312

Timeline (Approximately 12-14 Weeks)	Task Description	Roles and Responsibilities
	Topic Identification 1. Develop topic selection principles 2. Prioritize and finalize topic list	• HERC staff & CEbP staff develop draft topic selection principles, topic list, core sources, and process • HERC approves principles, topic list, core sources, and process
2 weeks	**Topic & Evidence Identification** 1. Identify base report(s) 2. Summarize evidence source	• HERC identifies topic and appropriate base report(s) • CEbP summarizes evidence report • If extensive summary required, additional time may be needed
2 weeks	**DRAFT Guidance Development** 1. Develop draft guidance 2. Present draft to EbGS/HTAS and incorporate comments	• HERC staff reviews base report(s) and develops draft guidance • HERC staff presents draft to EbGS/HTAS and incorporates comments • EbGS reviews revised draft ***(REQUIRES ADDITIONAL TIME)***
6 weeks	**Public Comment Process** 1. Post DRAFT for public comment	• HERC posts guideline for public comment (30 days)
2 weeks	**Public Comment Disposition** 1. Address public comments 2. Edit guidance as needed	• CEbP addresses public comments and edits guidance as needed • HERC staff review & approve edits as needed
2 weeks	**Final Guidance Review** 1. Present guidance to EbGS/HTAS for review and approval 2. Incorporate any necessary edits to guidance 3. Present final guidance to HERC	• HERC staff presents revised guidance to EbGS/HTAS & incorporates comments • EbGS/HTAS reviews final guidance ***(REQUIRES ADDITIONAL TIME)*** • HERC staff present final guidance to HERC

EbGS Guideline Development Process

DRAFT 022312

Timeline (Approximately 4 Months)	Task Description	Roles and Responsibilities
1 week	**Topic Identification** 1. Develop topic selection principles 2. Prioritize and finalize topic list	• HERC staff & CEbP staff develop draft topic selection principles, topic list, core sources, and process • HERC approves principles, topic list, core sources, and process
1 week	**Topic Refinement** Determine PICO and key questions, as needed	• HERC staff & CEbP staff develop draft PICO and key questions • HERC staff & CEbP staff develop peer review list
2 weeks	**Existing Guidelines Review** 1. Search for and quality assess existing guidelines 2. Select base guideline(s) 3. If no base guideline identified, table topic	• CEbP conducts initial search (MED Core Sources), quality assessment, and recommends base guideline(s) • HERC staff approves use of any base guideline(s)
2 weeks	**DRAFT Guideline Development** 1. Develop draft guideline 2. Present draft to EbGS and incorporate comments	• CEbP develops draft guideline • HERC staff reviews and approves draft • CEbP presents draft to EbGS and incorporates comments • EbGS reviews revised draft ***(REQUIRES ADDITIONAL TIME)***
6 weeks	**Public & Peer Comment Process** 1. Post draft guideline for public comment 2. Concurrently engage peer reviewers	• HERC posts guideline for public comment (30 days) • CEbP coordinates peer review process
2 weeks	**Public & Peer Comment Disposition** 1. Address public & peer comments 2. Develop disposition chart 3. Edit guideline as needed	• CEbP addresses public & peer comments, develops disposition chart, and edits guideline as needed • HERC staff review & approve edits as needed
2 weeks	**Final Guideline Review** 1. Present guideline to EbGS for review and approval 2. Make final edits to guideline, as needed 3. Present final guideline to HERC	• CEbP presents revised guideline to EbGS and incorporates comments • EbGS reviews final guideline ***(REQUIRES ADDITIONAL TIME)*** • CEbP presents final guideline to HERC

HTAS Technology Assessment Development Process

DRAFT 022312

Timeline (4-5 Months)	Task Description	Roles and Responsibilities
	Topic Identification 1. Develop topic selection principles 2. Prioritize and finalize topic list	• HERC staff & CEbP staff develop draft topic selection principles, topic list, core sources, and process • HERC approves principles, topic list, core sources, and process
8 weeks	**Topic Refinement** 1. Present PICO and key questions to HTAS & incorporate comments 2. Post draft for public comment and solicit peer reviewers 3. Address public comments & develop disposition chart 4. Edit PICO and key questions, as needed 5. Present revised draft to HTAS	• CEbP staff present PICO & key questions to HTAS and incorporate comments • HERC posts PICO & key questions for public comment (30 days) and solicits peer reviewers • CEbP addresses public comments & develops disposition chart • HERC staff review & approve edits as needed • CEbP presents revised draft to HTAS • HERC staff & CEbP staff develop peer review list
2 weeks	**Existing TA Review** 1. Search for & quality assess existing TAs 2. Select base TA(s) 3. If no base TA identified, table topic	• CEbP conducts initial search (MED Core Sources), quality assessment, & recommends base TA(s) • HERC staff approves use of any base TA(s)
2 weeks	**DRAFT TA Development** 1. Develop draft TA 2. Present draft to HTAS and incorporate comments	• CEbP develops draft TA • HERC staff reviews and approves draft • CEbP presents draft to HTAS and incorporates comments • HTAS reviews revised draft ***(REQUIRES ADDITIONAL TIME)***
6 weeks	**Public & Peer Comment Process** 1. Post draft TA for public comment 2. Concurrently engage peer reviewers	• HERC posts TA for public comment (30 days) • CEbP coordinates peer review process
2 weeks	**Public & Peer Comment Disposition** 1. Address public & peer comments 2. Develop disposition chart 3. Edit TA as needed	• CEbP addresses public & peer comments, develops disposition chart, and incorporates edits as needed • HERC staff review & approve edits as needed
2 weeks	**Final TA Review** 1. Present revised TA to HTAS 2. Incorporate final edits to TA 3. Present final TA to HERC	• CEbP presents revised TA to HTAS and incorporates comments • HTAS reviews final TA ***(REQUIRES ADDITIONAL TIME)*** • CEbP presents final TA to HERC

OREGON CLINICAL GUIDELINES PROJECT
PUBLIC COMMENT FORM

Name

Address

City State Zip Code

Country

Phone Number

Email:

Note: You are required to provide personal identification in order to comment on this guideline. However, name and contact information will be kept confidential. Only your profession, location, and comments will be made publicly available.

DISCLOSURE

Disclosure Policy for Oregon Clinical Guidelines Project Public Review

(Acceptance of Disclosure Policy required for comment acceptance)

The Oregon Clinical Guidelines Project supports and is committed to an open process. Comments submitted and received during a draft guideline review period will be included in the HERC Evidence-based Guideline Subcommittee meeting materials. Comments will be publicly available on the HERC web site and will include the reviewer's profession and location. I understand and agree to these terms.

Signature

Date

Oregon Health

PUBLIC COMMENT INSTRUCTIONS

Word limits are attached to the public comment form to encourage brief, clear, concise, and constructive comments. The word limit for each comment section is 500 words. Please be concise. If you suggest additional peer-reviewed literature, please provide a full citation and email a copy of the article, along with your form, to: HERC.Info@state.or.us. Other types of materials that are not peer-reviewed will not be accepted. Do not give links to additional materials in your comments. These will not be reviewed. Only one public comment form per person will be accepted.

YOUR COMMENTS

Title of Guideline:	
Objective/ Background:	
Methods of Guideline Development:	
Recommendations:	
Appendices:	
General Comments:	

Evidence Based Guidelines - Current Topics and Schedule

		STATUS	REPORTS AVAILABLE	REASON(S) CHOSEN	HERC MEETING	PUBLIC POSTING	PUBLIC POSTING OF DRAFT COVERAGE GUIDANCE
TOPICS COMPLETED	Evaluation and Management of Low Back Pain	*Completed*		OHP & OEBB utilization data, stakeholder input, collaborative opportunity	*Presented to HERC meeting on 1/12/12 for approval*	2/17/2012 (final)	
TOPICS CURRENTLY UNDER DEVELOPMENT	Preventing readmission for CHF in the first 30 days after hospitalization	*On Hold - Partnering with Q-Corp*		OHP & OEBB utilization data, stakeholder input, collaborative opportunity			
	Preventing readmission for COPD in the first 30 days after hospitalization	*On Hold - Partnering with Q-Corp*		OHP & OEBB utilization data, stakeholder input, collaborative opportunity			
	Advanced Imaging for Low Back Pain	*Draft guideline 1 developed. Draft 2 of guideline being revised*		OHP & OEBB utilization data, stakeholder input		2/17/2012 (Draft)	
	Percutaneous interventions for Low Back Pain	*Reviewed existing guidelines. Developing guideline Draft 1.*		OHP & OEBB utilization data, stakeholder input		2/17/2012 (Draft)	
	Spinal Fusion (Foraminal v central stenosis, Instrumented fusion (fusion cage) versus not (grafting)	*Reviewing existing guidelines*		OHP & OEBB utilization data, stakeholder input			
NEXT TOPICS FOR DEVELOPMENT BY EbGS	Arthroscopic surgery of the knee for osteoarthritis	*High priority*	Public MED report & WA HTA		*Chosen at HERC Mtg - 2/12/12*		
	Elective cesarean section	*High priority*	Public MED report & HSC guideline		*Chosen at HERC Mtg - 2/12/12*		
	Elective induction of labor	*High priority*	Public MED report & HSC guideline	OHP & OEBB utilization data, stakeholder input	*Chosen at HERC Mtg - 2/12/12*		
	Femoroacetabular impingement (FAI) syndrome	*High priority*	Washington HTA		*Chosen at HERC Mtg - 2/12/12*		
	PET scan guidelines	*High priority*	MED report, WA HTA & HSC guideline		*Chosen at HERC Mtg - 2/12/12*		
	Self-monitoring of blood glucose for type 1 and type 2 diabetes	*High priority*	MED report and WA HTA guideline		Chosen at HERC Mtg - 2/12/12		
	Nonpharmacologic Interventions for Treatment Resistant Depression	*Medium priority (CBT)*	AHRQ report		*Chosen at HERC Mtg - 2/12/12*		
	Ultrasound in low risk pregnancy	*Medium priority*	Washington HTA	OHP & OEBB utilization data, stakeholder input	*Chosen at HERC Mtg - 2/12/12*		
	Chronic Kidney Disease Stages 1-3: Screening, Monitoring and Treatment	*Low priority*	AHRQ report		*Chosen at HERC Mtg - 2/12/12*		
	Diagnosis and Treatment of Pediatric ADHD and Bipolar Disease	*Low priority*	MED report & AHRQ (addresses ADHD only)		*Chosen at HERC Mtg - 2/12/12*		
NEXT TOPICS FOR DEVELOPMENT BY HTAS	Discography	*High priority*	Washington HTA		*Chosen at HERC Mtg - 2/12/12*		
	Hip resurfacing	*High priority*	WA HTA & HSC guideline		*Chosen at HERC Mtg - 2/12/12*		
	MRIs of breast	*High priority*	Washington HTA	OHP & OEBB utilization data, stakeholder input	*Chosen at HERC Mtg - 2/12/12*		
	Vertebroplasty, kyphoplasty and sacroplasty	*High priority*	Washington HTA		*Chosen at HERC Mtg - 2/12/12*		
	Artificial discs	*Medium priority*	Washington HTA		*Chosen at HERC Mtg - 2/12/12*		
	Diagnosis of sleep apnea in adults	*Medium priority*	AHRQ report, WA HTA		*Chosen at HERC Mtg - 2/12/12*		
	Implantable infusion pumps	*Medium priority*	Washington HTA		*Chosen at HERC Mtg - 2/12/12*		
	Real time continuous glucose monitoring	*Medium priority*	MED report, Washington HTA (children only) & HSC guideline		*Chosen at HERC Mtg - 2/12/12*		
	Treatment of sleep apnea in adults	*Medium priority*	AHRQ report, WA HTA		*Chosen at HERC Mtg - 2/12/12*		
	Vagus nerve stimulators for depression	*Medium priority*	Public MED report, WA HTA		*Chosen at HERC Mtg - 2/12/12*		
	Vagus nerve stimulators for epilepsy	*Medium priority*	Public MED report, WA HTA		*Chosen at HERC Mtg - 2/12/12*		
	Viscosupplementation for osteoarthritis of the knee	*Medium priority*	Public MED report (needs updating) & WA HTA		Chosen at HERC Mtg - 2/12/12		
	Bone growth stimulators	*Low priority*	Public MED report & Washington HTA		*Chosen at HERC Mtg - 2/12/12*		

EbGS - Future Potential Guidance Topics

TOPIC	REPORTS AVAILABLE	PRIORITY
ENT		
Bilateral cochlear implants in children	MED report	
Pressure equalization tubes in children	MED report	
Sinus surgery	HSC guideline	
Chronic otitis media with effusion	HSC guideline	
Tonsillectomy	HSC guideline	
Gynecology		
Measurement of menstrual bleeding disorders	HSC guideline	
Urinary incontinence (female)	HSC guideline	
Imaging		
Advanced imaging for cardiac disease		
Coronary computed tomographic angiography	MED report	
Imaging in dementia	MED report	
Red flags and imaging in headache	HSC guidelines & MED Report	
Oncology		
Oncotype dx assay	MED report	
Prophylactic mastectomy	MED report & HSC guidelines	
Opthalmology		
Age-related macular degeneration	HSC guideline	
Cataract	HSC guideline	
Oral Health		
Caries Risk Assessment and Topical Flouride Application in Primary Care Settings	MED report	
Dental Radiographs for Diagnosing Caries	MED report	
Early Childhood Caries Treatment: Stainless Steel Crowns vs. Other	MED report	
Sedation vs. Anaesthesia for Pediatric Dental Care	MED report	
Topical Flouride for Prevention of Caries in Children and Adolescents	MED report	
Miscellaneous		
Botulinum toxin type A for chronic migraine prophylaxis	MED report	
Diagnosis of sleep apnea in children	MED report	
Laser based treatment of venous disease	AHRQ draft report	Low

HTAS - Future Potential Guidance Topics

TOPIC	REPORTS AVAILABLE	PRIORITY
Upper endoscopy (Indications: GERD and dyspepsia)	AHRQ report	(High priority, waiting for WA HTA report)
Functional electrical stimulators for spinal cord and head injury, CP and upper motor neuron diseases	MED report	
Insulin pumps vs multiple daily injections for type 1 and 2 diabetes	MED report	
Left ventricular assist devices (LVAD)	MED report & HSC Guideline	
New radiation therapies for non-intercranial malignancies	MED report	
Spinal cord stimulators for chronic pain	MED report	
Vacuum wound closure (negative pressure wound therapy)	MED report	

Evidence Based Guidelines - Topics Embarked upon but Dismissed

TOPIC	REPORTS AVAILABLE	DATE DISMISSED	REASON DISMISSED
Knee Arthoplasty		Dismissed at HERC mtg 2/9/12	Evidence was insufficient to develop a clinical guideline Feb 2012

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE FOR ELECTIVE DELIVERY: INDUCTION OF LABOR

DATE: XX/XX/XXXX

HERC COVERAGE GUIDANCE

Induction of labor without medical or obstetrical indication prior to 39 weeks of completed gestation should not be a covered service.

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RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. In addition to an evidence-based guideline developed by the Evidence-based Guideline Subcommittee and a health technology assessment developed by the Heath Technology Assessment Subcommittee, coverage guidance may utilize an existing evidence report produced in the last 5 years by the Agency for Health care Research and Quality, the Medicaid Evidence-based Decisions Project or the Washington Health Technology Assessment Program.

EVIDENCE SOURCE

King, V., Pilliod, R., & Little, A. (2010). *Rapid review: Elective induction of labor*. Portland: Center for Evidence-based Policy. Available at: http://www.ohsu.edu /xd/research/centers-institutes/evidence-based-policy-center/med/index.cfm

Oregon Health Authority

SUMMARY OF EVIDENCE

Clinical Background

The use of induction of labor (IOL) in the U.S. doubled between 1990 and 2006. Rates of labor induction vary substantially from state to state, from a low of 13.2% (California) to a high of 35.2% (Utah). The rate of increase in medically indicated IOL has been slower than the overall increase, suggesting that the increase in elective inductions has been more rapid. The increase in the overall use of induction is likely multifactorial. There appear to have been shifts in the threshold for induction at earlier gestations with both medically indicated and elective IOL. The practices and preferences of individual physicians also have an effect on the use of IOL and the subsequent risk of cesarean delivery. Women's requests may also contribute to increased demand for elective induction of labor (EIOL).

Evidence Review

Systematic reviews of randomized controlled trials find either a slight increase in cesarean delivery or no effect with EIOL, but there is some evidence of increased risk of operative vaginal delivery. Observational studies using spontaneous labor control groups find increased risk of cesarean delivery for nulliparous women with number needed to harm (NNH) of 4 to 10. Multiparous women may also have an increased risk of cesarean delivery with a NNH of 62 based on one study. Cesarean delivery is increased particularly among nulliparous women who have a low Bishop score (a measure of readiness for labor) at the time of EIOL and receive preinduction cervical ripening. Infants face an increased risk of admission to a neonatal intensive care unit (NICU) if their mothers undergo EIOL prior to 39 weeks of gestation. The length of active labor may be shorter with EIOL, although the total time spent on a labor and delivery unit or in the hospital may be greater. Most commonly cited indications for IOL are not well supported by evidence. Only the indications of a gestational age beyond 41 weeks and prelabor rupture of membranes at term are supported by strong evidence of net benefit. Quality improvement programs targeted at eliminating inappropriate EIOL can be effective at reducing cesarean delivery outcomes, particularly for nulliparous women with a low Bishop score.

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LIMITATIONS OF COVERAGE

Not applicable

PROCEDURE

Elective Induction of Labor

DIAGNOSES

Pregnancy

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
650	Normal delivery
659.0	Failed mechanical induction
659.1	Failed medical or unspecified induction
V22.0	Supervision of normal first pregnancy
V22.1	Supervision of other normal pregnancy
V22.2	Pregnant state, incidental
V30	Single liveborn
V39	Liveborn unspecified whether single twin or multiple
ICD-10	
O80	Single spontaneous delivery
Z34.0	Supervision of normal first pregnancy
Z34.8	Supervision of other normal pregnancy
Z34.9	Supervision of normal pregnancy, unspecified
ICD-9 Volume 3 (procedure codes)	
Other procedures inducing or assisting delivery	
73.0	Artificial rupture of membranes
73.1	Other surgical induction of labor: Induction by cervical dilation
73.4	Medical induction of labor
Forceps, vacuum, and breech delivery	
72.0 –	Forceps, vacuum, and breach delivery
Cesarean section and removal of fetus	
74.0 –	Cesarean section and removal of fetus
CPT	
Dilation	
57800	Dilation of cervical canal, instrumental (separate procedure)
59200	Insertion of cervical dilator (e.g., laminaria, prostaglandin) (separate procedure)
Infusions	
96365	Intravenous infusion for therapy, prophylaxis, or diagnosis; initial, up to 1 hour

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96366	Intravenous infusion for therapy, prophylaxis, or diagnosis; each additional hour
96367	Each additional sequential infusion up to 1 hour
96368	Concurrent infusion
Care associated with vaginal delivery	
59400	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care
59409	Vaginal delivery only, with or without postpartum care
59610	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery
59612,	Vaginal delivery only, after previous cesarean delivery
Care associated with Cesarean	
59510	Routine Obstetric care including antepartum care, Cesarean delivery, and postpartum care
59514	Cesarean Delivery only
59515	Cesarean Delivery only, including postpartum care59618: Routine Obstetric care including antepartum care, Cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery
59620	Cesarean Delivery only, following attempted vaginal delivery after previous Cesarean delivery.
59622	Cesarean Delivery only, following attempted vaginal delivery after previous Cesarean delivery. Including postpartum care
HCPCS Level II Codes	
J2590	Pitocin 10 units. [NOTE: Appears in a listing of “Drugs Administered Other Than Oral Method J0000-J9999.”]
S0191	Misoprostol, oral, 200 mcg [NOTE: Appears in a listing of Temporary National Codes (Non-Medicare), S0012-S9999)

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HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE FOR ELECTIVE DELIVERY: CESAREAN SECTION

DATE: XX/XX/XXXX

HERC COVERAGE GUIDANCE

Cesarean delivery on maternal request without medical or obstetrical indication should not be a covered service.

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RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. In addition to an evidence-based guideline developed by the Evidence-based Guideline Subcommittee and a health technology assessment developed by the Heath Technology Assessment Subcommittee, coverage guidance may utilize an existing evidence report produced in the last 5 years by the Agency for Health care Research and Quality, the Medicaid Evidence-based Decisions Project or the Washington Health Technology Assessment Program.

EVIDENCE SOURCE

Risser, A., & King, V. (2010*). Rapid review: Elective cesarean section*. Portland: Center for Evidence-based Policy. Available at: http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/med/upload/Elective-Delivery-Elective-Cesarean_PUBLIC_Rapid-Review_Final_12_1_10.pdf

Oregon Health Authority

SUMMARY OF EVIDENCE

Clinical Background

According to NCHS statistics, the national rate of cesarean section reached 32.3 percent of all live births in 2006 (Hamilton, 2010). The largest contributions to this rising rate are an increase in primary cesareans to a rate of 20.6 percent in 2004 and a steep decline in the rate of vaginal birth after cesarean (VBAC) from 28.3% in 1996 to 9.2% in 2004. Over ninety percent of women who have had a cesarean section will deliver by repeat cesarean (MacDorman, 2008). This increase is not well explained by changes in the population risk profile. There is interest in understanding the factors underlying this increase and to understand to what extent primary planned cesarean sections done without an identifiable medical risk (elective cesarean section (ECS)) and cesarean delivery by maternal request (CDMR) contribute to this rate. The best estimate is that between 4% and 18% of primary cesarean sections in the United States are elective.

Evidence Review

Overall, the research summarized in this report show that if a study were ever designed that accurately measured ECS and prospectively investigated outcomes, that these outcomes would likely be associated with ECS:

- longer hospital stays;
- increased NICU admissions;
- increased neonatal respiratory problems; and
- maternal urinary or fecal incontinence is less likely in the short term, with no difference in longer term follow up.

The differences between an intended vaginal delivery group and an intended cesarean group are less marked for these outcomes at 39 or more weeks of gestation. Elective cesarean delivery likely has no benefit for urinary or fecal continence in the longer term, although immediate postpartum outcomes may favor ECS. There are important downstream effects to consider in the performance of ECS, most notably in maternal morbidity due to abnormal placentation. There are some important issues around quality of life such as post partum pain, recovery time, and postpartum mood which are important, but which have not been well studied as they apply to ECS.

Most indications for cesarean delivery do not have a strong evidence base. At present, it would be reasonable to assume that many or most women with breech presentation, HIV infection, and concurrent Hepatitis C/HIV infection would be best served by planned cesarean delivery. This group likely includes women with a complete previa as well, although research evidence is lacking for this indication. Hepatitis B infection is not a substantiated indication for cesarean delivery. There is at least a moderate strength of

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evidence to support these indications. In cases of uncomplicated twin gestation, with a cephalic first twin, the evidence does not show that cesarean delivery results in a clear benefit to the second twin. Similarly, in cases of prematurity or small for gestational age, it is not clear that any benefit is obtained with routine versus selective cesarean delivery.

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LIMITATIONS OF COVERAGE

Not applicable

PROCEDURE

Elective Cesarean Section

DIAGNOSES

Pregnancy

APPLICABLE CODES

CODES	DESCRIPTION
ICD 9 Codes	
V22.0	Supervision of normal first pregnancy
V22.1	Supervision of other normal pregnancy
V22.2	Pregnant state, incidental
V30	Single liveborn
V39	Liveborn unspecified whether single twin or multiple
ICD 9 Volume 3 (procedure codes)	
74.0	Classical cesarean section
74.1	Low cervical caesarean section
74.4	Cesarean section of other specified type
ICD 10 Codes	
O82	Single delivery by caesarean section
O82.0	Delivery by elective caesarean section
O82.2	Delivery by caesarean hysterectomy
O82.8	Other single delivery by caesarean section
O82.9	Delivery by caesarean section, unspecified

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CPT Codes	
Elective Cesarean	
59510	Routine Obstetric care including antepartum care, Cesarean delivery, and postpartum care
59514	Cesarean Delivery only
59515	Cesarean Delivery only, including postpartum care
Nonelective Cesarean (comparator)	
59618	Routine Obstetric care including antepartum care, Cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery
59620	Cesarean Delivery only, following attempted vaginal delivery after previous Cesarean delivery.
59622	Cesarean Delivery only, following attempted vaginal delivery after previous Cesarean delivery. Including postpartum care
Vaginal Delivery (comparator)	
59400	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care
59409, 59410	Vaginal delivery only, with and without postpartum care
59610	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery
59612, 59614	Vaginal delivery only, after previous cesarean delivery; with or without postpartum care

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State of Oregon Evidence-based Clinical Guidelines Project

Evaluation and Management of Low Back Pain

A Clinical Practice Guideline Based on the Joint Practice Guideline of the American College of Physicians and the American Pain Society (Diagnosis and Treatment of Low Back Pain)

October 2011

Oregon Health Authority

Guideline Development Group

Jeanene Smith, MD, MPH; David Pass, MD; Darren Coffman, MS
Office for Oregon Health Policy and Research

Cat Livingston, MD, MPH
Office for Oregon Health Policy and Research [Consultant]
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Mylia Christenson
Oregon Health Care Quality Corporation

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Oregon Health Leadership Council

Valerie King, MD, MPH; Alison Little, MD, MPH; Catherine Pettinari, PhD; Aasta Thielke, MPH; Cathy Gordon, MPH
Center for Evidence-based Policy, Oregon Health & Science University

Suggested Citation

Livingston, C., King, V., Little, A., Pettinari, C., Thielke, A., & Gordon, C. (2011). *State of Oregon Evidence-based Clinical Guidelines Project. Evaluation and management of low back pain: A clinical practice guideline based on the joint practice guideline of the American College of Physicians and the American Pain Society (Diagnosis and treatment of low back pain).* Salem: Office for Oregon Health Policy and Research. Available at: http://www.oregon.gov/OHA/OHPR/HERC/Evidence-Based-Guidelines.shtml

This document was prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center) on behalf of the Guideline Development Group and the Office for Oregon Health Policy & Research. This document is intended to help providers, consumers and purchasers of health care in Oregon make informed decisions about health care services. The document is intended as a reference and is provided with the understanding that neither the Center nor the Guideline Development Group are engaged in rendering any clinical, legal, business or other professional advice.

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

The statements in this document do not represent official policy positions of the Center, the Guideline Development Group, or the Office for Oregon Health Policy and Research. Researchers and authors involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

Objective

This guideline was developed by a collaborative group of public and private partners to provide up-to-date evidence-based guidance on the evaluation and management of low back pain. The purpose of this guideline is to assist licensed clinicians, working within their scope of practice in the State of Oregon, in the assessment and management of low back pain among non-pregnant adults. Implementation of recommendations in this guideline will be determined by individual health plans and providers.

Background

In June 2009, the Oregon legislature passed health reform legislation, HB 2009, which created the Oregon Health Policy Board and charged it with creating a comprehensive health reform plan for our state. In December 2010, the Board released *Oregon's Action Plan for Health*, which lays out "strategies that reflect the urgency of the health care crisis and a timeline for actions that will lead Oregon to a more affordable, world-class health care system." They outlined eight foundational strategies, one of which is to "set standards for safe and effective care." To accomplish this, the plan directs the state to "Identify and develop 10 sets of Oregon-based best practice guidelines and standards that can be uniformly applied across public and private health care to drive down costs and reduce unnecessary care. This work will be conducted by the Health Services Commission and Health Resources Commission in close collaboration with providers, the Center for Evidence-Based Practice, and other key stakeholders." [1]

During the same time period when this guideline was under development by the State of Oregon, the Oregon Healthcare Leadership Council and the Oregon Health Care Quality Corporation both independently began pursuing the development of practice guidelines that could be used across the state, and the value of collaboration became apparent. The three entities agreed to develop the first guideline together, and in the fall of 2010, selected Evaluation and Management of Low Back Pain as their first guideline topic. Representatives from the three organizations formed the Guideline Development Group (GDG), while clinical evidence specialists from the Center for Evidence-based Policy provided expertise and research to support guideline development.

Methods

The GDG was guided in developing this guideline by the ADAPTÉ[2] framework which is a systematic approach to the endorsement or modification of guideline(s) produced in one cultural context or organization setting for application in another context. Guideline adaptation is used as an alternative to wholly new guideline development, which is time consuming, expensive and an inefficient use of resources, when quality guidelines are available.

The process for developing this guideline began by searching 17 different databases and other sources for guidelines related to Acute Low Back Pain (see appendix A). Candidate guidelines were required to be evidence-based (recommendations based on a systematic review of the literature), address the comprehensive clinical management of adults with an acute episode of low back pain, be published in English and be widely available. By "comprehensive," the GDG meant that the guideline would include recommendations on the initial assessment of a patient with a new episode of low back pain, the use of both pharmacologic and nonpharmacologic therapies and the appropriate ongoing management of

[1] Effective January 1, 2012, House Bill 2100 (2011) terminates the Health Services Commission and Health Resources Commission and transfers their duties related to evidence-based guideline development to a new Health Evidence Review Commission.

[2] http://www.adapte.org/www/

people who experience continuing low back pain. The GDG required that evidence-based recommendations be made on the basis of both the quality and strength of the underlying data from the guideline's systematic reviews.

Thirteen candidate guidelines were identified, of which 10 were sufficiently comprehensive to address most management issues (Appendix B). Those 10 guidelines were then assessed for methodologic quality using a modified AGREE (Appraisal of Guidelines Research and Evaluation) II[3] instrument (Appendix C) by two different guideline quality assessors from the Center for Evidence-based Policy. Five of those guidelines were rated either Good quality, or Fair quality with Good rigor of development according to the modified AGREE rating tool. These five guidelines were then examined further for scope and clarity of presentation.

After considering guideline age, source, specific treatment elements addressed and presentation, the GDG selected the two guidelines of highest quality that were most comprehensive. The two selected were both good quality and completed in the last five years, whereas the other three were more than 5 years old and were rated fair quality. Of the two selected, the American College of Physicians/ American Pain Society (ACP/APS) guideline was preferred as the base guideline, primarily because it had recommendations concerning the early care of acute low back pain and contained algorithms that were felt to be useful implementation tools.

The ACP/APS guideline in its entirety can be found at the following link: http://www.annals.org/content/147/7/478.long. The ACP/APS guideline is accompanied by full systematic reviews on nonpharmacologic therapies for low back pain (http://www.annals.org/content/147/7/492.full.pdf+html) and the use of medications for low back pain (http://www.annals.org/content/147/7/505.full.pdf+html). Comparison was then made to the other high quality, comprehensive guideline, which was produced by the National Institute for Health and Clinical Excellence (NICE). The full NICE guideline and reviews of the evidence are available at the following link: http://www.nice.org.uk/CG88. There were two significant areas of difference. First, the NICE guideline does not address treatment in the first six weeks. Second, the NICE guideline excludes patients with leg pain or radiculopathy. However, there were no significant differences in other assessment or treatment recommendations between the two guidelines.

The GDG found no guidelines that focused exclusively on acute low back pain during the first 12 weeks of the episode of back pain. This is primarily because many of the studies in the field include people with back pain of longer duration. The GDG felt that the ACP/APS guideline concentrated on acute low back pain and was also able to contribute guidance toward those patients experiencing more persistent or recurrent back pain. For this reason, the GDG decided to change the focus of the guideline to the evaluation and management of low back pain, regardless of duration. Figure 1 & 2 of the guideline are an algorithm that addresses the initial assessment and management of low back pain, as well as provides management options including both pharmacologic and nonpharmacologic interventions.

The ACP/APS guideline used the ACP's guideline grading system that was adapted from the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) working group. Guideline recommendations were rated as either strong or weak. Strong recommendations were required to have clear evidence of benefit or harm. Weak recommendations were based on finely balanced benefits, risks and burdens. The overall strength of evidence for each intervention was rated based on factors such as

[3] http://www.agreecollaboration.org/

the quality, quantity, consistency, generalizability and directness of the evidence. The ACP/APS guideline panel considered interventions to have "proven" benefit if there was at least fair quality evidence of moderate or substantial benefit (or of small benefit with no significant harms, costs or burdens).

Updating
The ACP/APS guideline was published in 2007. The authors of the guideline were contacted in March 2011 and stated that there had been no new published evidence which would change the recommendations of the guideline and that it was considered current. The GDG recommends that this guideline be reevaluated if the ACP/APS issues an updated guideline and at least every two years for currency if the original guideline is not updated.

Recommendations

Below are the recommendations of the ACP/APS clinical practice guideline. The GDG found that all of these recommendations apply to the objectives and purposes stated above. The recommendations relate to the algorithm which follows (Figure 1 and Figure 2 from the guideline publication) and the algorithm makes reference to the specific numbered guideline recommendations below. Recommendations 2, 3 and 4 are further supported by a systematic review and meta-analysis of imaging strategies published in 2009[4], as well as Best Practice Advice from the American College of Physicians published in 2011[5].

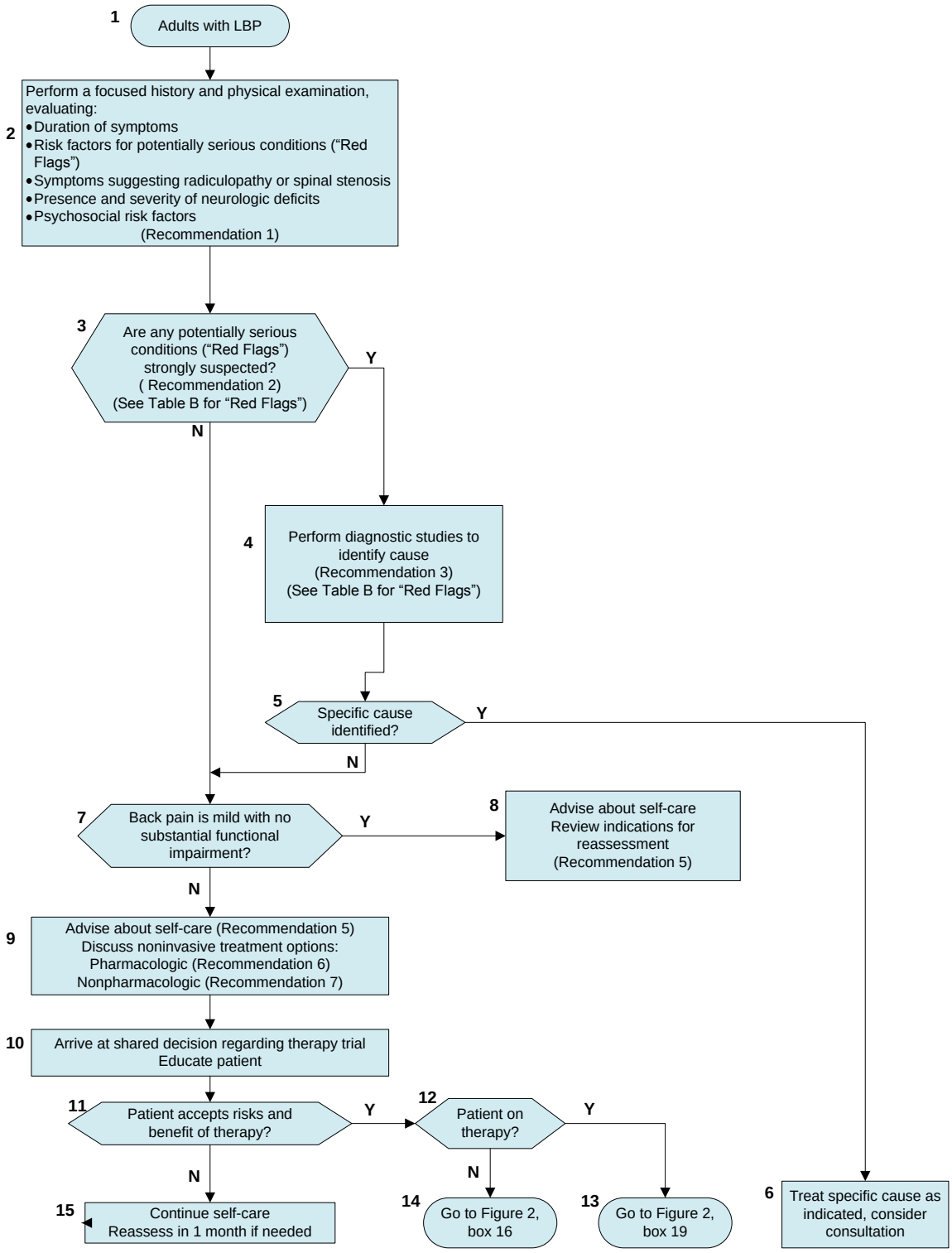
Table A: State of Oregon Evidence-based Clinical Guideline Recommendations for the Management of Low Back Pain

Recommendations		
Recommendation	**Content**	**Strength of Recommendation & Evidence Grade**
1. Focused History & Physical	Clinicians should conduct a focused history and physical examination, including a neurological exam, to help place patients with low back pain into 1 of 3 broad categories: nonspecific low back pain, back pain potentially associated with radiculopathy or spinal stenosis or back pain potentially associated with another specific spinal cause. The history should include assessment of psychosocial risk factors, which predict risk for chronic disabling back pain. *Appropriate referrals for management of potentially serious conditions (see Table B) could be considered at this time.*[6]	Recommendation: Strong Grade: Moderate-quality evidence

[4] Chou, R, Fu, R, Carrino, J & Deyo, R. (2009). Imaging strategies for low-back pain: systematic review and meta-analysis. *The Lancet,* 373(9662): 463-72.
[5] Chou, R, Qaseem, A, Owens, D, Shekelle, P for the Clinical Guidelines Committee of the American College of Physicians. (2011). Diagnostic imaging for low back pain: Advice for high-value health care from the American College of Physicians. *Annals of Internal Medicine,* 154(3), 181-189.
[6] Making referrals for management of psychosocial risk factors predictive of chronic disabling back pain are not supported by evidence at this time.

Recommendations		
Recommendation	**Content**	**Strength of Recommendation & Evidence Grade**
2. Routine Imaging for non-specific pain (X-ray, CT, MRI)	Clinicians ***should not*** routinely obtain imaging or other diagnostic tests in patients with nonspecific low back pain.	Recommendation: Strong Grade: Moderate-quality evidence
3. Imaging for underlying conditions present or suspected (X-ray, CT, MRI)	Clinicians should perform diagnostic imaging and testing for patients with low back pain when severe or progressive neurologic deficits are present or when serious underlying conditions are suspected on the basis of history and physical examination. (See Table B for a list of potentially serious conditions)	Recommendation: Strong Grade: Moderate-quality evidence
4. Advanced Imaging (CT, MRI)	Clinicians should evaluate patients with persistent low back pain and signs or symptoms of radiculopathy or spinal stenosis with magnetic resonance imaging (preferred) or computed tomography only if they are potential candidates for surgery or epidural steroid injection (for suspected radiculopathy).	Recommendation: Strong Grade: Moderate-quality evidence
5. Patient Education	Clinicians should provide patients with evidence-based information on low back pain with regard to their expected course, advise patients to remain active, and provide information about effective self-care options.	Recommendation: Strong Grade: Moderate-quality evidence
6. Pharmacologic therapy	For patients with low back pain, clinicians should consider the use of medications with proven benefits in conjunction with back care information and self-care. Clinicians should assess severity of baseline pain and functional deficits, potential benefits, risks, and relative lack of long-term efficacy and safety data before initiating therapy. Note: For most patients, first-line medication options are acetaminophen or non-steroidal anti-inflammatory drugs	Recommendation: Strong Grade: Moderate-quality evidence
7. Non-pharmacologic therapy	For patients who do not improve with self-care options, clinicians should consider the addition of nonpharmacologic therapy with proven benefits—for acute low back pain, spinal manipulation; for chronic or subacute low back pain, intensive interdisciplinary rehabilitation, exercise therapy, acupuncture, massage therapy, spinal manipulation, yoga, cognitive-behavioral therapy, or progressive relaxation.	Recommendation: Weak Grade: Moderate-quality evidence

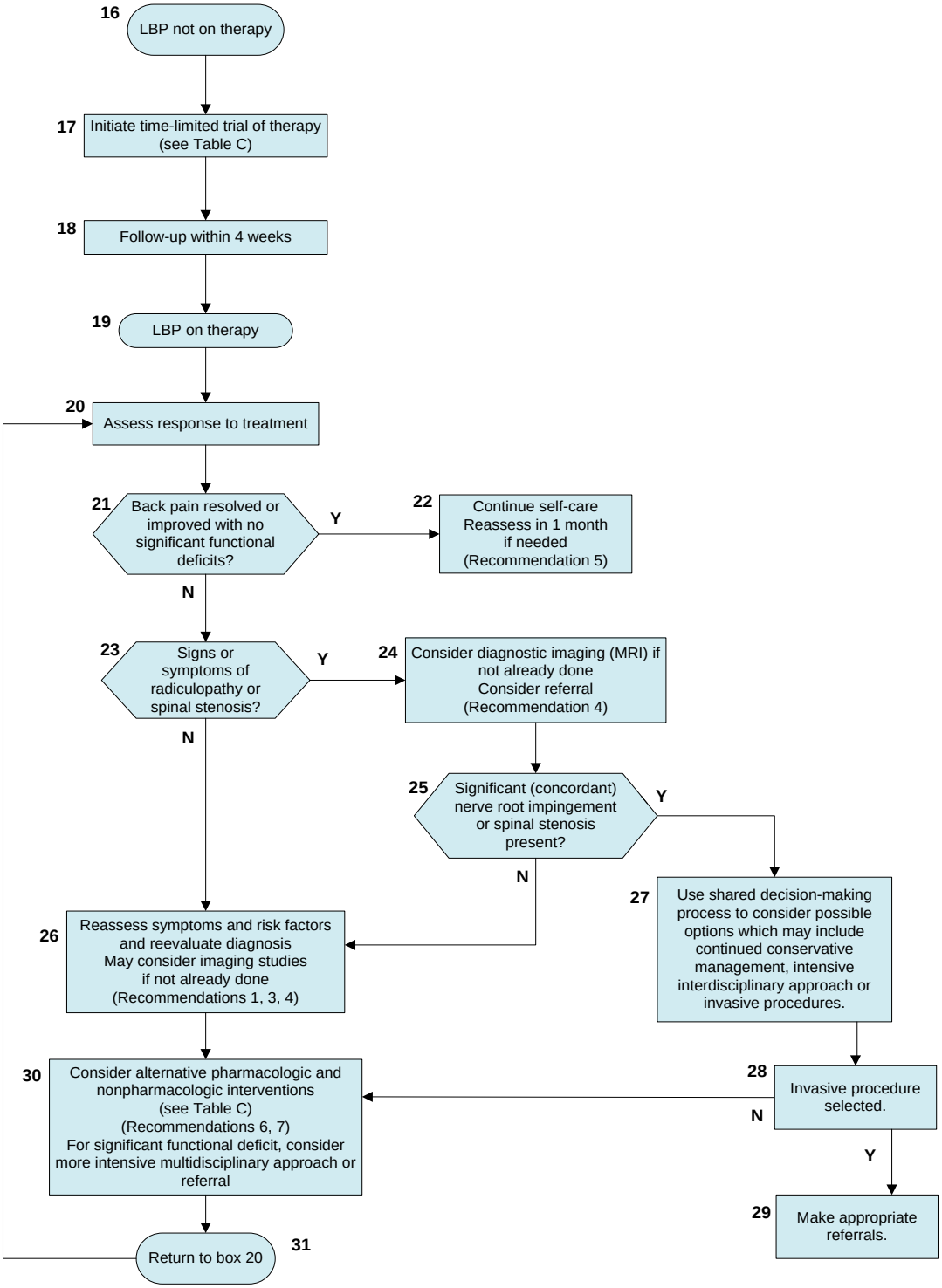
Figure 1. **Initial evaluation & management of low back pain (LBP).**



This algorithm should not be used for back pain associated with major trauma, nonspinal back pain, or back pain due to systemic illness.

Extracted and modified from Chou R, Qaseem A, Snow V, et al: Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society. Ann Intern Med. 2007;147:478-491.

***Figure 2*. Management of low back pain (LBP).**



Extracted and modified from Chou R, Qaseem A, Snow V, et al: Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society. Ann Intern Med. 2007;147:478-491.

Table B: Potentially Serious Conditions ("Red Flags") and Recommendations for Initial Diagnostic Work-up (Addresses Recommendations 1-4)

Possible cause	Key features on history or physical examination	Imaging*	Additional studies*
Cancer	History of cancer with new onset of LBP	MRI	ESR
	• Unexplained weight loss • Failure to improve after 1 month • Age >50 years	Lumbosacral plain radiography	
	Multiple risk factors present	Plain radiography or MRI	
Spinal column infection	• Fever • Intravenous drug use • Recent infection	MRI	ESR and/or CRP
Cauda equina syndrome	• Urinary retention • Motor deficits at multiple levels • Fecal incontinence • Saddle anesthesia	MRI	None
Vertebral compression fracture	• History of osteoporosis • Use of corticosteroids • Older age	Lumbosacral plain radiography	None
Ankylosing spondylitis	• Morning stiffness • Improvement with exercise • Alternating buttock pain • Awakening due to back pain during the second part of the night • Younger age	Anterior-posterior pelvis plain radiography	ESR and/or CRP, HLA-B27
Nerve compression /disorders (e.g. herniated disc with radiculopathy) (Recommendation 4)	• Back pain with leg pain in an L4, L5, or S1 nerve root distribution • Positive straight-leg-raise test or crossed straight-leg-raise test	None	None
	• Radiculopathic symptoms present >1 month • Severe/progressive neurologic deficits, progressive motor weakness	MRI**	Consider EMG/NCV
Spinal stenosis (Recommendation 4)	• Radiating leg pain • Older age • Pain usually relieved with sitting • (Pseudoclaudication a weak predictor)	None	None
	Spinal stenosis symptoms present >1 month	MRI**	Consider EMG/NCV

* Level of evidence for diagnostic evaluation is variable

** Only if patient is a potential candidate for surgery or epidural steroid injection

Red Flag: Red flags are findings from the history and physical examination that may be associated with a higher risk of serious disorders. CRP = C-reactive protein; EMG = electromyography; ESR = erythrocyte sedimentation rate; MRI = magnetic resonance imaging; NCV = nerve conduction velocity.

Extracted and modified from Chou R, Qaseem A, Snow V, et al: Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society. Ann Intern Med. 2007; 147:478-491.

Table C: Interventions (Addresses Recommendations 5-7)

Intervention Category*	Intervention	Acute < 4 Weeks	Subacute & Chronic > 4 Weeks
Self-care	Advice to remain active	●	●
	Books, handout	●	●
	Application of superficial heat	●	
Nonpharmacologic therapy	Spinal manipulation	●	●
	Exercise therapy		●
	Massage		●
	Acupuncture		●
	Yoga		●
	Cognitive-behavioral therapy		●
	Progressive relaxation		●
Pharmacologic therapy (Carefully consider risks/harms)	Acetaminophen	●	●
	NSAIDs	●(▲)	●(▲)
	Skeletal muscle relaxants	●	
	Antidepressants (TCA)		●
	*Benzodiazepines***	●(▲)	●(▲)
	*Tramadol, opioids***	●(▲)	●(▲)
Interdisciplinary therapy	Intensive interdisciplinary rehabilitation		●

- Interventions supported by grade B evidence (at least fair-quality evidence of moderate benefit, or small benefit but no significant harms, costs, or burdens). No intervention was supported by grade "A" evidence (good-quality evidence of substantial benefit).

▲ *Carries greater risk of harms than other agents in table*.

NSAIDs = nonsteroidal anti-inflammatory drugs; TCA = tricyclic antidepressants.

*These are general categories only. Individual care plans need to be developed on a case by case basis. For more detailed information please see: http://www.annals.org/content/147/7/478.full.pdf

**Associated with significant risks related to potential for abuse, addiction and tolerance. This evidence evaluates effectiveness of these agents with relatively short term use studies. Chronic use of these agents may result in significant harms.

Extracted and modified from Chou R, Qaseem A, Snow V, et al: Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society. Ann Intern Med. 2007; 147:478-491.

Appendix A. Sources Searched for Low Back Pain Guidelines

1. British Medical Journal – Clinical Evidence
2. Cochrane Library
3. Agency for Healthcare Research and Quality
4. ECRI
5. Hayes, Inc
6. Veterans Administration – Technology Assessment Program (VA TAP)
7. Blue Cross Blue Shield HTA
8. Centers for Medicare and Medicaid
9. CADTH
10. Washington HTA Program
11. US Preventive Services Task Force
12. ICSI
13. Guidelines.gov
14. American College of Physicians AND American Pain Society
15. American Physical Therapy Association
16. PEDro.org.au (evidence-based physiotherapy database)
17. GIN Guidelines Database

Appendix B. Low Back Pain Guidelines Identified

Methods Summary:
Initially, 17 databases and other sources for guidelines related to Acute Low Back Pain were searched. Candidate guidelines were required to:

- be evidence-based (recommendations based on a full systematic review)
- be comprehensive
- be published in English
- be freely available to the public

Thirteen pertinent guidelines were identified, of which 10 were sufficiently comprehensive and were assessed by two clinical epidemiologists for methodologic quality using a modified AGREE (Appraisal of Guidelines Research and Evaluation) II[7] instrument.
Candidate guidelines were then assessed considering:

- age
- source
- specific treatment elements addressed
- presentation

The GDG selected the two guidelines of highest quality that were most comprehensive. (See guideline text for comprehensive Methods discussion)

Low Back Pain Guidelines Identified in Search – Selected for Quality Assessment

American College of Occupational and Environmental Medicine (ACOEM). (2007). Low back disorders. Occupational medicine practice guidelines: Evaluation and management of common health problems and functional recovery in workers. 2nd ed. Elk Grove Village, IL: ACOEM.
Overall guideline quality rating: Fair

Chou, R., Qaseem, A., Snow, V., Casey, D., Cross, J.T. Jr., Shekelle, P., Owens, D.K., Clinical Efficacy Assessment Subcommittee of the American College of Physicians, American College of Physicians, American Pain Society Low Back Pain Guidelines Panel. (2007).Diagnosis and treatment of low back pain: A joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Ann Intern Med, 147*(7), 478-91.
Overall guideline quality rating: Good

Institute for Clinical Systems Improvement (ICSI). (2010). Adult low back pain. Fourteenth edition. Bloomington, MN: ICSI.
Overall guideline quality rating: Poor

Michigan Quality Improvement Consortium. (2008). Management of acute low back pain. Southfield, MI: Michigan Quality Improvement Consortium.
Overall guideline quality rating: Poor

National Health and Medical Research Council. Australian Acute Musculoskeletal Pain Guidelines Group. (2003). Evidence-based management of acute musculoskeletal pain. (Website states that status is "current"). [Chapter 4 of document is on Acute Low Back Pain.]
http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses /cp94.pdf
Overall guideline quality rating: Fair

National Institute for Health and Clinical Excellence (NICE). (2009). Low back pain: Early management of persistent non-specific low back pain. London, UK: National Institute for Health and Clinical Excellence. Retrieved September 30, 2010, from http://www.nice.org.uk/nicemedia/live/11887/44343/44343.pdf
Overall guideline quality rating: Good

[7] http://www.agreecollaboration.org/

New Zealand Guidelines Group. (2004). New Zealand acute low back pain guide. Wellington, NZ: New Zealand Guidelines Group. Retrieved December 13, 2010, from http://www.nzgg.org.nz/guidelines/0072/acc1038_col.pdf
Overall guideline quality rating: Fair

Philadelphia Panel. (2001). Philadelphia Panel evidence-based clinical practice guidelines on selected rehabilitation interventions for low back pain. *Physical Therapy, 81*(10), 1641-74.
Overall guideline quality rating: Fair

Towards Optimized Practice. (2009). Management of low back pain. Edmonton, AB: Towards Optimized Practice Program.
Overall guideline quality rating: Fair

University of Michigan Health System. (2010). Acute low back pain. Ann Arbor, MI: University of Michigan Health System.
Overall guideline quality rating: Poor

Low Back Pain Guidelines Identified in Search– Not Selected for Quality Assessment

Burton, A.K., Müller, G., Balagué, F., Gardon, G., Eriksen, H.R., Hänninen, O., et al. (2004). European guidelines for prevention in low back pain. Retrieved November 22, 2010, from http://www.backpaineurope.org/web/files/WG3_Guidelines.pdf
Reason for exclusion: Age of underlying evidence review

Davis, P.C., Wippold, F.J. II, Brunberg, J.A., Cornelius, R.S., De La Paz, R.L., Dormont, D., Gray, L, Jordan, J.E., Mukherji, S.K., Seidenwurm, D.J., Turski, P.A., Zimmerman, R.D., Sloan, M.A., Expert Panel on Neurologic Imaging. (2008). ACR Appropriateness Criteria ® low back pain. Reston, VA: American College of Radiology (ACR).
Reason for exclusion: Specific treatment elements not addressed

Globe, G.A., Morris, C.E., Whalen, W.M., Farabaugh, R.J., Hawk, C, Council on Chiropractic Guidelines and Practice Parameter. (2008) Chiropractic management of low back disorders: Report from a consensus process. *Journal of Manipulative Physiological Therapy, 31*(9), 651-8.
Reason for exclusion: Specific treatment elements not addressed

McIntosh, G., & Hall, H. (2007). Low back pain (acute). *BMJ Clinical Evidence, 10*, 1102-1131.
Reason for exclusion: Not a guideline

Resnick, D.K., Choudhri, T.F., Dailey, A.T., Groff, M.W., Khoo, L., Matz, P.G., Mummaneni, P., Watters, W.C. 3rd, Wang, J., Walters, B.C., Hadley, M.N., American Association of Neurological Surgeons/Congress of Neurological Surgeons. (2005). Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 2: Assessment of functional outcome. *Journal of Neurosurgery: Spine, 2*(6), 639-46.
Reason for exclusion: Specific treatment elements not addressed

US Preventive Services Task Force (USPSTF). (2004). Primary care interventions to prevent low back pain in adults. Rockville, MD: USPSTF.
Reason for exclusion: Recommendations pertain to prevention, not diagnosis or management

Work Loss Data Institute (WLDI). (2008). Low back - lumbar & thoracic (acute & chronic). Corpus Christi, TX: WLDI. Retrieved November 22, 2010, from http://guidelines.gov/content.aspx?id=12674 [Full version for purchase only]
Reason for exclusion: Not freely available to the public

Appendix C: Methodology Checklist Adapted from the AGREE II materials

Methodology Checklist: Guidelines		
Guideline citation *(Include name of organization, title, year of publication, journal title, pages)*		
Guideline Topic:		
Checklist completed by:		Date:
SECTION 1: PRIMARY CRITERIA		
To what extent is there		***Assessment/Comments:***
1.1	**RIGOR OF DEVELOPMENT: Evidence** • Systematic literature search • Study selection criteria clearly described • Quality of individual studies and overall strength of the evidence assessed • Explicit link between evidence & recommendations *(If any of the above are missing, rate as poor)*	GOOD FAIR POOR
1.2	**RIGOR OF DEVELOPMENT: Recommendations** • Methods for developing recommendations clearly described • Strengths and limitations of evidence clearly described • Benefits/side effects/risks considered • External review	GOOD FAIR POOR
1.3	**EDITORIAL INDEPENDENCE**[8] • Views of funding body have not influenced the content of the guideline • Competing interests of members have been recorded and addressed	GOOD FAIR POOR
If any of three primary criteria are rated poor, the entire guideline should be rated poor.		
SECTION 2: SECONDARY CRITERIA		
2.1	**SCOPE AND PURPOSE** • Objectives described • Health question(s) specifically described • Population (patients, public, etc.) specified	GOOD FAIR POOR

[8] Editorial Independence is a critical domain. However, it is often very poorly reported in guidelines. The assessor should not rate the domain, but write "unable to assess" in the comment section. If the editorial independence is rated as "poor", indicating a high likelihood of bias, the entire guideline should be assessed as poor.

SECTION 2: SECONDARY CRITERIA, Cont.		
2.2	**STAKEHOLDER INVOLVEMENT** • Relevant professional groups represented • Views and preferences of target population sought • Target users defined	GOOD FAIR POOR
2.3	**CLARITY AND PRESENTATION** • Recommendations specific, unambiguous • Management options clearly presented • Key recommendations identifiable • Application tools available • Updating procedure specified	GOOD FAIR POOR
2.4	**APPLICABILITY** • Provides advice and/or tools on how the recommendation(s) can be put into practice • Description of facilitators and barriers to its application • Potential resource implications considered • Monitoring/audit/review criteria presented	GOOD FAIR POOR
SECTION 3: OVERALL ASSESSMENT OF THE GUIDELINE		
3.1	How well done is this guideline?	GOOD FAIR POOR
3.2	Other reviewer comments:	

Description of Ratings: Methodology Checklist for Guidelines

The checklist for rating guidelines is organized to emphasize the use of evidence in developing guidelines and the philosophy that "evidence is global, guidelines are local." This philosophy recognizes the unique situations (e.g., differences in resources, populations) that different organizations may face in developing guidelines for their constituents. The second area of emphasis is transparency. Guideline developers should be clear about how they arrived at a recommendation and to what extent there was potential for bias in their recommendations. For these reasons, rating descriptions are only provided for the primary criteria in section one. There may be variation in how individuals might apply the good, fair, and poor ratings in section two based on their needs, resources, organizations, etc.

Section 1. Primary Criteria (rigor of development and editorial independence) ratings:

Good: All items listed are present, well described, and well executed (e.g., key research references are included for each recommendation).
Fair: All items are present, but may not be well described or well executed.
Poor: One or more items are absent or are poorly conducted

Appendix D. List of External Reviewers

Invited: Accepted & Reviewed

Susan Bamberger, PT, DIP MDT
President
Oregon Physical Therapy Association

Roger Chou, MD
Scientific Director
Oregon Evidence-based Practice Center
Oregon Health & Science University

Rick Deyo, MD, MPH
Kaiser Permanente Professor of Evidence-Based Family Medicine
Director, KL2 Multidisciplinary Clinical Research Career Development Program
Director, OCTRI Community and Practice-based Research Program
Departments of Family Medicine and Internal Medicine
Oregon Health & Science University

Dorothy Epstein, DPT, OCS
Physical Therapist
Legacy Good Samaritan Pain Management Center
Legacy Good Samaritan Outpatient Rehabilitation

Marc Gosselin, MD
Associate Professor
Director, Thoracic Imaging
Department of Diagnostic Radiology
Oregon Health & Science University

Mitch Haas, DC, MA
Associate Vice President of Research
University of Western States

Luci Kovacevic, MD, MPH
Occupational Medicine Physician
Cascade Medical Associates

Invited: Declined/Did Not Respond/Did Not Review

Thirteen additional reviewers were invited but either declined, did not respond, missed the deadline or did not return the review. Areas of professional expertise for invited reviewers included:

Behavioral Health
Complementary and Alternative Medicine
Family Medicine
Internal Medicine
Occupational Medicine
Orthopedic Surgery
Neurosurgery
Pain Advocacy
Physical Therapy
Physical Medicine and Rehabilitation
Sports Medicine
Worker's Compensation

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE FOR LOW BACK PAIN EVALUATION, PHARMACOLOGIC AND NON-PHARMACOLOGIC/NON-INVASIVE INTERVENTIONS*

DATE: XX/XX/XXXX

HERC COVERAGE GUIDANCE

Appropriate assessment and intervention of a low back pain visit include:

- History and focused physical examination including neurologic examination
- Patient education to stay active and discuss effective self-care

Pharmacologic therapy

- Initial pharmacologic therapy should be acetaminophen or non-steroidal anti-inflammatory medications and/or skeletal muscle relaxants.
- Second line agents include benzodiazepines, and opioids due to associated risks.
- Systemic steroids should NOT be covered for this diagnosis.
- For chronic low back pain, tricyclic antidepressants should be covered

Initial non-pharmacologic interventions

For pain ≤ 4 weeks, self-care is recommended and for those who do not improve with self-care, spinal manipulation should be covered

For pain > 4 weeks duration, the following treatments may be covered:

- Intensive interdisciplinary rehabilitation
- Exercise therapy
- Acupuncture
- Massage therapy
- Spinal manipulation
- Cognitive-behavioral therapy
- *Progressive relaxation*
- *Yoga*

The following should NOT be covered for low back pain

- Transcutaneous electrical nerve stimulation
- Continuous or intermittent traction

*Coverage guidance for imaging, percutaneous interventions and surgery for low back pain will be addressed in subsequent documents.

DRAFT

Oregon Health Authority

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. In addition to an evidence-based guideline developed by the Evidence-based Guideline Subcommittee and a health technology assessment developed by the Heath Technology Assessment Subcommittee, coverage guidance may utilize an existing evidence report produced in the last 5 years by the Agency for Healthcare Research and Quality, the Medicaid Evidence-based Decisions Project or the Washington Health Technology Assessment Program.

EVIDENCE SOURCE

Livingston, C., King, V., Little, A., Pettinari, C., Thielke, A., & Gordon, C. (2011). *State of Oregon Evidence-based Clinical Guidelines Project. Evaluation and management of low back pain: A clinical practice guideline based on the joint practice guideline of the American College of Physicians and the American Pain Society (Diagnosis and treatment of low back pain).* Salem: Office for Oregon Health Policy and Research. Available at: http://www.oregon.gov/OHA/OHPR/HERC/Evidence-Based-Guidelines.shtml

Chou, R., Huffman, L. *Nonpharmacologic Therapies for Acute and Chronic Low Back Pain:A Review of the Evidence for an American Pain Society/American College of Physicians Clinical Practice Guideline.* Ann Intern Med. 2007; 147; 492-504. Available at: http://www.annals.org/content/147/7/492.full.pdf+html

Chou, R., Huffman, L. *Medications for Acute and Chronic Low Back Pain:A Review of the Evidence for an American Pain Society/American College of Physicians Clinical Practice Guideline.* Ann Intern Med. 2007; 147; 505-514. Available at: http://www.annals.org/content/147/7/505.full.pdf+html

Chou R., Qaseem, A., Snow, V., Casey, D., Cross, J.T., Jr., Shekelle, P., Owens, D.K.; Clinical Efficacy Assessment Subcommittee of the American College of Physicians; American College of Physicians; American Pain Society Low Back Pain Guidelines Panel. *Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society.* Annals of Internal Med. 2007; 147(7); 478-491. Available at: http://www.annals.org/content/147/7/478.long

DRAFT

SUMMARY OF EVIDENCE

Clinical Background

Low back pain is the fifth most common reason for all physician visits in the United States. Approximately one quarter of U.S. adults reported having low back pain lasting at least 1 whole day in the past 3 months, and 7.6% reported at least 1 episode of severe acute low back pain within a 1-year period. Low back pain is also very costly: Total incremental direct health care costs attributable to low back pain in the U.S. were estimated at $26.3 billion in 1998. In addition, indirect costs related to days lost from work are substantial, with approximately 2% of the U.S. work force compensated for back injuries each year.

Many patients have self-limited episodes of acute low back pain and do not seek medical care. Among those who do seek medical care, pain, disability, and return to work typically improve rapidly in the first month. However, up to one third of patients report persistent back pain of at least moderate intensity 1 year after an acute episode, and 1 in 5 report substantial limitations in activity. Approximately 5% of the people with back pain disability account for 75% of the costs associated with low back pain.

Many options are available for evaluation and management of low back pain. However, there has been little consensus, either within or between specialties, on appropriate clinical evaluation and management of low back pain. Numerous studies show unexplained, large variations in use of diagnostic tests and treatments. Despite wide variations in practice, patients seem to experience broadly similar outcomes, although costs of care can differ substantially among and within specialties.

Evidence Review

A systematic review of the evidence and a guideline development process results in the following recommendations:

Recommendation 1: Clinicians should conduct a focused history and physical examination to help place patients with low back pain into 1 of 3 broad categories: nonspecific low back pain, back pain potentially associated with radiculopathy or spinal stenosis, or back pain potentially associated with another specific spinal cause. The history should include assessment of psychosocial risk factors, which predict risk for chronic disabling back pain (strong recommendation, moderate-quality evidence).

Recommendation 2: Clinicians should provide patients with evidence-based information on low back pain with regard to their expected course, advise patients to remain active, and provide information about effective self-care options (strong recommendation, moderate-quality evidence).

Recommendation 3: For patients with low back pain, clinicians should consider the use of medications with proven benefits in conjunction with back care information and self-

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care. Clinicians should assess severity of baseline pain and functional deficits, potential benefits, risks, and relative lack of long-term efficacy and safety data before initiating therapy (strong recommendation, moderate-quality evidence). For most patients, first-line medication options are acetaminophen or nonsteroidal anti-inflammatory drugs.

Recommendation 4: For patients who do not improve with self-care options, clinicians should consider the addition of nonpharmacologic therapy with proven benefits—for acute low back pain, spinal manipulation; for chronic or subacute low back pain, intensive interdisciplinary rehabilitation, exercise therapy, acupuncture, massage therapy, spinal manipulation, yoga, cognitive-behavioral therapy, or progressive relaxation (weak recommendation, moderate-quality evidence).

Additional Findings: Transcutaneous electrical nerve stimulation and intermittent or continuous traction (in patients with or without sciatica) have not been proven effective for chronic low back pain.

LIMITATIONS OF COVERAGE

Not applicable

PROCEDURE

DIAGNOSES

Low back pain

APPLICABLE CODES

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HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE FOR LOW BACK PAIN: EVALUATION, PHARMACOLOGIC AND NON-PHARMACOLOGIC/NON-INVASIVE INTERVENTIONS*

DATE: XX/XX/XXXX

HERC COVERAGE GUIDANCE

Appropriate assessment and intervention of a low back pain visit include:

- History and focused physical examination including neurologic examination
- Patient education to stay active and discuss effective self-care

Pharmacologic therapy

- Initial pharmacologic therapy should be acetaminophen or non-steroidal anti-inflammatory medications and/or skeletal muscle relaxants.
- Second line agents include benzodiazepines, and opioids due to associated risks.
- Systemic steroids should NOT be covered for this diagnosis.
- For chronic low back pain, tricyclic antidepressants should be covered

Initial non-pharmacologic interventions

For pain ≤ 4 weeks, self-care is recommended and for those who do not improve with self-care, spinal manipulation should be covered

For pain > 4 weeks duration, the following treatments may be covered:

- Intensive interdisciplinary rehabilitation
- Exercise therapy
- Acupuncture
- Massage therapy
- Spinal manipulation
- Cognitive-behavioral therapy
- *Progressive relaxation*
- *Yoga*

The following should NOT be covered for low back pain

- Transcutaneous electrical nerve stimulation
- Continuous or intermittent traction

*Coverage guidance for imaging, percutaneous interventions and surgery for low back pain will be addressed in subsequent documents.

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Oregon Health Authority

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. In addition to an evidence-based guideline developed by the Evidence-based Guideline Subcommittee and a health technology assessment developed by the Heath Technology Assessment Subcommittee, coverage guidance may utilize an existing evidence report produced in the last 5 years by the Agency for Healthcare Research and Quality, the Medicaid Evidence-based Decisions Project or the Washington Health Technology Assessment Program.

EVIDENCE SOURCE

Livingston, C., King, V., Little, A., Pettinari, C., Thielke, A., & Gordon, C. (2011). *State of Oregon Evidence-based Clinical Guidelines Project. Evaluation and management of low back pain: A clinical practice guideline based on the joint practice guideline of the American College of Physicians and the American Pain Society (Diagnosis and treatment of low back pain).* Salem: Office for Oregon Health Policy and Research. Available at: http://www.oregon.gov/OHA/OHPR/HERC/Evidence-Based-Guidelines.shtml

Chou, R., Huffman, L. *Nonpharmacologic Therapies for Acute and Chronic Low Back Pain:A Review of the Evidence for an American Pain Society/American College of Physicians Clinical Practice Guideline.* Ann Intern Med. 2007; 147; 492-504. Available at: http://www.annals.org/content/147/7/492.full.pdf+html

Chou, R., Huffman, L. *Medications for Acute and Chronic Low Back Pain:A Review of the Evidence for an American Pain Society/American College of Physicians Clinical Practice Guideline.* Ann Intern Med. 2007; 147; 505-514. Available at: http://www.annals.org/content/147/7/505.full.pdf+html

Chou R., Qaseem, A., Snow, V., Casey, D., Cross, J.T., Jr., Shekelle, P., Owens, D.K.; Clinical Efficacy Assessment Subcommittee of the American College of Physicians; American College of Physicians; American Pain Society Low Back Pain Guidelines Panel. *Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society.* Annals of Internal Med. 2007; 147(7); 478-491. Available at: http://www.annals.org/content/147/7/478.long

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SUMMARY OF EVIDENCE

Clinical Background

Low back pain is the fifth most common reason for all physician visits in the United States. Approximately one quarter of U.S. adults reported having low back pain lasting at least 1 whole day in the past 3 months, and 7.6% reported at least 1 episode of severe acute low back pain within a 1-year period. Low back pain is also very costly: Total incremental direct health care costs attributable to low back pain in the U.S. were estimated at $26.3 billion in 1998. In addition, indirect costs related to days lost from work are substantial, with approximately 2% of the U.S. work force compensated for back injuries each year.

Many patients have self-limited episodes of acute low back pain and do not seek medical care. Among those who do seek medical care, pain, disability, and return to work typically improve rapidly in the first month. However, up to one third of patients report persistent back pain of at least moderate intensity 1 year after an acute episode, and 1 in 5 report substantial limitations in activity. Approximately 5% of the people with back pain disability account for 75% of the costs associated with low back pain.

Many options are available for evaluation and management of low back pain. However, there has been little consensus, either within or between specialties, on appropriate clinical evaluation and management of low back pain. Numerous studies show unexplained, large variations in use of diagnostic tests and treatments. Despite wide variations in practice, patients seem to experience broadly similar outcomes, although costs of care can differ substantially among and within specialties.

Evidence Review

More than 85% of patients who present to primary care have low back pain that cannot reliably be attributed to a specific disease or spinal abnormality (nonspecific low back pain), and no evidence suggests that labeling most patients with low back pain by using specific anatomical diagnoses improves outcomes. In a minority of patients presenting for initial evaluation in a primary care setting, low back pain is caused by a specific disorder, such as cancer (approximately 0.7% of cases), compression fracture (4%), or spinal infection (0.01%). Estimates for prevalence of ankylosing spondylitis in primary care patients range from 0.3% to 5%. Spinal stenosis and symptomatic herniated disc are present in about 3% and 4% of patients, respectively. The cauda equina syndrome is most commonly associated with massive midline disc herniation but is rare, with an estimated prevalence of 0.04% among patients with low back pain.

Evidence is insufficient to guide appropriate intervals or methods (such as office visit vs. telephone follow-up) for reassessment of history, physical examination, or psychosocial factors. However, patients with acute low back pain generally experience substantial improvement in the first month after initial presentation, suggesting that a reasonable approach is to reevaluate patients with persistent, unimproved symptoms after 1 month.

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In patients with severe pain or functional deficits, older patients, or patients with signs of radiculopathy or spinal stenosis, earlier or more frequent reevaluation may also be appropriate.

The natural history of lumbar disc herniation with radiculopathy in most patients is for improvement within the first 4 weeks with noninvasive management. Clinicians should inform all patients of the generally favorable prognosis of acute low back pain with or without sciatica, including a high likelihood for substantial improvement in the first month. General advice on self-management for nonspecific low back pain should include recommendations to remain active, which is more effective than resting in bed for patients with acute or subacute low back pain. Self-care education books based on evidence-based guidelines, such as *The Back Book*, are recommended because they are an inexpensive and efficient method for supplementing clinician-provided back information and advice and are similar or only slightly inferior in effectiveness to such costlier interventions as supervised exercise therapy, acupuncture, massage, and spinal manipulation.

Medications in several classes have been shown to have moderate, primarily short-term benefits for patients with low back pain. Each class of medication is associated with unique trade-offs involving benefits, risks, and costs. For example, acetaminophen is a slightly weaker analgesic than NSAIDs but is a reasonable first-line option for treatment of acute or chronic low back pain because of a more favorable safety profile and low cost. Nonselective NSAIDs are associated with well-known gastrointestinal and renovascular risks, and there is an association between exposure to cyclooxygenase-2–selective or most nonselective NSAIDs and increased risk for myocardial infarction. Opioid analgesics or tramadol are an option when used judiciously in patients with acute or chronic low back pain who have severe, disabling pain that is not controlled (or is unlikely to be controlled) with acetaminophen and NSAIDs. Because of substantial risks, including aberrant drug-related behaviors with long-term use in patients vulnerable or potentially vulnerable to abuse or addiction, potential benefits and harms of opioid analgesics should be carefully weighed before starting therapy.

For skeletal muscle relaxants, although the antispasticity drug tizanidine has been well studied for low back pain, there is little evidence for the efficacy of baclofen or dantrolene, the other FDA-approved drugs for the treatment of spasticity. Other medications in the skeletal muscle relaxant class are an option for short-term relief of acute low back pain, but all are associated with central nervous system adverse effects (primarily sedation). Tricyclic antidepressants are an option for pain relief in patients with chronic low back pain and no contraindications to this class of medications. Antidepressants in the selective serotonin reuptake inhibitor class and trazodone have not been shown to be effective for low back pain, and serotonin–norepineprhine reuptake inhibitors (duloxetine and venlafaxine) have not yet been evaluated for low back pain.

Gabapentin is associated with small, short-term benefits in patients with radiculopathy and has not been directly compared with other medications or treatments. There is

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insufficient evidence to recommend for or against other antiepileptic drugs for back pain with or without radiculopathy. For acute or chronic low back pain, benzodiazepines seem similarly effective to skeletal muscle relaxants for short-term pain relief but are also associated with risks for abuse, addiction, and tolerance. Herbal therapies, such as devil's claw, willow bark, and capsicum, seem to be safe options for acute exacerbations of chronic low back pain, but benefits range from small to moderate. Systemic corticosteroids are not recommended for treatment of low back pain with or without sciatica, because they have not been shown to be more effective than placebo.

For acute low back pain (duration <4 weeks), spinal manipulation administered by providers with appropriate training is associated with small to moderate short-term benefits. Supervised exercise therapy and home exercise regimens are not effective for acute low back pain, and the optimal time to start exercise therapy after the onset of symptoms is unclear. For subacute (duration >4 to 8 weeks) low back pain, intensive interdisciplinary rehabilitation (defined as an intervention that includes a physician consultation coordinated with a psychological, physical therapy, social, or vocational intervention) is moderately effective, and functional restoration with a cognitive-behavioral component reduces work absenteeism due to low back pain in occupational settings. For chronic low back pain, moderately effective nonpharmacologic therapies include acupuncture, exercise therapy, massage therapy, Viniyoga-style yoga, cognitive-behavioral therapy or progressive relaxation, spinal manipulation, and intensive interdisciplinary rehabilitation.

With the exception of continuous or intermittent traction, which has not been shown to be effective in patients with sciatica, few trials have evaluated the effectiveness of treatments specifically in patients with radicular pain or symptoms of spinal stenosis. In addition, there is insufficient evidence to recommend any specific treatment as first-line therapy. Transcutaneous electrical nerve stimulation and intermittent or continuous traction (in patients with or without sciatica) have not been proven effective for chronic low back pain. Acupressure, neuroreflexotherapy, and spa therapy have not been studied in the United States, and percutaneous electrical nerve stimulation is not widely available. There is insufficient evidence to recommend interferential therapy, low-level laser therapy, shortwave diathermy, or ultrasonography. Evidence is inconsistent on back schools, which have primarily been evaluated in occupational settings, with some trials showing small, short-term benefits.

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LIMITATIONS OF COVERAGE

Not applicable

PROCEDURE

DIAGNOSES

Low back pain

APPLICABLE CODES

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HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE FOR LOW BACK PAIN: NON-PHARMACOLOGIC/NON-INVASIVE INTERVENTIONS*

DATE: XX/XX/XXXX

HERC COVERAGE GUIDANCE

Initial non-pharmacologic interventions

For pain ≤ 4 weeks, self-care is recommended, and for those who do not improve with self-care, spinal manipulation should be covered.

For pain > 4 weeks duration, the following treatments may be covered:

- Intensive interdisciplinary rehabilitation
- Exercise therapy
- Acupuncture
- Massage therapy
- Spinal manipulation
- Cognitive-behavioral therapy
- *Progressive relaxation*
- *Yoga*

The following should NOT be covered for low back pain:

- Transcutaneous electrical nerve stimulation
- Continuous or intermittent traction

*Coverage guidance for imaging, percutaneous interventions and surgery for low back pain will be addressed in subsequent documents.

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

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Oregon Health Authority

Coverage guidance development follows to translate the evidence review to a policy decision. In addition to an evidence-based guideline developed by the Evidence-based Guideline Subcommittee and a health technology assessment developed by the Heath Technology Assessment Subcommittee, coverage guidance may utilize an existing evidence report produced in the last 5 years by the Agency for Healthcare Research and Quality, the Medicaid Evidence-based Decisions Project or the Washington Health Technology Assessment Program.

EVIDENCE SOURCES

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Chou R., Qaseem, A., Snow, V., Casey, D., Cross, J.T., Jr., Shekelle, P., Owens, D.K.; Clinical Efficacy Assessment Subcommittee of the American College of Physicians; American College of Physicians; American Pain Society Low Back Pain Guidelines Panel. *Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society.* Annals of Internal Med. 2007; 147(7); 478-491. Available at: http://www.annals.org/content/147/7/478.long

SUMMARY OF EVIDENCE

Clinical Background

Low back pain is the fifth most common reason for all physician visits in the United States. Approximately one quarter of U.S. adults reported having low back pain lasting at least 1 whole day in the past 3 months, and 7.6% reported at least 1 episode of severe acute low back pain within a 1-year period. Low back pain is also very costly: Total incremental direct health care costs attributable to low back pain in the U.S. were estimated at $26.3 billion in 1998. In addition, indirect costs related to days lost from work are substantial, with approximately 2% of the U.S. work force compensated for back injuries each year.

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Many patients have self-limited episodes of acute low back pain and do not seek medical care. Among those who do seek medical care, pain, disability, and return to work typically improve rapidly in the first month. However, up to one third of patients report persistent back pain of at least moderate intensity 1 year after an acute episode, and 1 in 5 report substantial limitations in activity. Approximately 5% of the people with back pain disability account for 75% of the costs associated with low back pain.

Many options are available for evaluation and management of low back pain. However, there has been little consensus, either within or between specialties, on appropriate clinical evaluation and management of low back pain. Numerous studies show unexplained, large variations in use of diagnostic tests and treatments. Despite wide variations in practice, patients seem to experience broadly similar outcomes, although costs of care can differ substantially among and within specialties.

Evidence Review

Recommendation 1: *Clinicians should provide patients with evidence-based information on low back pain with regard to their expected course, advise patients to remain active, and provide information about effective self-care options (strong recommendation, moderate-quality evidence).*

Clinicians should inform all patients of the generally favorable prognosis of acute low back pain with or without sciatica, including a high likelihood for substantial improvement in the first month. General advice on self-management for nonspecific low back pain should include recommendations to remain active, which is more effective than resting in bed for patients with acute or subacute low back pain. Self-care education books (see Glossary) based on evidence-based guidelines, such as *The Back Book*(67), are recommended because they are an inexpensive and efficient method for supplementing clinician-provided back information and advice and are similar or only slightly inferior in effectiveness to such costlier interventions as supervised exercise therapy, acupuncture, massage, and spinal manipulation.

Recommendation 2: *For patients who do not improve with self-care options, clinicians should consider the addition of nonpharmacologic therapy with proven benefits—for acute low back pain, spinal manipulation; for chronic or subacute low back pain, intensive interdisciplinary rehabilitation, exercise therapy, acupuncture, massage therapy, spinal manipulation, yoga, cognitive-behavioral therapy, or progressive relaxation (weak recommendation, moderate-quality evidence).*

For acute low back pain (duration <4 weeks), spinal manipulation administered by providers with appropriate training is associated with small to moderate short-term benefits. Supervised exercise therapy and home exercise regimens are not effective for acute low back pain, and the optimal time to start exercise therapy after the onset of symptoms is unclear. For subacute (duration >4 to 8 weeks) low back pain, intensive interdisciplinary rehabilitation (defined as an intervention that includes a physician

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consultation coordinated with a psychological, physical therapy, social, or vocational intervention) is moderately effective, and functional restoration with a cognitive-behavioral component reduces work absenteeism due to low back pain in occupational settings. For chronic low back pain, moderately effective nonpharmacologic therapies include acupuncture, exercise therapy, massage therapy, Viniyoga-style yoga, cognitive-behavioral therapy or progressive relaxation, spinal manipulation, and intensive interdisciplinary rehabilitation.

Additional Findings: Transcutaneous electrical nerve stimulation and intermittent or continuous traction (in patients with or without sciatica) have not been proven effective for chronic low back pain.

LIMITATIONS OF COVERAGE

Not applicable

PROCEDURE

DIAGNOSES

Low back pain

APPLICABLE CODES

DRAFT

State of Oregon Evidence-based Clinical Guidelines Project

Advanced Imaging for Low Back Pain

A Clinical Practice Guideline Based on the Joint Practice Guideline of the American College of Physicians and the American Pain Society (Diagnosis and Treatment of Low Back Pain)

February 2012

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Oregon Health Authority

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Livingston, C., Little, A., King, V., Pettinari, C., Thielke, A., Vandegriff, S., & Gordon, C. (2012). *State of Oregon Evidence-based Clinical Guidelines Project. Advanced imaging for low back pain: A clinical practice guideline based on the joint practice guideline of the American College of Physicians and the American Pain Society (Diagnosis and treatment of low back pain).* Salem: Office of Oregon Health Policy & Research. Available at: http://www.oregon.gov/OHA/OHPR/HERC/Evidence-Based-Guidelines.shtml

This document was prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center) on behalf of the Guideline Development Group and the Office for Oregon Health Policy & Research. This document is intended to help providers, consumers and purchasers of health care in Oregon make informed decisions about health care services. The document is intended as a reference and is provided with the understanding that neither the Center nor the Guideline Development Group are engaged in rendering any clinical, legal, business or other professional advice.

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

The statements in this document do not represent official policy positions of the Center, the Guideline Development Group, or the Office for Oregon Health Policy and Research. Researchers and authors involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

Objective:
This guideline was developed by a collaborative group of public and private partners to provide up-to-date evidence-based guidance on the role of advanced imaging in low back pain. The guideline offers recommendations for the use of advanced imaging for evaluation of low back pain of any duration. The aim of the guideline is to identify evidence-based, appropriate indications for imaging of non-pregnant adults with low back pain. This guideline can then be used to create practice standards and coverage guidelines for use across public and private payors. Additional evidence concerning other elements of evaluation as well as recommendations for management of low back pain can be found in the State of Oregon Evidence-based Clinical Guidelines:

- Evaluation and Management of Low Back Pain[1] and
- Percutaneous Interventions for Low Back Pain[2].

Background to the Oregon Evidence-based Clinical Guidelines Project:
In June 2009, the Oregon legislature passed health reform legislation, HB 2009, which created the Oregon Health Policy Board and charged it with creating a comprehensive health reform plan for our state. In December 2010, the Board released *Oregon's Action Plan for Health*, which lays out "strategies that reflect the urgency of the health care crisis and a timeline for actions that will lead Oregon to a more affordable, world-class health care system." They outlined eight foundational strategies, one of which is to "set standards for safe and effective care." To accomplish this, the plan directs the state to "Identify and develop 10 sets of Oregon-based best practice guidelines and standards that can be uniformly applied across public and private health care to drive down costs and reduce unnecessary care. This work will be conducted by the Health Services Commission and Health Resources Commission in close collaboration with providers, the Center for Evidence-Based Practice, and other key stakeholders." [3]

Development of this guideline:
This guideline was developed by a Guideline Development Group (GDG) consisting of representatives from the State's Health Authority with support from clinical evidence specialists from the Center for Evidence-based Policy. The Center provided expertise in the process of guideline development and undertook analysis and appraisal to support the development of this guideline.

Methods:
The GDG developed this guideline using the ADAPTÉ[4] framework which is a systematic approach to the endorsement or modification of guideline(s) produced in one cultural context or organizational setting for application in another context or setting. Guideline adaptation is used as an alternative to wholly

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[1] Livingston, C., King, V., Little, A., Pettinari, C., Thielke, A., & Gordon, C. (2012). *State of Oregon Evidence-based Clinical Guidelines Project. Evaluation and management of low back pain: A clinical practice guideline based on the joint practice guideline of the American College of Physicians and the American Pain Society (Diagnosis and treatment of low back pain).* Salem: Office for Oregon Health Policy and Research.
[2] Livingston, C., Little, A., King, V., Pettinari, C., Thielke, A., Pensa, M., Vandegriff, S., & Gordon, C. (2012). *State of Oregon Evidence-based Clinical Guidelines Project. Percutaneous interventions for low back pain: A clinical practice guideline based on the 2009 American Pain Society Guideline (Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain).* Salem: Office for Oregon Health Policy and Research.
[3] Effective January 1, 2012, House Bill 2100 (2011) terminates the Health Services Commission and Health Resources Commission and transfers their duties related to evidence-based guideline development to a new Health Evidence Review Commission.
[4] http://www.adapte.org/www/

new guideline development, which can be time consuming, expensive and an inefficient use of resources, when existing quality guidelines are available.

The process for developing this guideline began by searching 17 different databases and other sources for guidelines related to Imaging for Low Back Pain (see appendix A). Candidate guidelines were required to satisfy the following requirements:

- To be evidence-based, that is, guideline recommendations are based on systematic reviews of the literature,
- to address the use of advanced imaging in adults with low back pain,
- to be published in English and,
- to be freely available to the public.

The GDG required that evidence-based recommendations be made on the basis of both the quality and strength of the underlying data from the guideline's systematic reviews.

The initial search identified nine guidelines which met the above stated criteria (Appendix B). Of the nine original candidate guidelines, three were rated as poor quality during the development of a previous State of Oregon guideline[5] and one was not sufficiently comprehensive (did not address the use of MRI or CT scanning) to warrant further assessment. The five remaining guidelines were then assessed for methodological quality using a modified AGREE II[6] (Appraisal of Guidelines Research and Evaluation) instrument (Appendix C). Assessments were conducted by two guideline quality assessors from the Center for Evidence-based Policy and discordant ratings were reconciled through further review and consensus. Two of the five guidelines were rated good quality, and the other three were rated fair quality. The two good quality guidelines were then examined further for scope and clarity of presentation.

After considering guideline scope and specific imaging modalities addressed, the GDG selected the American College of Physicians/ American Pain Society (ACP/APS) guideline as the base guideline, primarily because it had recommendations concerning the use of CT scanning, thermography and electrophysiology testing which were lacking in the National Institute for Clinical Excellence (NICE) guideline. Neither guideline addressed myelography. The ACP/APS guideline in its entirety can be found at the following link: http://www.annals.org/content/147/7/478.long. The ACP/APS guideline is accompanied by a full systematic review on imaging strategies for low back pain (http://www.annals.org/content/147/7/492.full.pdf+html).

The ACP/APS guideline used the ACP's guideline grading system that was adapted from the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) working group[7]. Guideline recommendations were rated as either strong or weak. Strong recommendations were required to have clear evidence of benefit or harm. Weak recommendations were based on finely balanced benefits, risks and burdens. The overall strength of evidence for each intervention was rated based on factors such as the quality, quantity, consistency, generalizability and directness of the evidence. The ACP/APS guideline

[5] Evaluation and Management of Low Back Pain: A Clinical Practice Guideline Based on the Joint Practice Guideline of the American College of Physicians and the American Pain Society (Diagnosis and Treatment of Low Back Pain) (2011).
[6] http://www.agreecollaboration.org/
[7] http://www.gradeworkinggroup.org/

panel considered interventions to have "proven" benefit if there was at least fair quality evidence of moderate or substantial benefit (or of small benefit with no significant harms, costs or burdens).

Updating:
The ACP/APS guideline was published in 2007. The authors of the guideline were contacted in March 2011 and stated that there had been no new published evidence which would change the recommendations of the guideline and that it was considered current. The GDG recommends that this guideline be reevaluated if the ACP/APS issues an updated guideline and at least every two years for currency if the original guideline is not updated.

Recommendations

Below are the recommendations of the ACP/APS clinical practice guideline, followed by discussion of each recommendation. These recommendations are further supported by a systematic review and meta-analysis of imaging strategies published in 2009[8], as well as Best Practice Advice from the American College of Physicians published in 2011[9].

Table A: State of Oregon Evidence-based Clinical Guideline Recommendations for Advanced Imaging for Evaluation of Low Back Pain

Recommendations		
Recommendation	**Content**	**Strength of Recommendation & Evidence Grade**
1. Routine Imaging for non-specific pain (X-ray, CT, MRI)	Clinicians **should not** routinely obtain imaging in patients with nonspecific low back pain.	Recommendation: Strong Grade: Moderate-quality evidence
2. Imaging for underlying conditions present or suspected (X-ray, CT, MRI)	Clinicians should perform diagnostic imaging and testing for patients with low back pain when severe or progressive neurologic deficits are present or when serious underlying conditions are suspected on the basis of history and physical examination. (See Table B for a list of potentially serious conditions)	Recommendation: Strong Grade: Moderate-quality evidence
3. Advanced Imaging* (CT, MRI)	Clinicians should evaluate patients with persistent low back pain and signs or symptoms of radiculopathy or spinal stenosis with magnetic resonance imaging (preferred) or computed tomography only if they are potential candidates for surgery or epidural steroid injection (for suspected radiculopathy).	Recommendation: Strong Grade: Moderate-quality evidence

*This guideline does not address the appropriate use of myelography or other advanced imaging other than CT and MRI

[8] Chou, R, Fu, R, Carrino, J & Deyo, R. (2009). Imaging strategies for low-back pain: systematic review and meta-analysis. *The Lancet,* 373(9662): 463-72.
[9] Chou, R, Qaseem, A, Owens, D, Shekelle, P for the Clinical Guidelines Committee of the American College of Physicians. (2011). Diagnostic imaging for low back pain: Advice for high-value health care from the American College of Physicians. *Annals of Internal Medicine,* 154(3), 181-189.

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Recommendation #1[10]:

There is no evidence that routine plain radiography in patients with nonspecific low back pain is associated with a greater improvement in patient outcomes than selective imaging (Deyo 1987, Kendrick 2001, Kerry 2002). In addition, exposure to unnecessary ionizing radiation should be avoided. This issue is of particular concern in young women because the amount of gonadal radiation from obtaining a two view radiographic exam of the lumbar spine is equivalent to being exposed to a daily chest radiograph for more than one year (Jarvik 2003a). Routine advanced imaging (computed tomography [CT] or magnetic resonance imaging [MRI]) is also not associated with improved patient outcomes (Gilbert 2004) and identifies many radiographic abnormalities that are poorly correlated with symptoms (Jarvik 2002) but could lead to additional, possibly unnecessary interventions (Jarvik 2003b, Lurie 2003). Plain radiography is recommended for initial evaluation of possible vertebral compression fracture in selected higher-risk patients, such as those with a history of osteoporosis or steroid use (Jarvik 2002). Evidence to guide optimal imaging strategies is not available for low back pain that persists for more than one to two months despite standard therapies if there are no symptoms suggesting radiculopathy or spinal stenosis, although plain radiography may be a reasonable initial option. (See recommendation 2 for imaging recommendations in patients with symptoms suggesting radiculopathy or spinal stenosis.) Thermography and electrophysiologic testing are not recommended for evaluation of nonspecific low back pain.

Recommendation #2[11]:

Prompt work-up with MRI or CT is recommended in patients who have severe or progressive neurologic deficits or are suspected of having a serious underlying condition (such as vertebral infection, the cauda equina syndrome, or cancer with impending spinal cord compression) because delayed diagnosis and treatment are associated with poorer outcomes (Loblaw 2005, Todd 2005, Tsiodras 2006). Magnetic resonance imaging is generally preferred over CT if available because it does not use ionizing radiation and provides better visualization of soft tissue, vertebral bone marrow, and the spinal canal (Jarvik 2002). There is insufficient evidence to guide precise recommendations on diagnostic strategies in patients who have risk factors for cancer but no signs of spinal cord compression. Several strategies have been proposed for such patients (Jarvik 2002, Joines 2001), but none have been prospectively evaluated. Proposed strategies generally recommend plain radiography or measurement of erythrocyte sedimentation rate (a rate of ≥ 20 mm/h is associated with 78% sensitivity and 67% specificity for cancer [van den Hoogen 1995]), with MRI reserved for patients with abnormalities on initial testing (Jarvik 2002, Joines 2001). An alternative strategy is to directly perform MRI in patients with a history of cancer, the strongest predictor of vertebral cancer (Joines 2001). While age over 50 years may be considered a red flag and justify moe immediate imaging, delaying imaging while offering standard treatments and reevaluating within 1 month may also be a reasonable option for patients without other risk factors for cancer (Suarez-Almazor 1997).

[10] Extracted verbatim from Chou, et al. (2007)
[11] Extracted verbatim from Chou, et al. (2007)

Recommendation #3[12]:

The natural history of lumbar disc herniation with radiculopathy in most patients is for improvement within the first four weeks with noninvasive management (Vroomen 2002, Weber 1983). There is no compelling evidence that routine imaging affects treatment decisions or improves outcomes (Modic 2005). For prolapsed lumbar disc with persistent radicular symptoms despite noninvasive therapy, discectomy or epidural steroids are potential treatment options (Gibson 2000, Gibson 2005, Nelemans 2001, Peul 2007, Weinstein, 2006). Surgery is also a treatment option for persistent symptoms associated with spinal stenosis (Amundsen 2000, Atlas 2005, Weinstein 2007, Malmivaara, 2007).

Magnetic resonance imaging (preferred if available) or CT is recommended for evaluating patients with persistent back and leg pain who are potential candidates for invasive interventions—plain radiography cannot demonstrate discs or accurately show the degree of spinal stenosis (Jarvik 2002). However, clinicians should be aware that findings on MRI or CT (such as bulging disc without nerve root impingement) are often nonspecific. Recommendations for specific invasive interventions, interpretation of radiographic findings, and additional work-up (such as electrophysiologic testing) are beyond the scope of this guideline, but decisions should be based on the clinical correlation between symptoms and radiographic findings, severity of symptoms, patient preferences, surgical risks (including the patient's comorbid conditions), and costs and will generally require specialist input.

Additionally, the Best Practice Advice from the American College of Physicians published in 2011[13] provides the following advice:

> "The ACP has found strong evidence that routine imaging for low back pain by using radiography or advanced imaging methods is not associated with a clinically meaningful effect on patient outcomes. Unnecessary imaging exposes patients to preventable harms, may lead to additional unnecessary interventions, and results in unnecessary costs. Diagnostic imaging studies should be performed only in selected, higher-risk patients who have severe or progressive neurologic deficits or are suspected of having a serious or specific underlying condition. Advanced imaging with MRI or CT should be reserved for patients with a suspected serious underlying condition or neurologic deficits, or who are candidates for invasive interventions. Decisions about repeated imaging should be based on development of new symptoms or changes in current symptoms. Patient education strategies should be used to inform patients about current and effective standards of care."

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[12] Extracted verbatim from Chou, et al. (2007)

[13] Chou, R, Qaseem, A, Owens, D, Shekelle, P for the Clinical Guidelines Committee of the American College of Physicians. (2011). Diagnostic imaging for low back pain: Advice for high-value health care from the American College of Physicians. *Annals of Internal Medicine,* 154(3), 181-189.

Table B: Potentially Serious Conditions ("Red Flags") and Recommendations for Initial Diagnostic Work-up

Possible cause	Key features on history or physical examination	Imaging*	Additional studies*
Cancer	History of cancer with new onset of LBP	MRI	ESR
	• Unexplained weight loss • Failure to improve after 1 month • Age >50 years	Lumbosacral plain radiography	
	Multiple risk factors for cancer present	Plain radiography or MRI	
Spinal column infection	• Fever • Intravenous drug use • Recent infection	MRI	ESR and/or CRP
Cauda equina syndrome	• Urinary retention • Motor deficits at multiple levels • Fecal incontinence • Saddle anesthesia	MRI	None
Vertebral compression fracture	• History of osteoporosis • Use of corticosteroids • Older age	Lumbosacral plain radiography	None
Ankylosing spondylitis	• Morning stiffness • Improvement with exercise • Alternating buttock pain • Awakening due to back pain during the second part of the night • Younger age	Anterior-posterior pelvis plain radiography	ESR and/or CRP, HLA-B27
Nerve compression /disorders (e.g. herniated disc with radiculopathy)	• Back pain with leg pain in an L4, L5, or S1 nerve root distribution • Positive straight-leg-raise test or crossed straight-leg-raise test	None	None
	• Radiculopathic symptoms present >1 month • Severe/progressive neurologic deficits, progressive motor weakness	MRI**	Consider EMG/NCV
Spinal stenosis	• Radiating leg pain • Older age • Pain usually relieved with sitting • (Pseudoclaudication a weak predictor)	None	None
	Spinal stenosis symptoms present >1 month	MRI**	Consider EMG/NCV

* Level of evidence for diagnostic evaluation is variable

** Only if patient is a potential candidate for surgery or epidural steroid injection

Red Flag: Red flags are findings from the history and physical examination that may be associated with a higher risk of serious disorders. CRP = C-reactive protein; EMG = electromyography; ESR = erythrocyte sedimentation rate; MRI = magnetic resonance imaging; NCV = nerve conduction velocity.

Extracted and modified from Chou R, Qaseem A, Snow V, et al: Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society. Ann Intern Med. 2007; 147:478-491.

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Appendix A. Sources Searched for Advanced Imaging for Low Chronic Back Pain Guidelines

1. British Medical Journal – Clinical Evidence
2. Cochrane Library
3. Agency for Healthcare Research and Quality
4. ECRI
5. Hayes, Inc
6. Veterans Administration – Technology Assessment Program (VA TAP)
7. Blue Cross Blue Shield HTA
8. Centers for Medicare and Medicaid
9. CADTH
10. Washington HTA Program
11. US Preventive Services Task Force
12. ICSI
13. Guidelines.gov
14. American College of Physicians AND American Pain Society
15. American Physical Therapy Association
16. PEDro.org.au (evidence-based physiotherapy database)
17. GIN Guidelines Database

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Appendix B. Low Back Pain Guidelines Identified

Methods Summary:
Initially, 17 databases and other sources for guidelines related to Advanced Imaging for Low Back Pain were searched. Candidate guidelines were required to:

- be evidence-based (recommendations based on a full systematic review)
- be comprehensive
- be published in English
- be freely available to the public

Nine pertinent guidelines were identified, of which five were sufficiently comprehensive and were assessed by two clinical epidemiologists for methodologic quality using a modified AGREE (Appraisal of Guidelines Research and Evaluation) II[14] instrument.
Candidate guidelines were then assessed considering:

- age
- source
- specific treatment elements addressed
- presentation

The GDG selected the two guidelines of highest quality that were most comprehensive. (See guideline text for comprehensive Methods discussion)

Low Back Pain Guidelines Identified in Search – Selected for Quality Assessment

Brussieres, A.E., Taylor, J.A., & Peterson, C. (2008). Diagnostic imaging practice guidelines for musculoskeletal complaints in adults: An evidence-based approach-part 3: spinal disorders. *Journal of Manipulative and Physiological Therapeutics, 31*(1), 33-88.
Overall guideline quality rating: Fair

Chou, R., Qaseem, A., Snow, V., Casey, D., Cross, J.T. Jr., Shekelle, P., Owens, D.K., Clinical Efficacy Assessment Subcommittee of the American College of Physicians, American College of Physicians, American Pain Society Low Back Pain Guidelines Panel. (2007).Diagnosis and treatment of low back pain: A joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Ann Intern Med, 147*(7), 478-91.
Overall guideline quality rating: Good

National Health and Medical Research Council. Australian Acute Musculoskeletal Pain Guidelines Group. (2003). Evidence-based management of acute musculoskeletal pain. (Website states that status is "current"). [Chapter 4 of document is on Acute Low Back Pain.]
http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses /cp94.pdf
Overall guideline quality rating: Fair

National Institute for Health and Clinical Excellence (NICE). (2009). Low back pain: Early management of persistent non-specific low back pain. London, UK: National Institute for Health and Clinical Excellence. Retrieved September 30, 2010, from http://www.nice.org.uk/nicemedia/live/11887/44343/44343.pdf
Overall guideline quality rating: Good

New Zealand Guidelines Group. (2004). New Zealand acute low back pain guide. Wellington, NZ: New Zealand Guidelines Group. Retrieved December 13, 2010, from
http://www.nzgg.org.nz/guidelines/0072/acc1038_col.pdf
Overall guideline quality rating: Fair

[14] http://www.agreecollaboration.org/

Low Back Pain Guidelines Identified in Search– Not Selected for Quality Assessment

Institute for Clinical Systems Improvement (ICSI). (2010). Adult low back pain. Fourteenth edition. Bloomington, MN: ICSI.
Overall guideline quality rating: Poor

Michigan Quality Improvement Consortium. (2008). Management of acute low back pain. Southfield, MI: Michigan Quality Improvement Consortium.
Overall guideline quality rating: Poor

Towards Optimized Practice. (2009). Management of low back pain. Edmonton, AB: Towards Optimized Practice Program.
Overall guideline quality rating: Fair

University of Michigan Health System. (2010). Acute low back pain. Ann Arbor, MI: University of Michigan Health System.
Overall guideline quality rating: Poor

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Appendix C: Methodology Checklist Adapted from the AGREE II materials

Methodology Checklist: Guidelines				
Guideline citation *(Include name of organization, title, year of publication, journal title, pages)*				
Guideline Topic:				
Checklist completed by:			Date:	
SECTION 1: PRIMARY CRITERIA				
To what extent is there		***Assessment/Comments:***		
1.1	**RIGOR OF DEVELOPMENT: Evidence** • Systematic literature search • Study selection criteria clearly described • Quality of individual studies and overall strength of the evidence assessed • Explicit link between evidence & recommendations *(If any of the above are missing, rate as poor)*	GOOD	FAIR	POOR
1.2	**RIGOR OF DEVELOPMENT: Recommendations** • Methods for developing recommendations clearly described • Strengths and limitations of evidence clearly described • Benefits/side effects/risks considered • External review	GOOD	FAIR	POOR
1.3	**EDITORIAL INDEPENDENCE**[15] • Views of funding body have not influenced the content of the guideline • Competing interests of members have been recorded and addressed	GOOD	FAIR	POOR
If any of three primary criteria are rated poor, the entire guideline should be rated poor.				
SECTION 2: SECONDARY CRITERIA				
2.1	**SCOPE AND PURPOSE** • Objectives described • Health question(s) specifically described • Population (patients, public, etc.) specified	GOOD	FAIR	POOR

[15] Editorial Independence is a critical domain. However, it is often very poorly reported in guidelines. The assessor should not rate the domain, but write "unable to assess" in the comment section. If the editorial independence is rated as "poor", indicating a high likelihood of bias, the entire guideline should be assessed as poor.

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SECTION 2: SECONDARY CRITERIA, Cont.		
2.2	**STAKEHOLDER INVOLVEMENT** • Relevant professional groups represented • Views and preferences of target population sought • Target users defined	GOOD FAIR POOR
2.3	**CLARITY AND PRESENTATION** • Recommendations specific, unambiguous • Management options clearly presented • Key recommendations identifiable • Application tools available • Updating procedure specified	GOOD FAIR POOR
2.4	**APPLICABILITY** • Provides advice and/or tools on how the recommendation(s) can be put into practice • Description of facilitators and barriers to its application • Potential resource implications considered • Monitoring/audit/review criteria presented	GOOD FAIR POOR
SECTION 3: OVERALL ASSESSMENT OF THE GUIDELINE		
3.1	How well done is this guideline?	GOOD FAIR POOR
3.2	Other reviewer comments:	

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Description of Ratings: Methodology Checklist for Guidelines

The checklist for rating guidelines is organized to emphasize the use of evidence in developing guidelines and the philosophy that "evidence is global, guidelines are local." This philosophy recognizes the unique situations (e.g., differences in resources, populations) that different organizations may face in developing guidelines for their constituents. The second area of emphasis is transparency. Guideline developers should be clear about how they arrived at a recommendation and to what extent there was potential for bias in their recommendations. For these reasons, rating descriptions are only provided for the primary criteria in section one. There may be variation in how individuals might apply the good, fair, and poor ratings in section two based on their needs, resources, organizations, etc.

Section 1. Primary Criteria (rigor of development and editorial independence) ratings:

Good: All items listed are present, well described, and well executed (e.g., key research references are included for each recommendation).
Fair: All items are present, but may not be well described or well executed.
Poor: One or more items are absent or are poorly conducted

Appendix D. List of External Reviewers

Invited: Accepted & Reviewed
TBD

Invited: Declined/Did Not Respond/Did Not Review
TBD

XX additional reviewers were invited but either declined, did not respond, missed the deadline or did not return the review. Areas of professional expertise for invited reviewers included:

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Appendix E. References

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Malmivaara A., Slatis P., Heliovaara M., et al. (2007). Finnish Lumbar Spinal Research Group. Surgical or nonoperative treatment for lumbar spinal stenosis? A randomized controlled trial. Spine. 32:1-8.

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State of Oregon Evidence-based Clinical Guidelines Project

Percutaneous Interventions for Low Back Pain

A clinical practice guideline based on the 2009 American Pain Society Guideline (Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain)

February 2012

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Oregon Health Authority

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This document was prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center) on behalf of the Guideline Development Group and the Office for Oregon Health Policy & Research. This document is intended to help providers, consumers and purchasers of health care in Oregon make informed decisions about health care services. The document is intended as a reference and is provided with the understanding that neither the Center nor the Guideline Development Group are engaged in rendering any clinical, legal, business or other professional advice.

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

The statements in this document do not represent official policy positions of the Center, the Guideline Development Group, or the Office for Oregon Health Policy and Research. Researchers and authors involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

Objective

This guideline was developed by a collaborative group of public and private partners to provide up-to-date evidence-based guidance on the role of percutaneous interventions in low back pain. The aim of the guideline is to identify evidence-based, appropriate indications for the use of percutaneous interventions in patients with low back pain of any duration, with and without leg pain. This guideline can then be used to create practice standards and coverage guidelines for use across public and private payors. It does not address patients with back pain associated with major trauma, tumor, metabolic disease, inflammatory back disease, fracture, dislocation, major instability or deformity, progressive or severe neurologic deficits, or back pain in children, adolescents or pregnant women. Percutaneous interventions addressed in this guideline include intradiscal, facet joint, sacroiliac joint and epidural steroid injections, prolotherapy, botulinum toxin injections, local injections, medial branch block, radiofrequency denervation, intradiscal electrothermal therapy, percutaneous intradiscal radiofrequency thermocoagulation and coblation nucleoplasty.

Additional evidence concerning other elements of evaluation as well as recommendations for management of low back pain can be found in the State of Oregon Evidence-based Clinical Guidelines:

- Evaluation and Management of Low Back Pain[1]
- Advanced Imaging for Low Back Pain[2]

Background

In June 2009, the Oregon legislature passed health reform legislation HB 2009, which created the Oregon Health Policy Board and charged it with creating a comprehensive health reform plan for our state. In December 2010, the Board released *Oregon's Action Plan for Health*, which lays out "strategies that reflect the urgency of the health care crisis and a timeline for actions that will lead Oregon to a more affordable, world-class health care system." They outlined eight foundational strategies, one of which is to "set standards for safe and effective care." To accomplish this, the plan directs the state to "Identify and develop 10 sets of Oregon-based best practice guidelines and standards that can be uniformly applied across public and private health care to drive down costs and reduce unnecessary care." This work is being conducted by the Oregon Health Services Commission and the Oregon Health Resources Commission in close collaboration with providers, the Center for Evidence-Based Policy, and other key stakeholders. [3]

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[1] Livingston, C., King, V., Little, A., Pettinari, C., Thielke, A., & Gordon, C. (2011). *State of Oregon Evidence-based Clinical Guidelines Project. Evaluation and management of low back pain: A clinical practice guideline based on the joint practice guideline of the American College of Physicians and the American Pain Society (Diagnosis and treatment of low back pain).* Salem: Office for Oregon Health Policy and Research.

[2] Livingston, C., Little, A., King, V., Pettinari, C., Thielke, A., Vandegriff, S., & Gordon, C. (2012). *State of Oregon Evidence-based Clinical Guidelines Project. Advanced imaging for low back pain: A clinical practice guideline based on the joint practice guideline of the American College of Physicians and the American Pain Society (Diagnosis and treatment of low back pain).* Salem: Office of Oregon Health Policy & Research.

[3] Effective January 1, 2012, House Bill 2100 (2011) terminates the Health Services Commission and Health Resources Commission and transfers their duties related to evidence-based guideline development to a new Health Evidence Review Commission.

Development of this guideline:
This guideline was developed by a Guideline Development Group (GDG) consisting of representatives from the State of Oregon Health Authority, the Oregon Healthcare Leadership Council, and the Oregon Corporation for Healthcare Quality with support from clinical evidence specialists from the Center for Evidence-based Policy. The Center provided expertise in the process of guideline development and undertook analysis and appraisal to support the development of this guideline.

Methods:
The GDG developed this guideline using the ADAPTÉ[4] framework which is a systematic approach to the endorsement or modification of guideline(s) produced in one cultural context or organizational setting for application in another context. Guideline adaptation is used as an alternative to wholly new guideline development, which can be time consuming, expensive and an inefficient use of resources, when existing quality guidelines are available.

The process for developing this guideline began by searching 17 different databases and other sources for guidelines related to percutaneous interventions for chronic back pain (see appendix A). Candidate guidelines were required to satisfy the following requirements:

- to be evidence-based, that is, guideline recommendations are based on systematic reviews of the literature,
- to address the use of percutaneous interventions in adults with chronic back pain,
- to be published in English and,
- to be freely available to the public.

The GDG required that evidence-based recommendations be made on the basis of both the quality and strength of the underlying evidence from any included guideline's systematic reviews. The initial search identified 10 candidate guidelines which met the above stated criteria (Appendix B). Of the original candidate guidelines, three had been rated as poor quality during the development of a previous guideline and one was excluded because it was not publically available. The six remaining guidelines were then assessed for methodologic quality using a modified AGREE (Appraisal of Guidelines Research and Evaluation) II[5] instrument (Appendix C) by two different guideline quality assessors from the Center for Evidence-based Policy. Two of those guidelines were rated good quality, and one was rated fair with good rigor of development of the evidence and recommendations according to the modified AGREE rating tool. These three guidelines were then examined further for scope and clarity of presentation.

Comparison of the APS guideline was made to the other high quality, comprehensive guidelines, which were produced by the National Institute for Health and Clinical Excellence (NICE), and Towards Optimized Practice, Alberta Clinical Guidelines Program. Of the guidelines considered for review, the GDG felt that the APS guideline was the most comprehensive.

After considering guideline scope and specific modalities addressed, the GDG selected the American Pain Society's 2009 guideline "Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: An evidence-based clinical practice guideline from the American Pain Society" as the base guideline, primarily because it had recommendations concerning a broader range of interventions than guidelines from the National Institute for Health and Clinical Evidence (NICE) or from Towards

[4] http://www.adapte.org/www/
[5] http://www.agreecollaboration.org/

Optimized Practice (TOP). (See Appendix E for procedures addressed in the APS guideline.) The APS guideline in its entirety can be found at the following link: http://journals.lww.com/spinejournal/Abstract/2009/05010/Interventional_Therapies,_Surgery,_and.14.aspx. The APS guideline is accompanied by a full systematic review on nonsurgical interventional therapies for low back pain in the same journal issue at: http://www.ampainsoc.org/library/pdf/LBPEvidRev.pdf.

The APS guideline panel arrived at treatment recommendations by first evaluating the evidence for treatments according to a system adapted from the US Preventive Services Task Force for grading the evidence, then estimating the magnitude of effects, including whether the benefits of the treatment outweigh the harms. (See Appendix D for the APS criteria for arriving at recommendations.)

Updating:
The APS guideline was published in 2009. The authors of the guideline were contacted in March 2011 and stated that there had been no new published evidence which would change the recommendations of the guideline and that it was considered current. The GDG recommends that this guideline be reevaluated if the APS issues an updated guideline and at least every two years for currency if the original guideline is not updated.

Recommendations

Below are the recommendations of the APS clinical practice guideline followed by discussion of each recommendation.

Table A. State of Oregon Evidence-based Clinical Guideline Recommendations for Percutaneous Injections of the Spine

Condition	Intervention	Net Benefit	Recommendation	Strength of Recommendation and Quality of Evidence Rating*
Non-radicular Low Back Pain				
Non-specific Low Back Pain	• Prolotherapy	No net benefit	In patients with persistent nonradicular low back pain, **clinicians should not** provide prolotherapy.	Recommendation: Strong Grade: High-quality evidence
	• Local injections • Botulinum toxin injection • Epidural steroid injection • Therapeutic medial branch block • Radiofrequency denervation • Sacroiliac joint steroid injection • Coblation nucleoplasty	Unknown	In patients with persistent nonradicular low back pain, there is insufficient evidence to adequately evaluate the benefits of local injections, botulinum toxic injection, epidural steroid injection, therapeutic medial branch block, radiofrequency denervation, sacroiliac joint steroid injection, or coblation nucleoplasty.	Insufficient evidence to determine net benefits or harms

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Condition	Intervention	Net Benefit	Recommendation	Strength of Recommendation and Quality of Evidence Rating*
Presumed discogenic pain	• Intradiscal steroid injection	No net benefit	In patients with presumed discogenic pain, **clinicians should not** provide intradiscal steroid injection.	Recommendation: Strong Grade: High quality-evidence
	• Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) • Intradiscal electrothermal therapy (IDET)	Unknown	In patients with presumed discogenic pain, there is insufficient evidence to adequately evaluate the benefits of PIRFT or IDET	Insufficient evidence to determine net benefits or harms
Presumed facet joint pain	• Facet joint steroid injection	No net benefit	In patients with presumed facet joint pain, **clinicians should not** provide facet joint steroid injection.	Recommendation: Strong Grade: Moderate-quality evidence
	• Radiofrequency denervation	Unknown	In patients with presumed facet joint pain, there is insufficient evidence to adequately evaluate the benefits of radiofrequency denervation.	Insufficient evidence to determine net benefits or harms
Presumed sacroiliac joint pain	• Sacroiliac joint steroid injection	Unknown	In patients with presumed sacroiliac joint pain, there is insufficient evidence to adequately evaluate the benefits of sacroiliac joint steroid injection.	Insufficient evidence to determine net benefits or harms
Radiculopathy or Spinal Stenosis				
Radiculopathy with prolapsed lumbar disc	• Epidural steroid injection	**Moderate benefit (short-term)**	In patients with persistent radiculopathy due to herniated lumbar disc, **clinicians should** discuss the risks and benefits of epidural steroid injections as an option. It is recommended that Shared decision-making regarding epidural steroid injection includes a specific discussion about inconsistent evidence showing moderate short-term benefits and lack of long-term benefits.	Recommendation: Weak Grade: Moderate-quality evidence

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Condition	Intervention	Net Benefit	Recommendation	Strength of Recommendation and Quality of Evidence Rating*
Radiculopathy with prolapsed lumbar disc, cont.	• Coblation nucleoplasty	Unknown	In patients with radiculopathy with prolapsed lumbar disc, there is insufficient evidence to adequately evaluate the benefits.	Insufficient evidence to determine net benefits or harms
Radiculopathy	• Radiofrequency denervation	Unknown	In patients with radiculopathy, there is insufficient evidence to adequately evaluate the benefits.	Insufficient evidence to determine net benefits or harms
Symptomatic Spinal Stenosis	• Epidural steroid injection	Unknown	In patients with spinal stenosis, there is insufficient evidence to adequately evaluate the benefits.	Insufficient evidence to determine net benefits or harms

***See Appendix D for complete description of APS and ACP evidence grading methods. Chou, et al. (2009) utilize the US Prevent Services Task Force criteria for rating the strength of recommendation and quality of evidence. Recommendations in this table are modified to fit GRADE terminology for consistency among State of Oregon guidelines.**

Recommendation #1[6] :

Epidural Steroid Injection for persistent radiculopathy due to herniated lumbar disc

> *In patients with persistent radiculopathy due to herniated lumbar disc, it is recommended that clinicians discuss risks and benefits of epidural steroid injection as an option (weak recommendation, moderate-quality evidence). It is recommended that shared decision-making regarding epidural steroid injection include a specific discussion about inconsistent evidence showing moderate short-term benefits, and lack of long-term benefits. There is insufficient evidence to adequately evaluate benefits and harms of epidural steroid injection for spinal stenosis.*

For radiculopathy due to herniated lumbar disc, evidence on benefits of epidural steroid injection is mixed. Although some higher-quality trials (Arden 2005; Bush 1991; Dilke 1973; Wilson-MacDonald 2005) found epidural steroid injection associated with moderate short-term (through up to 6 weeks) benefits in pain or function, others (Carette 1997; Karppinen 2001; Ng 2005) found no differences *versus* placebo injection. Reasons for the discrepancies between trials is uncertain, but could be related to the type of comparator treatment, as trials (Beliveau 1971; Breivik 1976; Bush 1991; Carette 1997; Cuckler 1985; Karppinen 2001; Klenerman 1984; Ng 2005; Rogers 1992; Snoek 1977; Zahaar 1991) that compared an epidural steroid injection to an epidural saline or local anesthetic injection tended to report poorer results than trials (Arden 2005; Dilke 1973; Helliwell 1985; Mathews 1987; Ridley 1988; Wilson-MacDonald 2005) that compared an epidural steroid injection to a soft-tissue (usually

[6] Extracted and modified from Chou, et. al. (2009)

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interspinous ligament) placebo injection. Regardless of the comparator intervention, there is no convincing evidence that epidural steroids are associated with long-term benefits and most trials (Arden 2005; Carette 1997; Riew 2000; Wilson-MacDonald 2005) found no reduction in rates of subsequent surgery. Although serious complications following epidural steroid injection are rare in clinical trials, (Arden 2005; Karppinen 2001; Kolsi 2000; Kraemer 1997; Ng 2005) there are case reports of paralysis and infections. (Glaser 2005; Hooten 2006; Huntoon 2004) There is insufficient evidence on clinical outcomes to recommend a specific approach for performing epidural steroid injection (Ackerman 2007; Kolsi 2000; Kraemer 1997; McGregor 2001; Thomas 2003) or on use of fluoroscopic guidance. In addition, insufficient evidence exists to recommend how many epidural injections to perform, though 1 higher-quality trial found that if an initial epidural steroid injection did not result in benefits, additional injections over a 6-week period did not improve outcomes (Arden 2005).

Epidural steroid injection for the treatment of radiculopathy with prolapsed lumbar disc is the only percutaneous intervention found to have a net benefit, and the benefit appears to be short-term.

Decisions regarding use of epidural steroid injection should be based on a shared decision-making process that includes a discussion of the inconsistent evidence for short-term benefit, lack of long-term benefit, potential risks, and costs. Patient preferences and individual factors should also be considered. For example, epidural steroid injection may be a reasonable option for short-term pain relief in patients who are less optimal surgery candidates due to comorbidities. There is insufficient evidence to guide specific recommendations for timing of epidural steroid injection, though most trials enrolled patients with at least subacute (greater than 4 weeks) symptoms.

Evidence on efficacy of epidural steroid injection for spinal stenosis is sparse and shows no clear benefit, though more trials are needed to clarify effects (Cuckler 1985; Fukusaki 1998; Zahaar 1991). Although chymopapain chemonucleolysis (see glossary, Supplemental Digital Content 1, http://links.lww.com/A840) is effective for radiculopathy due to herniated lumbar disc, (Gibson 2007a, 2007b) it is less effective than discectomy (see glossary, Supplemental Digital Content 1, http://links.lww.com/A840) and is no longer widely available in the United States, in part due to risk of severe allergic reactions.

Recommendation #2[7]:
Facet Joint Injection, Prolotherapy, Intradiscal Corticosteroid Injection

> *In patients with persistent nonradicular low back pain, facet joint corticosteroid injection, prolotherapy, and intradiscal corticosteroid injection* **are not recommended** *(strong recommendation, moderate-quality evidence).*

Injections and most interventional therapies for nonradicular low back pain target specific areas of the back that are potential sources of pain, including the muscles and soft tissues (botulinum toxin injection, prolotherapy, and local injections [see glossary, Supplemental Digital Content 1, http://links.lww.com/A840]), facet joints (facet joint steroid injection, therapeutic medial branch block, and radiofrequency denervation [see glossary, Supplemental Digital Content 1, http://links.lww.com/A840]), degenerated

[7] Extracted and modified from Chou, et. al. (2009)

intervertebral discs (intradiscal steroid injection, IDET, [see glossary, Supplemental Digital Content 1, http://links.lww.com/A840] and related procedures), and sacroiliac joints (sacroiliac joint injection)

There is no convincing evidence from randomized trials that injections and other interventional therapies are effective for nonradicular low back pain. Facet joint steroid injection (Carette 1991; Lilius 1989) prolotherapy (Dagenais 2007) and intradiscal steroid injections (Khot 2004; Simmons 1992) are not recommended because randomized trials consistently found them to be no more effective than sham therapies.

Five randomized, placebo-controlled trials evaluated prolotherapy (Gibson 2007a; Huntoon 2004; Klenerman 1984; Malmivaara 2007; Weber 1983). All were included in a higher quality Cochrane review (Willems 2004). Four trials were rated higher quality (Huntoon 2004; Klenerman 1984; Malmivaara 2007; Weber 1983). For chronic nonspecific low back pain, 3 trials (2 higher quality: Klenerman 1984, Malmivaara 2007) found no difference between prolotherapy and either saline or local anesthetic control injections for short-or long-term (up to 24 months) pain or disability (Malmivaara 2007).

Recommendation #3[8] :
Other Interventional Procedures

> *There is insufficient evidence to adequately evaluate benefits of local injections, botulinum toxin injection, epidural steroid injection, intradiscal electrothermal therapy (IDET), therapeutic medial branch block, radiofrequency denervation, sacroiliac joint steroid injection, coblation nucleoplasty, percutaneous intradiscal radiofrequency thermocoagulation …. or other medications for nonradicular low back pain.*

For local injections, there is insufficient evidence to accurately judge benefits because available trials are small, lower-quality, and evaluate heterogeneous populations and interventions (Collee 1991; Garvey 1989; Hameroff 1981; Sonne 1985). Trials of IDET (Freeman 2005; Pauza 2004) and radiofrequency denervation (Leclaire 2001; Nath 2008; van Kleef 1999; van Wijk 2005) reported inconsistent results. There were a small number of higher quality trials, and in the case of radiofrequency denervation, the trials had technical or methodologic shortcomings (Hooten 2005), making it difficult to reach conclusions about benefits**.** For other interventional therapies, data are limited to 1-2 small placebo-controlled randomized trials (botulinum toxin injection (Foster 2001), epidural steroid injection for nonradicular low back pain (Serrao 1992), PIRFT (Barendse 2001, Ercelen 2003) and sacroiliac joint steroid injection [see glossary, Supplemental Digital Content 1, http://links.lww.com/A840] (Luukkainen 2002), or there are no placebo-controlled randomized trials (therapeutic medial branch block, coblation nucleoplasty….or other medications).

[8] Extracted and modified from Chou, et. al. (2009)

Appendix A. Sources Searched for Low Back Pain Guidelines

1. British Medical Journal – Clinical Evidence
2. Cochrane Library
3. Agency for Healthcare Research and Quality
4. ECRI
5. Hayes, Inc
6. Veterans Administration – Technology Assessment Program (VA TAP)
7. Blue Cross Blue Shield HTA
8. Centers for Medicare and Medicaid
9. CADTH
10. Washington HTA Program
11. US Preventive Services Task Force
12. ICSI
13. Guidelines.gov
14. American College of Physicians AND American Pain Society
15. American Physical Therapy Association
16. PEDro.org.au (evidence-based physiotherapy database)
17. GIN Guidelines Database

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Appendix B. Low Back Pain Guidelines Identified

Methods Summary:
Initially, 17 databases and other sources for guidelines related to percutaneous Interventions for low back pain were searched. Candidate guidelines were required to:

- be evidence-based (recommendations based on a full systematic review)
- be comprehensive
- be published in English
- be freely available to the public

Ten candidate guidelines were identified, of which six were sufficiently comprehensive and were assessed by two clinical epidemiologists for methodologic quality using a modified AGREE (Appraisal of Guidelines Research and Evaluation) II[9] instrument.
Candidate guidelines were then assessed considering:

- age
- source
- specific treatment elements addressed
- presentation

The GDG selected the guideline of highest quality and that was most comprehensive. (See guideline text for comprehensive Methods discussion)

Low Back Pain Guidelines Identified in Search – Selected for Quality Assessment

Armon, C., Argoff, C.E., Samuels, J., Backonja, M.M. (2007). Assessment: Use of epidural steroid injections to treat radicular lumbosacral pain: Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology 68:723-729.
Overall guideline quality rating: Fair

Chou, R., Loesser, J.D., Owens, D.K., Rosenquist, R.W., Atlas, S.J., Baisden, J., Carragee, E.J., Grabois, M., Murphy, D.R., Resnick, D.K., Stanos, S.P., Shaffer, W.O., Wall E.M. (2009) Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: An evidence-based clinical practice guideline from the American Pain Society. Spine 34:10:1066-1077. – accompanied by:
Chou, R., Atlas, S.J., Stanos, S.P., Rosenquist, R.W. (2009). A review of the evidence for an American Pain Society clinical practice guideline. Spine 34:10:1078-1094.
Overall guideline quality rating: Fair with good rigor of development of evidence and recommendations

Manchikanti, L ., Boswell, M.V., Singh, V., Benyamin, R.M., Fellows, B., Abdi, S., Buenaventura, R.M., Conn, A., Datta, S., Derby, R., Falco, F.J.E., Erhart, S., Diwan, S., Hayek, S.M., Helm II, S., Parr, A.T., Schultz, D.M., Smith, H.S., Wolfer, L. R., Hirsch, J.A. (2009). Comprehensive evidence-based guidelines for interventional techniques in the management of chronic spinal pain. Pain Physician 12:699-802.
Overall guideline quality rating: Poor

National Health and Medical Research Council. Australian Acute Musculoskeletal Pain Guidelines Group. (2003). Evidence-based management of acute musculoskeletal pain. (Website states that status is "current"). [Chapter 4 of document is on Acute Low Back Pain.]
http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses /cp94.pdf
Overall guideline quality rating: Fair

[9] http://www.agreecollaboration.org/

National Institute for Health and Clinical Excellence (NICE). (2009). Low back pain: Early management of persistent non-specific low back pain. London, UK: National Institute for Health and Clinical Excellence. Retrieved September 30, 2010, from http://www.nice.org.uk/nicemedia/live/11887/44343/44343.pdf
Overall guideline quality rating: Good

Towards Optimized Practice. (2009). Management of low back pain. Edmonton, AB: Towards Optimized Practice Program.
Overall guideline quality rating: Good

Low Back Pain Guidelines Identified in Search– Not Selected for Quality Assessment

American College of Occupational and Environmental Medicine (ACOEM). (2007). Low back disorders. Occupational medicine practice guidelines: Evaluation and management of common health problems and functional recovery in workers. 2nd ed. Elk Grove Village, IL: ACOEM.
Overall guideline quality rating: Fair

Institute for Clinical Systems Improvement (ICSI). (2010). Adult low back pain. Fourteenth edition. Bloomington, MN: ICSI.
Overall guideline quality rating: Poor

Michigan Quality Improvement Consortium. (2008). Management of acute low back pain. Southfield, MI: Michigan Quality Improvement Consortium.
Overall guideline quality rating: Poor

University of Michigan Health System. (2010). Acute low back pain. Ann Arbor, MI: University of Michigan Health System.
Overall guideline quality rating: Poor

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Appendix C: Methodology Checklist Adapted from the AGREE II materials

Methodology Checklist: Guidelines				
Guideline citation *(Include name of organization, title, year of publication, journal title, pages)*				
Guideline Topic:				
Checklist completed by:			Date:	
SECTION 1: PRIMARY CRITERIA				
To what extent is there		***Assessment/Comments:***		
1.1	**RIGOR OF DEVELOPMENT: Evidence** • Systematic literature search • Study selection criteria clearly described • Quality of individual studies and overall strength of the evidence assessed • Explicit link between evidence & recommendations *(If any of the above are missing, rate as poor)*	GOOD	FAIR	POOR
1.2	**RIGOR OF DEVELOPMENT: Recommendations** • Methods for developing recommendations clearly described • Strengths and limitations of evidence clearly described • Benefits/side effects/risks considered • External review	GOOD	FAIR	POOR
1.3	**EDITORIAL INDEPENDENCE**[10] • Views of funding body have not influenced the content of the guideline • Competing interests of members have been recorded and addressed	GOOD	FAIR	POOR
If any of three primary criteria are rated poor, the entire guideline should be rated poor.				
SECTION 2: SECONDARY CRITERIA				
2.1	**SCOPE AND PURPOSE** • Objectives described • Health question(s) specifically described • Population (patients, public, etc.) specified	GOOD	FAIR	POOR

[10] Editorial Independence is a critical domain. However, it is often very poorly reported in guidelines. The assessor should not rate the domain, but write "unable to assess" in the comment section. If the editorial independence is rated as "poor", indicating a high likelihood of bias, the entire guideline should be assessed as poor.

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SECTION 2: SECONDARY CRITERIA, Cont.		
2.2	**STAKEHOLDER INVOLVEMENT** • Relevant professional groups represented • Views and preferences of target population sought • Target users defined	GOOD FAIR POOR
2.3	**CLARITY AND PRESENTATION** • Recommendations specific, unambiguous • Management options clearly presented • Key recommendations identifiable • Application tools available • Updating procedure specified	GOOD FAIR POOR
2.4	**APPLICABILITY** • Provides advice and/or tools on how the recommendation(s) can be put into practice • Description of facilitators and barriers to its application • Potential resource implications considered • Monitoring/audit/review criteria presented	GOOD FAIR POOR
SECTION 3: OVERALL ASSESSMENT OF THE GUIDELINE		
3.1	How well done is this guideline?	GOOD FAIR POOR
3.2	Other reviewer comments:	

Description of Ratings: Methodology Checklist for Guidelines
The checklist for rating guidelines is organized to emphasize the use of evidence in developing guidelines and the philosophy that "evidence is global, guidelines are local." This philosophy recognizes the unique situations (e.g., differences in resources, populations) that different organizations may face in developing guidelines for their constituents. The second area of emphasis is transparency. Guideline developers should be clear about how they arrived at a recommendation and to what extent there was potential for bias in their recommendations. For these reasons, rating descriptions are only provided for the primary criteria in section one. There may be variation in how individuals might apply the good, fair, and poor ratings in section two based on their needs, resources, organizations, etc.

Section 1. Primary Criteria (rigor of development and editorial independence) ratings:

Good: All items listed are present, well described, and well executed (e.g., key research references are included for each recommendation).
Fair: All items are present, but may not be well described or well executed.
Poor: One or more items are absent or are poorly conducted

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Appendix D. APS Guideline Criteria for Treatment Recommendations

The APS guideline panel arrived at treatment recommendations by first evaluating the evidence for treatments according to a system adapted from the US Preventive Services Task Force for grading the evidence, then estimating the magnitude of effects, including whether the benefits of the treatment outweigh the harms.

The underlying strength of the evidence for each intervention was given a rating of good, fair or poor based on factors such as the quality, quantity, consistency, and generalizability of the evidence (Table 1).

Table 1. APS Criteria for Grading the Strength of Evidence

Rating	Strength
Good	Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes (at least 2 consistent, higher-quality trials)
Fair	Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, size, or consistency of included studies; generalizability to routine practice; or indirect nature of the evidence on health outcomes (at least 1 higher-quality trial of sufficient sample size; 2 or more higher-quality trials with some inconsistency; at least 2 consistent, lower-quality trials, or multiple consistent observational studies with no significant methodologic flaws
Poor	Evidence is insufficient to assess effects on health outcomes because of limited number or power of studies, large and unexplained inconsistency between higher-quality trials, important flaws in trial design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

Depending on the strength of the evidence for an intervention, the APS used the following criteria for making a recommendation.

Table 2. APS Criteria for making treatment recommendations

Grade	Criteria for making a recommendation
A	The panel strongly recommends that clinicians consider offering the intervention to eligible patients. The panel found good evidence that the intervention improves health outcomes and concludes that benefits substantially outweigh harms.
B	The panel recommends that clinicians consider offering the intervention to eligible patients. The panel found at least fair evidence that the intervention improves health outcomes and concludes that benefits moderately outweigh harms, or that benefits are small but there are no significant harms, costs, or burdens associated with the intervention.
C	The panel makes no recommendation for or against the intervention. The panel found at least fair evidence that the intervention can improve health outcomes, but concludes that benefits only slightly outweigh harms, or the balance of benefits and harms is too close to justify a general recommendation.
D	The panel recommends against offering the intervention. The panel found at least fair evidence that the intervention is ineffective or that harms outweighs benefits.
I	The panel found insufficient evidence to recommend for or against the intervention. Evidence that the intervention is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

If a recommendation was made, the APS assigned an overall grade of its strength, adapting the grading system of the international Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) working group. Strong recommendations are required to have clear evidence of benefit or harm. Weak recommendations are based on finely balanced benefits, risks and burdens.

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Table 3. ACP Clinical Practice Guidelines Grading System[11]

Quality of Evidence	Strength of Recommendation	
	Benefits Do or Do Not Clearly Outweigh Risks	**Benefits and Risks and Burdens Are Finely Balanced**
High	Strong	Weak
Moderate	Strong	Weak
Low	Strong	Weak
Insufficient evidence to determine net benefits or harms		

The ACP/APS guideline panel considered interventions to have "proven" benefit if there was at least fair quality evidence of moderate or substantial benefit (or of small benefit with no significant harms, costs or burdens).

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[11] Adapted from the system developed by the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) workshop by the American College of Physicians.

Appendix E. Treatments addressed in APS guidelines*

Treatment	Definitions Procedures are defined according to APS http://links.lww.com/A840
Prolotherapy (sclerotheraphy) Injections	A procedure involving the repeated injection of an irritant chemical into the soft tissues of the back in order to provoke an inflammatory response that will theoretically subsequently lead to strengthening of the soft tissues with decrease in pain and disability. Also referred to as sclerotherapy
Facet joint corticosteroid injections	Injection of corticosteroid into the facet joints.
Therapeutic medial branch block	Injection of local anesthetic with or without corticosteroid in the area of the medial branch of the posterior primary ramus, the primary nerve innervating the intervertebral facet joint. Usually used as a diagnostic procedure to identify facet joint pain, but has also been used as a therapeutic procedure
Intradiscal corticosteroid injections	Injection of corticosteroid into the intervertebral disc.
Radiofrequency denervation	A procedure involving the destruction of nerves using heat generated by a radiofrequency current.
Intradiscal electrothermal therapy (IDET)	A procedure involving the placement of an electrode or catheter into the intervertebral disc annulus or nucleus and applying electrothermal energy to alter adjacent pain receptors or other structures.
Epidural steroid injection	Injection of corticosteroids via a catheter into the space between the dura and the spine. Common approaches for administering epidural steroid injections are through the interlaminar space, via the neuroforamen under fluoroscopic guidance (transforaminal), and through the sacral hiatus at the sacral canal (caudal).
Local injections	Injection of local anesthetic (with or without corticosteroid) into the muscles or soft tissues of the back. Trigger point injections, a type of local injection, involve an injection performed at a tender area, often with a palpable nodule or band.
Sacroiliac joint steroid Injection	Injection of corticosteroid into or around the sacroiliac joint.
Botulinium toxin injection	Injection of botulinum toxin (an antispasmodic) into the muscles of the back.
Chemonucleolysis	Treatment of herniated discs with intradiscal injections of a proteolysis enzyme, most commonly chymopapain (an extract from papaya). Chymopapain acts by digesting the jelly-like inner portion of the disc known as the nucleus pulposus, while at the same time, leaving the outer portion, the annulus fibrosis, essentially intact.
Adhesiolysis and forceful epidural injection	(not defined)
Coblation® nucleoplasty	A procedure involving the use of a bipolar radiofrequency current in order to create a series of channels in an intervertebral disc and reduce the volume of tissue.
Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)	A procedure involving the placement of an electrode of catheter into the intervertebral disc and applying alternating radiofrequency current. Sometimes classified as a variant of intradiscal electrothermal therapy (IDET).

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Appendix F. List of Peer Reviewers

Invited: Accepted & Reviewed
TBD

Invited: Declined/Did Not Respond/Did Not Review
TBD

XX additional reviewers were invited but either declined, did not respond, missed the deadline or did not return the review. Areas of professional expertise for invited reviewers included:

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State of Oregon Spinal Fusion Guideline

Spinal Fusion Candidate Guidelines	APS (2009)	NICE (2009)	NICE: Lateral interbody fusion (2009)	NICE: transaxial lumbrosacral interbody fusion (2011)
Type of Guideline	Evidence and Opinion	Evidence and Opinion	Evidence and Opinion	Evidence and Opinion
Topic	Specific (Surgery for LBP)	General (Low Back Pain)	Specific	Specific
Target User	Clinicians caring for patients with low back pain of any duration	Patients and clinicians	Patients and clinicians	Patients and clinicians
Population	Nonpregnant adults >18 with low back pain of any duration.	Adults >18 with nonspecific low back pain.	Patients with back pain	Patients with refractory degenerative low back pain
Disease	Nonradicular low back pain with common degenerative changes, radiculopathy with herniated lumbar disc, and symptomatic spinal stenosis	Nonspecific LBP 6 weeks- 12 months.	Back pain	Degenerative LBP (pseudoarthrosis, DDD or spondylolisthesis)
Exclusions	Acute major trauma, cancer, infection, cauda equina syndrome, osteoporosis or vertebral compression fracture. Surgery for isthmic spondylolistheseis is not reviewed in this report (but reviewed in larger APS LBP report) because this condition often affects adolescents and younger adults and is an uncommon reason for spine surgery in adults	Malignancy, infection, fracture, Anklyosising Spondylitis, radicular pain from nerve root compression, cauda equina. Isthmic spondylolisthesis not included.		

State of Oregon Spinal Fusion Guideline

Spinal Fusion Candidate Guidelines	APS (2009)	NICE (2009)	NICE: Lateral interbody fusion (2009)	NICE: transaxial lumbrosacral interbody fusion (2011)
Diseases from Trials	Chronic LBP w DDD at L4/L5 or L5/S1 without prior discetomy (1 trial), Chronic LBP w DDD at L4/L5 or L5/S1 forllowing discectomy (1 trial), Chronic LBP and considered a candidate for spinal fusion (1 trial), and Chronic LBP and DDD at L4/L5 or L5/S1	Same as APS		
Therapies	Instumented posterolateral fusion using pedical screws and iliac crest autograft (2 trials), Graf ligamentoplasty or Fusion with technique left to discretion of surgeon (1 trial), Noninstrumented posterolateral fusion using iliac crest autograft, instrumented posterolateral fusion using pedicle screws and iliac crest autograft, or instrumented circumferential fusion (1 trial)	Same as APS	Lateral interbody fusion	transaxial lumbrosacral interbody fusion
Comparators	physical therapy without intensive CBT component (1 trial), intensive therapy with CBT (3 trials)	physical therapy, intensive therapy, cognitive therapy	none	none

State of Oregon Spinal Fusion Guideline

Spinal Fusion Candidate Guidelines	APS (2009)	NICE (2009)	NICE: Lateral interbody fusion (2009)	NICE: transaxial lumbrosacral interbody fusion (2011)
Outcomes	Back specific function, generic health status, pain, work disability, or patient satisfaction	Oswestry disability index,pain, general function score, depression index, cost effectivness	Safety and efficacy	Safety (Evidence of Complications) and Efficacy (ODI, fusion on imaging)
Disease Timeframe				
Patient factors (ie smoking)				
Studies	4 high-quality trials of surgery vs nonsurgical therapy; 2 had >100 patients	4 high quality RCTs of surgery vs non-surgical therapy (same as in APS)	2 case series, 1 non-randomized controlled trial, and 1 case report (134 patients)	5 case series and 1 case report (156 patients)

Spinal Fusion Candidate Guidelines	APS (2009)	NICE (2009)	NICE: Lateral interbody fusion (2009)	NICE: transaxial lumbrosacral interbody fusion (2011)
Treatment Recommendations				
SOR, quality of evidence	Weak recommendation, moderate quality evidence	1+		
Spinal Fusion	Yes vs Standard Physical Therapy (1 trial) No vs Intensive Rehabilitation (CBT included) (3 trials). Net benefit is small to moderate. *Benefits of fusion vs nonsurgical therapt have only be deomonstated in a narrow group of patients with at least moderately severe pain or disability unresponsive to nonsurgical therapies for a least 1 year and without serious psychiatric or medical comorbidities or other RFs for poor surgical outcomes.*	Yes. Referral for spinal fusion should be reserved for small group who fail to respond to combined physical and psychological intervention. One econmomic evaluation conducted alongside a RCT of spinal fusion vs intesive rehab showed that the chance that surgery will be cost effecitive at 2 years is less than 20%.	Current evidence on the safety and efficacy of lateral interbody fusion in the lumbar spine is inadequate in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.	Current evidence on the efficacy of transaxial interbody lumbosacral fusion is inadequate in quantity but shows symptom relief in the short term in some patients. Evidence on safety shows that there is a risk of rectal perforation. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

Health Technology Clinical Committee

Findings and Coverage Decision
Date: 11/16/07
Topic: Lumbar Fusion – Updated 02/15/08

Number and Coverage Topic

2001101 – Lumbar Fusion

HTCC Coverage Determination

Lumbar fusion for patients with chronic low back pain and lumbar degenerative disc disease is a **covered benefit** only under the criteria identified in the reimbursement determination. This decision does not apply to patients with the following conditions:

- Radiculopathy
- Functional neurologic deficits (motor weakness or EMG findings of radiculopathy)
- Spondylolisthesis (>Grade 1)
- Isthmic spondylolysis
- Primary neurogenic claudication associated with stenosis
- Fracture, tumor, infection, inflammatory disease
- Degenerative disease associated with significant deformity

HTCC Reimbursement Determination

- **Limitations of Coverage**
  - Covered under certain conditions: when there is a failure or inability to access a structured, intensive, multi-disciplinary program.
- **Non-Covered Indicators**
  - Not applicable.

Agency	Contact Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plans	1-866-214-3724
Health and Recovery Services Administration	1-800-562-3022

***Due to time constraints, the committee did not discuss or make a coverage determination on discography. This technology, as it relates to diagnosing patients with chronic low back pain appropriate for lumbar fusion, will be reviewed at the next HTCC meeting conducted. Until that time, current agency policy remains in place.**

Health Technology Background

Low back pain is the most common cause of disability and loss of productivity in patients under age 45. Disabling, chronic low back pain impacts 1.2 million patients in the United States.

Spinal fusion is one treatment alternative that is used to reduce back pain by permanently immobilizing the spinal column vertebrae surrounding the disc(s) that is (are) thought to cause discogenic low back pain. Immobilizing the vertebrae is believed to reduce pain by limiting movement of degenerated discs. There are five surgical approaches that are used for spinal fusion in patients with discogenic low back pain that is attributed to degenerative disc disease. They are: posterolateral fusion, posterior lumbar interbody lumbar fusion, transforaminal lumbar interbody fusion, anterior lumbar interbody fusion, and circumferential fusion. The surgeries use various forms of instrumentation such as pedicle and facet screws, rods, and cages. The potential advantage of spinal fusion surgery is that surgery can more effectively immobilize disc movement, and thus reduce pain and disability caused by chronic back pain.

Harms caused by fusion surgery, regardless of surgical approach, include: the need for reoperation, infection, various device-related complications, neurologic complications, thrombosis, bleeding/vascular complications, and dural injury. These harms do not occur with non-surgical treatments. Non-surgical treatments for chronic low back pain include cognitive behavioral therapy, medications (NSAID, Acetaminophen, anti-depressant) and rehabilitation (including psychological care, exercise, education, interdisplinary rehabilitation, and spinal manipulation). The potential impact on the health system is unknown. Potential benefits include reduction in back pain and disability, thus reducing utilization and cost of therapies to treat pain. The potential burden includes the initial intensity of the surgical intervention on health care resources and patient, cost of surgery and pre and post operative care; costs and burden of complication caused by surgery; and long term maintenance for implanted devices.

Committee Findings

The HTCC reviewed and considered the evidence on lumbar fusion as a treatment for uncomplicated, chronic low back pain (discogenic), including the technology assessment report, cited studies, information provided by the Administrator, and public and agency comments.

Effectiveness: The committee found that there was sufficient scientific evidence to draw conclusions about effectiveness based on a total of four randomized controlled trials of moderate quality. Committee members separated the evaluation of effectiveness of lumbar fusion into a comparison with usual care and cognitive behavioral therapy with intensive rehabilitation. Three outcomes were important in this evaluation: pain relief, disability improvement, and return to work.

- A majority of the committee found that the scientific evidence confirms that, as compared with usual care/no additional treatment, lumbar fusion provides greater benefit in terms of pain relief and disability improvement. However, a majority were not confident in the evidence (e.g. while evidence is sufficient, further evidence could change results). A majority of the committee found that the evidence is inconclusive on whether lumbar fusion resulted in an equivalent or improved number of patients returning to work.

- A majority of the committee found that the scientific evidence confirms that, as compared with cognitive behavioral therapy and intensive rehabilitation, lumbar fusion provides an equivalent benefit in terms of pain relief and disability improvement. However, a majority were not confident in the evidence (e.g. while evidence is sufficient, further evidence could change results). A majority of the committee found that the evidence is inconclusive on whether lumbar fusion resulted in an equivalent or improved number of patients returning to work.

Safety: The committee members found that there was sufficient scientific evidence to make conclusions about the safety of spinal fusion. Committee members were confident that the scientific evidence confirmed that spinal fusion resulted in a small increase in mortality; and more morbidity related to surgical complications (including infection, device complication, neurological complications, thrombosis, bleeding, vascular complication, and dural injuries) than any non-surgical alternative treatment. Compelling considerations included the reported adverse events from the randomized trials and the high disability rate and complications rate reported by the Labor and Industries study.

Cost: The committee members found that there was no independent cost analysis, though data from agencies, a follow up of one of the cited studies, and the technology assessment report were available. The technology assessment report cited average billed cost for a commercial carrier for an inpatient spinal fusion surgery cost $62,982. The cost to state agencies for lumbar fusion (including the facility and professional fees) ranged from $21,000 to $37,200. This estimate does not include any pre-surgery care, post surgical complications or outliers. Committee members found that there was sufficient evidence to conclude that the short term costs associated with lumbar fusion are greater than alternatives, but that there was insufficient evidence regarding long term costs.

Benefit Evaluation: A majority of the committee members found that spinal fusion resulted in a net benefit when compared with usual care, and an equivalent benefit when compared with intensive therapy and cognitive behavioral therapy; and that use of the technology is likely to increase costs. Given the increased cost and additional harms caused by the surgery, the committee discussed conditions for coverage, focused on ensuring that spinal fusion is a last resort option. Compelling considerations included the chronic nature of the condition, alternatives that were not effective for all patients or provided no greater benefit, harms of spinal fusion also apply in other surgical interventions, the inability to determine which patients benefit, and the potential to reduce utilization to only those that have tried non-invasive alternatives first.

Committee Authority

Participating state agencies are required by law to comply with the decisions of the Washington State Health Technology Clinical Committee (HTCC), an independent committee of eleven health practitioners. RCW 70.14.090 The HTCC makes coverage determinations for selected health technologies. A health technology may include medical and surgical devices and procedures, medical equipment, and diagnostic tests. The HTCC will also decide under what specific clinical situations the health technology is covered. RCW 70.14.110 HTCC decisions are based on evidence that the committee finds most valid that demonstrates the technology's safety, efficacy and cost effectiveness. Evidence includes a report concerning the technology, provided by a company specializing in objective reviews of the scientific literature, information submitted by the agencies, and public comments. The HCA Administrator considers technologies for re-review within 18 months or if new evidence becomes available. RCW 70.14.100