



Health Technology Clinical Committee
Date: August 24, 2007
Time: 8:00 am – 4:30 pm
Location: Marriott Hotel – 3201 South 176th Street, Seattle, WA 98188
Teleconference Bridge: 360-923-2997 Access Code: 360-946-1464

HTCC MINUTES

Members Present: Brian Budenholzer; C. Craig Blackmore; Michael Myint; Carson Odegard; Daniel Abrahamson; Richard Phillips; Michelle Simon and Michael Souter

Telephonic: Louise Kaplan

Members Absent: Lydia Bartholomew

HTCC Formal Action

- ✓ **Call to Order:** Dr. Budenholzer, Chair, called the meeting to order at 8:05 a.m. Sufficient members were present to constitute a quorum.
- ✓ **May 18, 2007 Minutes:** Dr. Budenholzer referred members to the draft minutes and called for discussion or objection, and received none.
 - *Outcome:* The committee unanimously approved the May 18, 2007 minutes.
- ✓ **Pediatric Bariatric Surgery Coverage Determination:** The HTCC reviewed and considered the Bariatric Surgery in Pediatric Patients technology assessment report, information provided by the Administrator, agency comments, ECRI Institute's presentation; and invited public testimony. The committee considered all the evidence and has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.
 - *Outcome:* The committee unanimously voted that Pediatric Bariatric Surgery for patients under age 18 is not a covered benefit due to insufficient evidence to conclude that it is safe, efficacious, and cost-effective.
 - *Outcome:* The committee decided by a majority vote that Pediatric Bariatric Surgery for patients aged 18 - 20 years is a covered benefit only under certain criteria:
 - Bariatric surgical procedure of Laparoscopic adjustable gastric banding only
 - Patients must meet and abide by all other agency bariatric surgery program criteria (e.g. body mass index, presence of co-morbid condition(s), pre-surgical weight loss, specified centers or practitioners)

For presentation and discussion details, please see following pages

Final Official Version

HTCC MEETING TOPICS, PRESENTATION, AND DISCUSSION

Agenda Item: Welcome & Introductions

Brian Budenholzer, Committee Chair, and Leah Hole-Curry, HTA Program Director, opened the meeting with an overview of the agenda, meeting purpose and introductions.

- ✓ The Health Technology Clinical Committee (HTCC) met on August 24, 2007, to discuss the evidence of Pediatric Bariatric surgery; hear ECRI Institute's presentation and public comment; approve the May 18, 2007 public meeting minutes; and determine a coverage determination based on the evidence regarding if the technology is safe, efficacious and cost-effective.
 - *Outcome:* Informational meeting context

Agenda Item: HTA Program Update

Leah Hole-Curry, HTA Program Director, presented an HTA program update

- ✓ HTA Goal: Achieve better health by paying for technologies that work.
 - Maintain an open and transparent process; eliminate bias; promote consistency; and remain flexible by reviewing evidence regularly to ensure updated information is included.
 - The purpose of the committee is to make coverage determinations for the participating agencies (Health Care Authority; Department of Social and Health Services; and Labor and Industries) based on a health technology assessment presented by Spectrum Research, Inc. that reviews the scientific evidence of the relative safety, efficacy, and cost; information from any special advisory groups; and their professional knowledge and expertise.
 - Key focus questions: Is it safe? Is it effective? Does it provide value?
- ✓ Program Progress: Current technologies under review
 - 3 topics selected in January 2007
 - Upright MRI: Clinical committee decision of no coverage in May 2007. Agencies have implemented coverage change (July 2007).
 - Pediatric Bariatric Surgery: committee decisions pending today.
 - Lumbar Fusion and discography: Report due September, 2007; public meeting for discussion scheduled for November 16, 2007.
- ✓ Coverage Determination Process:
 - As defined in the WAC when making a coverage determination, committee members shall review and consider the health technology assessment. The committee may also consider other information it deems relevant, including other information provided by the administrator, reports and/or testimony from an advisory group, and submission or comments from the public.
 - HCA Administrator selects technology → Vendor produce Technology Assessment Report → Clinical committee makes coverage determination → Agencies implement decision (unless statutory conflict).

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- The committee shall give the greatest weight to the evidence determined, based on objective factors, to be the most valid and reliable, considering the nature and source of the evidence, the empirical characteristic of the studies or trials upon which the evidence is based, and the consistency of the outcome with comparable studies. The committee may also consider additional evidentiary valuation factors such as recency (date of information); relevance (the applicability of the information to the key questions presented or participating agency programs and clients); and bias (presence of conflict of interest or political considerations).
 - *Outcome:* Informational context

Agenda Item: Topic Selection and Introduction

Leah Hole-Curry, HTA Program Director, introduced the technology selection process and the Pediatric Bariatric surgery topic.

- ✓ **Technology Selection Process:** The Administrator, in consultation with participating agencies and the committee, shall select the health technologies to be reviewed by the committee under RCW 70.14.110. Up to six technologies may be selected for review in the first year, and up to eight may be selected in the second year. In making the selection, priority shall be given to any technology for which: (a) There are concerns about its safety, efficacy, or cost-effectiveness, especially relative to existing alternatives, or significant variations in its use; (b) Actual or expected state expenditures are high, due to demand for the technology, its cost, or both; and (c) There is adequate evidence available to conduct the complete review.
 - **Primary Criteria**
 - Patient harm or safety concerns
 - Concerns about therapeutic efficacy or diagnostic accuracy and appropriateness of outcomes for patients
 - Cost impact for state purchasing agencies
 - **Secondary Criteria**
 - Number of persons affected
 - Severity of condition
 - Policy related urgency / diffusion concern
 - Potential or observed variation in care
 - Special populations or ethical concerns
 - *Note:* Key questions for this technology posted on HTA website: <http://www.hta.hca.wa.gov/docs/bariatric.pdf>
- ✓ **Pediatric Bariatric surgery** is intended to resolve co-morbid conditions linked to obesity (e.g., hypertension, diabetes type II) through weight loss. Many different types of bariatric surgical procedures are performed, so “bariatric surgery” cannot be considered a single procedure. Some Bariatric surgeries are purely restrictive – they cause weight loss by limiting the amount of food that can be consumed in one meal. Others are malabsorptive – they cause weight loss by reducing the amount of food that is absorbed into the body. The two most common Bariatric surgical procedures are laparoscopic adjustable gastric banding (LAGB), which is a purely restrictive procedure, and Roux-en-Y gastric bypass (RYGB), which is both restrictive and malabsorptive. While the mechanism of action differs from procedure to procedure, all Bariatric

procedures are intended to induce weight loss, improve medical co-morbidities, enhance quality of life, and (ultimately) extend survival.

- ✓ Current alternatives to LABG and RYGB for pediatric patients include: dietary modification, increasing physical activity and exercise, behavioral modification, and pharmacotherapy. The potential advantage of pediatric bariatric surgery is that with weight loss, altered perception of body image, depression and social stigmatization as well as co-morbid conditions may decrease.
- ✓ The potential advantage of pediatric bariatric surgery is that surgically limiting caloric intake can more effectively result in clinically significant weight loss. Sustained and significant weight loss improves or eliminates co-morbid conditions, body image, depression, and social stigmatization. Current alternatives are not as effective at weight loss and comparisons with other treatments for the co-morbid conditions aren't available.
- ✓ Potential risks of bariatric surgery include: failure of surgery to produce weight loss, patient compliance with required post-operative instructions and diet, complications requiring re-operation, intolerable side-effects resulting in revision/conversion surgery. Common surgical complications (infection, shock, peri/post operative bleeding, and death); procedure specific complications (band slippage, stomach erosion, port/tubing problems, pouch dilation, stomal stenosis, staple line disruption, internal hernia, cholestyctomy, gastrointestinal obstructions) and other complications including malnutrition, dumping syndrome, ulcers.
- ✓ The potential impact on the health system is unknown. Potential benefits include a reduction or elimination of obesity related health care disease burden and future cost savings related to prevention or alleviation of co-morbidities. The potential burden includes the initial intensity of the intervention on health care resources and patient, cost of surgery and pre and post operative care; costs and burden of surgical complications; and long term maintenance for implanted devices.

➤ *Outcome:* Informational context for technology under consideration.

Agenda Item: New Technologies Selected

Leah Hole-Curry, HTA Program Director, reported on the technologies selected by the administrator.

- ✓ On August 23rd, HCA Administrator Steve Hill, selected a new round of technologies to undergo review. Six technologies were selected based on the process and criteria identified previously:
- ✓ New selected technologies will be published to the website on Monday August 27, 2007 for a 30 day comment period. Work plans will be drafted and an update with timelines will be given for each of the technologies.
 - Cardiac Stent (Off Label usage)
 - Artificial Discs
 - Arthroscopic Surgery of the Knee
 - Computed Tomographic Angiography (CTA for cardiac care)
 - Virtual Colonoscopy (CTC)
 - Intrathecal Pump (Chronic non-cancer pain management)

Agenda Item: Technology Assessment Presentation

Jonathan Treadwell, Ph.D., and Karen Schoelles, M.D., S.M, from ECRI Institute presented a summary of the technology assessment report.

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- ✓ Pediatric population is defined as patients aged 21 or younger, corresponding to the definition of the American Association of Pediatrics.
 - ✓ Recent years have seen substantial increases in the prevalence of morbid obesity in both the adult and pediatric populations. Between 1988 and 1994, 2.9% of adults in the United States were morbidly obese; this percentage rose to 4.9% (10.8 million people) between 1999 and 2002. The condition was more common among women (6.4%) than among men (3.3%).
 - ✓ Studies in pediatric populations have demonstrated the health risks of obesity in pediatric populations, and that obesity during adolescence is highly likely to persist into adulthood and create greater risks of adult health problems. Pediatric obesity may also be associated with reduced quality-of-life and social marginalization. Obese individuals are at increased risk of type 2 diabetes, hypertension, coronary artery disease, stroke, gallbladder disease (cholelithiasis), osteoarthritis, sleep apnea, respiratory problems, and many types of cancer (including endometrial, breast, prostate, and colon). These health risks contribute to obesity-related increases in all-cause mortality.
 - ✓ Medical intervention for obesity is intended to promote weight loss and thereby reduce co-morbid conditions associated with excess weight. Categories of treatment include diet, exercise, behavioral modifications, pharmacotherapy, and bariatric surgery.
 - ✓ The goal of bariatric surgery in pediatric patients with morbid obesity is to halt the progression of obesity into adulthood to improve or eliminate medical conditions associated with obesity, and to improve the quality of life. Use of bariatric surgery to treat morbid obesity has increased dramatically in recent years, from approximately 13,000 operations in 1998 to approximately 121,000 operations in 2004. Patients under age 18 comprise about 0.1 – 1% of patients reported to have received bariatric surgery for morbid obesity.
 - ✓ Included studies: based on systematic review of the literature, 153 abstracts were identified – 38 articles were retrieved, 14 of these articles were excluded because they did not meet the inclusion criteria. After these exclusions, 17 unique studies in 24 publications comprised the evidence base. Eight studies reported outcomes after laparoscopic adjustable gastric banding (LAGB), six after Roux-en-Y gastric bypass (RYGB), two after vertical banded gastroplasty (VBG), and one after banded bypass.
 - ✓ Assessment of Overall Strength of Evidence
 - Key Question #1: Strength of evidence was weak in concluding that LAGB and RYGB for morbidly obese patients aged 21 or less does lead to sustained and clinically significant weight loss compared to non-operative approaches. The evidence is insufficient to permit quantitative estimates of the precise amount of weight loss after any bariatric surgical procedure for pediatric patients.
 - Key Question #2: Strength of evidence was weak in concluding that LAGB and RYGB for morbidly obese patients aged 21 or less resolves co-morbid conditions linked to obesity (diabetes, hypertension) compared to non-operative approaches. The evidence is insufficient to permit quantitative estimates of the likelihood of co-morbidity resolution, quality of life, or survival after any bariatric surgical procedure for pediatric patients.
 - Key Question #3: The review of 8 LAGB studies found no reported in-hospital or postoperative death; the most frequently reported complication after LAGB was band slippage; re-operations were performed on 26 (7.92%) of the 328 LAGB patients to correct various complications. The review of 6 RYGB studies found one reported postoperative death for RYGB; no in-hospital death was reported; the most frequently reported

complication was related to protein-calorie malnutrition and micronutrient deficiency; and potentially life-threatening complications were reported in the RYGB studies. The evidence is insufficient to permit any conclusions on potential harms in specific age surgery on growth and development of pediatric patients.

- Key Question #4: Nationally, the median inpatient hospital cost for bariatric surgeries performed in pediatric patients in 2004 was \$8,651; the median hospital charge was \$25,021. Nationally, the median inpatient hospital cost for restrictive bariatric procedures performed in pediatric patients in 2004 was \$6,688; the median inpatient hospital cost for bypass procedures was \$8,893. Nationally, for those aged 13-17, the median inpatient hospital cost for bariatric procedures performed in 2004 was \$7,973; the median inpatient hospital cost for those aged 18-21 was \$8,945. No conclusions can be drawn regarding the cost of patients aged 12 and under due to lack of data. The evidence was not sufficient to permit the development of a comprehensive cost profile of non-operative approaches to pediatric obesity management.
- Key Question #5: The evidence is insufficient to permit any conclusion that the effectiveness, safety and cost of bariatric surgery for patients varies based on patients' characteristics, including: chronological age; physiologic/skeletal age; pre-surgical BMI; pre-surgical BMI categories; sex; race; co-morbid conditions (e.g., hypertension); and other factors (e.g., psychosocial or socioeconomic factors).

Evidence-Based Summary and Conclusions

- ✓ The potential benefits of LAGB and RYGB for pediatric patients with morbid obesity are the substantial weight loss (key question 1) and the resolution of medical conditions associated with obesity (key question 2). The limited evidence available suggests these potential benefits in pediatric populations; however, direct evidence on enhanced quality of life and extended long term survival is too sparse (or simply unavailable) to support conclusions. Also, current evidence does not permit conclusions about whether certain patient characteristics (e.g., age, sex, pre-surgical BMI) are predictive of surgical outcomes (key question 5).
- ✓ The potential benefits of bariatric surgery must be weighed against the complications (key question 3). For LAGB, the primary concern is the need for re-operation to correct problems associated with the band and port. Reasons for re-operation include band slippage, intragastric migration, and port/tubing problems. For RYGB, there is a different profile of complications, varying from mild events (e.g., slight malnutrition, correctable by supplements) to severe events (e.g., pulmonary embolism, severe malnutrition, immediate postoperative bleeding, digestive obstruction, staple line leak). Precisely how often these events occur in pediatric patients is unknowable, due to the sparseness of the evidence.
- ✓ The costs associated with bariatric surgery (key question 4) include not only the hospital inpatient costs of the procedure, but also the costs for professional services and postoperative management. No published data exists covering all such costs for bariatric surgery in pediatric patients.
- ✓ Future research on the use of bariatric surgery should be performed to provide greater clarity about bariatric risks and benefits in the pediatric population. Longer follow-up in prospective studies of larger populations could provide insights into key issues of informed consent, compliance with post-surgical regimens, the impact on physical growth, influence on medical co-morbidities, quality of life, and long-term survival.

➤ *Outcome:* Technology Assessment Report Findings



Agenda Item: Public Comments

- ✓ Allergan provided an industry comment
- ✓ No other public members signed up or made public comments.

Agenda Item: HTCC Decision Tool

Brian Budenholzer, Chair, and the committee used the decision worksheet in evaluating the evidence of the technologies’ safety, efficacy, and cost effectiveness. The tool was a combination of efforts based on staff, committee input and Dr. Budenholzer’s research, it was refined after the first committee meeting based on input of the committee. Committee members use the worksheet to assist them in their discussion and evaluation of the technology.

Agenda Item: HTCC Pediatric Bariatric Surgery Technology Decision

Brian Budenholzer, Committee Chair, led a discussion of the evidence related to the safety, efficacy, and cost effectiveness of Pediatric Bariatric surgery.

- ✓ The HTCC reviewed and considered the pediatric bariatric surgery technology assessment report, information provided by the Administrator, and public and agency comments. Based on the technology assessment report, the cited studies, and information presented by the technology assessment center, committee members concluded that there were meaningful differences between the two primary surgical procedure types (RYGB and LAGB) and between individuals in the higher age bracket (18-21 years old) and those under 18 years old. Thus, where relevant to the question, certain findings were separated by the committee in these categories.
- ✓ Effectiveness: The committee found that there was sufficient scientific evidence, although weak because it was based on small, generally retrospective case studies, to draw conclusions about effectiveness. Three outcomes related to bariatric procedures were important: weight loss, reduction or elimination of medical co-morbidities, and improvement in psychological co-morbidities.
 - ❖ The committee was confident that the scientific evidence confirms that both LAGB and RYGB bariatric procedures were effective at inducing clinically significant weight loss.
 - ❖ The committee found that there was scientific evidence that confirms both LAGB and RYGB bariatric procedures improve at least some medical co-morbidity, but a majority was not confident in the evidence (e.g. while evidence is sufficient, further evidence could change results).
 - ❖ The committee found that the scientific evidence did not confirm that either LAGB or RYGB bariatric procedure improved psychological co-morbidity.

EFFECTIVENESS						
Compared to no treatment						
	Weight Loss		Co-Morbid		Psych	
	Y/N	Confid Y/N	Y/N	Confid Y/N	Y/N	Confid Y/N
Band	9/0	9/0	6/3	2/4	0/7 (2 abstain)	no vote
RYGB	9/0	9/0	6/3	1/5	0/9	no vote



EFFECTIVENESS						
Compared to an alternative						
	Weight Loss		Co-Morbid		Psych	
	Y/N	Confid Y/N	Y/N	Confid Y/N	Y/N	Confid Y/N
Band	4/5	2/2	3/6	2/1	0/8 (1 abstain)	no vote
RYGB	1/8	no vote	1/8	no vote	0/8 (1 abstain)	no vote

- ✓ Safety: The committee found that there was sufficient scientific evidence to make certain conclusions about whether LAGB and RYGB bariatric procedures are safe for patients under 21 years.

❖ *Patients under 18 years of age*

The committee found that there was insufficient scientific evidence to conclude that either LAGB or RYGB bariatric procedures are safe in patients under eighteen. Compelling concerns included the lack of evidence on the impact of performing the surgery on patients that have not yet reached full maturity, small but significant surgical complications, and concern over the ability of the patient to legally consent as well as adequately appreciate the long term impacts.

❖ *Patients 18 to 20 years of age*

The committee found that there was sufficient scientific evidence to conclude that the LAGB bariatric procedure is safe in patients aged eighteen to twenty, though a majority of committee members were not confident in the evidence. The committee found that there was insufficient scientific evidence to conclude that RYGB was safe in patients aged eighteen to twenty. Compelling concerns included the long term issues related to irreversibility, the more invasive surgical procedure, nutrition deficiency and malabsorption, and the increased and more serious procedural risks (reported post-operative death and serious surgical complications).

SAFETY					
Safety: 18 - 21 years of age			Safety: less than 18 years of age		
	Y/N	Confid Y/N		Y/N	Confid Y/N
Band	6/3	2/4	Band	0/8	no vote
RYGB	3/6	0/3	RYGB	0/8	no vote

- ✓ Cost: Committee members found that there were no independent cost analyses in any category. The cost to state agencies for bariatric surgery (including the facility and professional fees) was estimated to be \$16,000. This estimate does not include the pre-surgery multi-disciplinary care and surgery program or post surgical complications or outliers. Data was unavailable on other costs that could be saved through surgery, thus preventing committee members from estimating cost effectiveness.

COST							
Independent cost analysis less than 21 years old			If NO: will the use result in costs that are:				
	Y/N		Greater	Equivalent	Lower	Don't Know	
Band	No	Band	2	0	0	7	
RYGB	No	RYGB					



- ✓ **Benefit Evaluation:** A majority of committee members found that there was net benefit in morbidly obese patients aged 18-20 for the LAGB procedure based on the evidence regarding the technology’s safety and effectiveness and cost impact relative to currently available treatments. For the RYGB procedure, a majority of members found no net benefit either because there was insufficient evidence or because there was net harm. Considerations included the critical nature of morbid obesity and related medical co-morbid conditions; benefit of intervening after physical maturation but earlier in disease progression; the magnitude of potential benefit in significant weight loss and curing or preventing co-morbid conditions; sufficient, though low confidence, evidence; lack of effective alternative treatments; the relative safety profiles of the procedures; and the current agency selection criteria for adults used to mitigate certain risks. The committee will review this policy when new evidence is available that may inform a revision to this coverage determination.

BENEFIT EVALUATION					
Benefit for those 18 to 21 years of age					
	Net	Equivalent	Less	Net Harm	Don't Know
Band	6	0	0	0	3
RYGB	3	0	0	1	5
Coverage Determination for less than 18 years of age					
	Y/N	Don't Know			
Band	0/8	1			
RYGB	0/8	1			
If NO:	No. Evidence is insufficient to conclude that the health technology is safe, efficacious, and cost-effective.				
Coverage Determination for 18 to 21 years of age					
	Y/N	Coverage Determination			
Band	6/3	Yes: only when state agency guidelines are met			
RYGB	4/5	Evidence is insufficient to conclude that the health technology is safe, efficacious, and cost-effective.			

➤ **Outcome:** Committee’s coverage and reimbursement decision:

Pediatric Bariatric Surgery for patients under age 18 is **not a covered benefit** due to insufficient evidence to conclude that it is safe, efficacious, and cost-effective.

Pediatric Bariatric Surgery for patients aged 18 - 20 years is a **covered benefit** only under the criteria:

- Patients aged 18 to 20 years old
- Bariatric surgical procedure of Laparoscopic adjustable gastric banding only
- Patients must meet and abide by all other agency bariatric surgery program criteria (e.g. body mass index, presence of co-morbid condition(s), pre-surgical weight loss, specified centers or practitioners)



Health Technology Assessment Program

Health Technology Clinical Committee
November 16, 2007 Meeting



Presentation Overview

- HTA Program Update
 - Status update
- Selected Technology: Lumbar Fusion/Discography
 - General Program Process
 - Step One: Technology Selection
 - Concerns, Prioritization
 - Step Two: Report
 - Key Questions, Evidence report development
 - Step Three: Committee Decision
 - Statutory Factors
 - Agency Utilization and Experience Information

Washington's Health Technology Assessment Program Background

- **Part of Governor's 2006 Five point health strategy for state to lead by example**
 - **Emphasize evidence-based health care**
<http://www.hca.wa.gov/contf/doc/GovGregoireHealthBrief.pdf>

- **Program Purpose: Achieve better health by paying for technologies that work**
 - Better health with **better information**: investigate what works and maintain a centralized website.
 - Open and **transparent process**: publish process, criteria, reports, and committee decisions in public meeting.
 - **Eliminate Bias**: contract for independent evidence report and independent clinical committee.
 - Promote **consistency**: state agencies rely on a single, scientifically based source.
 - **Flexible**: review evidence regularly to ensure update information is included.

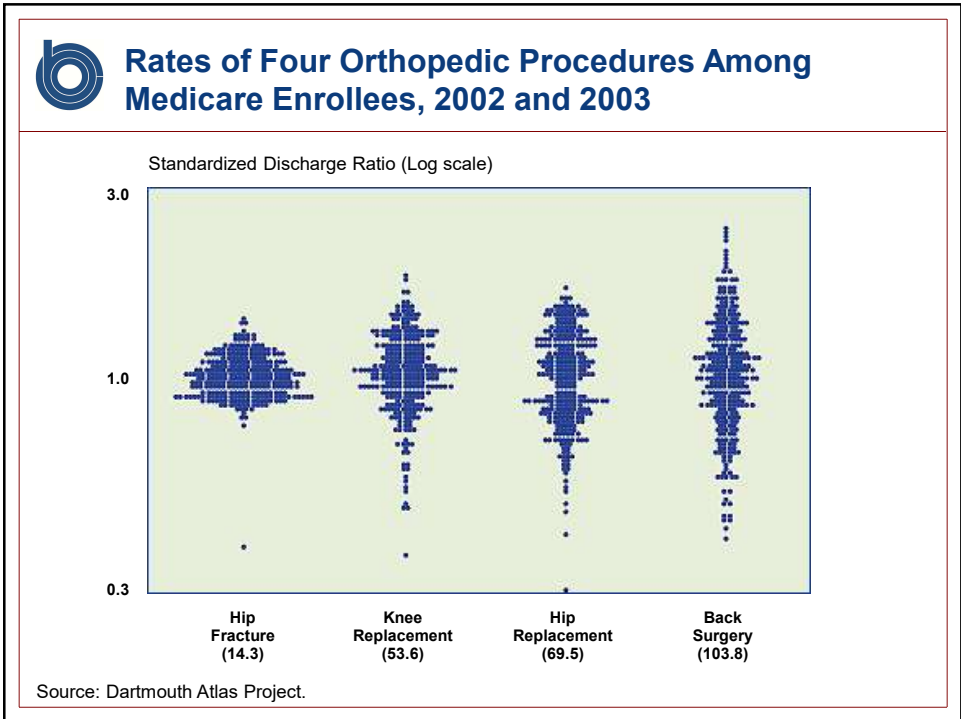
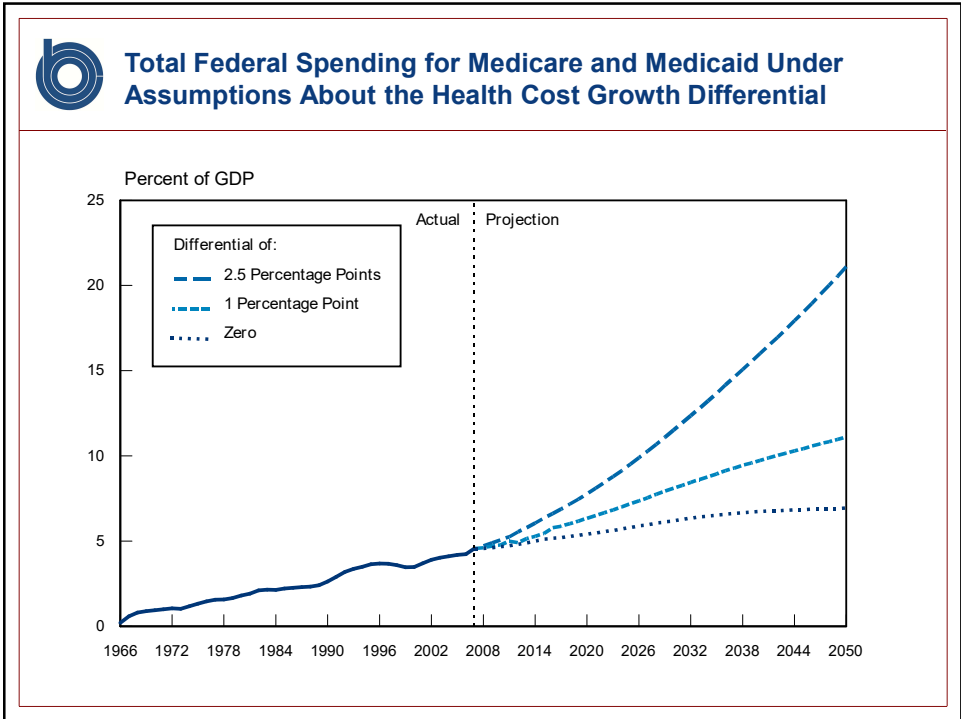
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Why Health Technology

Health Care Context

- **Part of an overall strategy**
- **Medical technology is a primary driver of cost**
 - The development and diffusion of medical technology are primary factors in explaining the persistent difference between health spending and overall economic growth.
 - Some health experts arguing that new medical technology may account for about one-half or more of real long-term spending growth.
Kaiser Family Foundation, March 2007: [How Changes in Medical Technology Affect Health Care Costs](#)
- **Medical Technology has quality gaps**
 - Medical technology diffusing without evidence of improving quality
 Highly correlated with misuses, overutilization, underutilization.
Cathy Schoen, Karen Davis, Sabrina K.H. How, and Stephen C. Schoenbaum, "U.S. Health System Performance: A National Scorecard," *Health Affairs*, Web Exclusive (September 20, 2006): w459

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Why Health Technology?

ConsumerReports.org

10 overused tests and treatments November 2007

- 1 BACK SURGERY.** ... surgery, which can cost \$20,000 plus physician's fees
- 2 HEARTBURN SURGERY.** operation, costs \$14,600 or more
- 3 PROSTATE TREATMENTS.** . . over treated with surgery that costs \$17,000, or by radiation therapy for \$20,700
- 4 IMPLANTED DEFIBRILLATORS.** ... cost some \$90,000 over a lifetime.
- 5 CORONARY STENTS.** Billions are spent each year....
- 6 CESAREAN SECTIONS.** ..cost almost \$7,000, about 55 percent more than natural delivery...
- 7 WHOLE-BODY SCREENS.** CT scans, which can cost \$1,000 ... no proven benefits for healthy people. A few CT scans a year can increase your lifetime risk of cancer.
- 8 HIGH-TECH ANGIOGRAPHY.** Using a CT ... costs an average of \$450...standard angiography is sometimes still needed.
- 9 HIGH-TECH MAMMOGRAPHY.** Using software to flag suspicious breast X-rays would add \$550 million a year to national costs if used for all mammograms. But a 2007 study found that this technique failed to improve the cancer-detection rate significantly, yet resulted in more needless biopsies.
- 10 VIRTUAL COLONOSCOPY.** ... Though less costly than a standard colonoscopy, the virtual test isn't cost-effective because any suspicious finding requires retesting with the real thing.


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- Level 1:** *“Would you have this done for yourself or for someone else in your immediate family?”*
 Influenced by one’s personal experience with the disease and capacity to deal with risk.
 Affects few people.
- Level II:** *“What would I recommend to my patient/client?”*
 Influenced by prior experience, but the scientific evidence may play a greater role.
 Affects possibly hundreds of people.
- Level III:** *“What would I recommend to the state or nation?”*
 Across-the-board recommendations for a population.
 Must be based on rigorous assessment of the scientific evidence.
 Affects hundreds of thousands, even millions of people.

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HTA Goal

Outcome: Pay for What Works

- Coverage decisions:
 - scientifically based
 - use transparent process, and
 - consistent across state health care purchasing agencies

- Formal, systematic process to identify, review, and cover appropriate health care technologies.
 - Is it safe?
 - Is it effective?
 - Does it provide value (improve health outcome)?

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HTA Program Progress

First Set of Technologies selected January 2007

- Upright MRI

□ Public Meeting, May 2007	Agencies Implement	, July 2007
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- Pediatric Bariatric Surgery

□ Public Meeting, August 2007 2008	Agencies Implement	, January 1,
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- Lumbar Fusion and Discography

□ Public Meeting, Nov. 2007	Agencies Implement	, TBD
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HTA Program Progress

Second set of technologies selected in September 2007

- Virtual Colonoscopy (CTC)
- Intrathecal Pump (Chronic non cancer pain management)
- Artificial Discs
- Arthroscopic Surgery of the Knee
- Cardiac Stent
- Computed Tomographic Angiography (CTA) for Cardiac Diagnosis


Activities Underway

- Posted for thirty day comment period
- Review of current assessments and guidelines
- Investigation of review strategy

Next Steps

- Technology Assessment Vendor Selection
- Key question development

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Process Overview

- 1. HCA Administrator Selects Technology**
 Nominate, Review, Public Input, Prioritize
- ↓ *Semi-annual*

2. Vendor Produce Technology Assessment Report
 Key Questions and Work Plan, Draft, Comments, Finalize
- ↓ *2-8 Months*

3. Clinical Committee makes Coverage Determination
 Review report, Public hearing
- ↓ *Meet Quarterly*

4. Agencies Implement Decision
 Implements within current process unless statutory conflict

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Lumbar Fusion and Discography Background

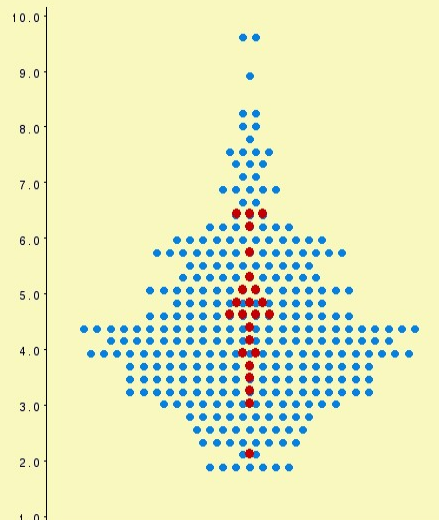
- Spinal Fusion Topic Concern
 - Concern relates to subset of patients with chronic low back pain (LBP)
 - Spinal fusion covered and not at issue for traumatic injuries, patients with significant instability, congenital defects, neurological issues
 - Fusion surgery outcomes, especially in workers comp. are poor
 - This patient subset suffers substantial and chronic pain that can be disabling and interferes with life function. There is no gold standard treatment that is curative. Some patients get better with no treatment while others experience temporary or sustained pain reduction or relief from:
 - Medication
 - Physical rehabilitation/care (exercise, rehabilitation, chiropractic, acupuncture)
 - Mental care (education, cognitive behavioral therapy)
 - Surgery followed by rehabilitation
 - Surgical premise for fusion is that disc degeneration causes pain that can be reduced/eliminated by immobilizing disc(s)
 - Question whether the surgery is effective (any improvement, incremental improvement, or full resolution)
 - Is effect attributable as much to placebo or the rehabilitative component
 - Question whether/ when the invasive procedure with attendant significant risk compared with non-surgical alternatives is appropriate
 - Re-operation and surgical complication rates are very high
 - If appropriate, when or who in the LBP group benefit

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Dartmouth Atlas

Back Surgery per 1,000 Medicare Enrollees (2003)
HRR/HSA Level Rates

City Name	State	Rates
Highest Five WA HSA Rates		
Centralia	WA	6.39
Wenatchee	WA	6.29
Spokane	WA	6.25
Longview	WA	6.18
Tacoma	WA	5.72
Lowest Five WA HSA Rates		
Richland	WA	3.68
Port Angeles	WA	3.30
Aberdeen	WA	3.09
Walla Walla	WA	2.96
Coupeville	WA	2.06




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Lumbar Fusion and Discography Background

- Discography Topic Concern
 - **Concern relates to using discography results to select or “confirm” a patient for fusion surgery**
 - There is no clear case definition of presence/absence of degenerative disc disease
 - Association between disease presence, pain, surgical benefit not established
 - Unclear that positive discogram patients undergoing surgery do better
 - The test is usually cumulative, not a replacement
 - Significant false positive rate (“normal” patients who experience pain/positive result)
 - **Discography premise is to diagnose source of pain as from disc through:**
 - Injection of contrast material to aid imaging of disc
 - Injection should provoke pain (look for a corresponding facial / subjective response)
 - **Diagnostic “gold standard” not established – generally:**
 - not recommended for uncomplicated cases, or
 - MRI or plain radiograph

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Step One: Selection Lumbar Fusion/Discography

<u>Primary Criteria</u>	
Potential patient harm/safety concerns:	High
Concerns about therapeutic efficacy or diagnostic accuracy and appropriateness of outcomes for patients:	High
Estimated total direct cost per year (estimated increase/decrease):	High
<u>Secondary Criteria</u>	
Number of persons affected per year:	Med Low
Severity of condition treated by technology:	Med
Policy related urgency/diffusion concern:	Med
Potential or observed variation:	High
Special populations/ethical concerns:	Low

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Washington State
Health Care Authority

Step Two: Report Lumbar Fusion/Discography

- Commissioning the Report – informing the committee and gathering information:
 - Committee must review and consider Health Technology Assessment
 - Committee may consider other relevant information
 - Information Provided by administrator
 - Reports and testimony from advisory groups
 - Submission or comments from public

WAC 182-55-030: Committee coverage determination process
- Why a technology assessment?
 - Volume of studies
 - Variation and bias

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Washington State
Health Care Authority

Step Two: Report Lumbar Fusion/Discography

- Key Question Development
 - Process to refine:
 - Target population
 - Target technology
 - Target domains
 - Unusual perspectives
- Lumbar Fusion/Discography key question process
 - Clinical consultant drafts, iterative process, consults with:
 - Experts for clinical perspective
 - Program for conformance to program mandates / purpose
 - Agencies regarding key concerns
 - Public comment for additional issues
 - Clinical committee comments
 - Technology assessment center for review impact

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Washington State
Health Care Authority

Step Two: Report

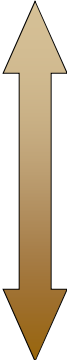
Lumbar Fusion/Discography

- **Clinical Committee Decision must give greatest weight to most valid and reliable evidence**
 - Objective Factors for evidence consideration
 - Nature and Source of evidence
 - Empirical characteristics of the studies or trials upon which evidence is based
 - Consistency of outcomes with comparable studies
 - Additional evaluation factors
 - Recency (date of information)
 - Relevance (applicability of the information to the key questions presented or participating agency programs and clients)
 - Bias (presence of conflict of interest or political considerations)

WAC 182-55-030: Committee coverage determination process

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Hierarchy of Evidence



Best: Meta-analysis of large randomized head-to-head trials.

Large, well-designed head-to head randomized controlled clinical trials (RCT):

- Long-term studies, real clinical endpoints
- Well accepted intermediates
- Poorly accepted intermediates

Smaller RCTs, or separate, placebo-controlled trials

Well-designed observational studies, e.g., cohort studies, case-control studies

Safety data without efficacy studies

Case series, anecdotes

Least: Expert opinion, non-evidence-based expert panel reports, and other documents with no direct clinical evidence

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WA - Health Technology Clinical Committee

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Step Two: Report Lumbar Fusion/Discography

Different Data Sources

- Efficacy
 - How technology functions in “best environments”
 - Randomized trials-distinguish technology from other variables
 - Meta-analysis
- Effectiveness
 - How technology functions in “real world”
 - Population level analyses
 - Large, multicenter, rigorous observational cohorts (consecutive pts/objective observers)
- Safety
 - Variant of effectiveness
 - Population level analyses
 - Case reports/series, FDA reports
- Cost
 - Direct and modeled analysis
 - Administrative/billing data (charge vs cost)
- Context
 - Mix of historic trend, utilization data, beneficiary status, expert opinion

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Step Two: Report Lumbar Fusion/Discography

Features of Meta-Analysis

- Bigger is Better?
 - Primary outcomes are “powered” outcomes
 - Helpful for uncommon events
 - Mutes out extremes (center effect)
 - Prevents over-emphasis of ant one study
- Depend on homogeneous populations, comparators, interventions
- Establish a threshold for clinical importance to avoid Type 1 error

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Technology Report

Administrator Data

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Step Three: Committee Decision Lumbar Fusion and Discography

Medicare Coverage, Guidelines, Agency Experience

- Committee determination must either:
 - be consistent with the identified Medicare decisions and expert guidelines or
 - specify the reason (s) for the decision and the evidentiary basis

WAC 182-55-035: Committee coverage determination process

- Committee must consider:
 - Information submitted by the Administrator

WAC 182-55-035: Committee coverage determination process

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Clinical Guidelines for Spinal Fusion

Four Entities published relevant guidelines on NGC

- ❑ American Association of Neurological Surgeons (2005) (8 guidelines)
- ❑ Work loss Data Institute (2006)
- ❑ American College of Occupational Health and Environmental Medicine (2004)
- ❑ Washington State Dept of Labor and Industries (2002)
- Indications vary, consensus generally among conditions excluded from report (e.g. deformity, instability, lumbar radiculopathy)

Evidence relied upon not explicit/variable quality

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Clinical Guidelines for Spinal Fusion

- No consensus that uncomplicated, chronic low back pain is indication for spinal fusion
 - ❑ AANS lists specific indication for “intractable low-back pain without stenosis or spondylolisthesis.”
 - ❑ WLDI includes “primary mechanical back pain/functional spinal unit failure (in cases other than workers’ comp)” as an indication
 - ❑ ACOHEM does not include any indication related to DDD or uncomplicated low back pain
 - ❑ WaL&I does not include any indication related to DDD or uncomplicated low back pain

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Discography Guidelines

- American Society of Interventional Pain Physicians (2007)
 - Work Loss Data Institute (2006)
 - American Association of Neurological Surgeons (2005)
 - Guyer and Ohnmeiss, Texas Back Institute (2003)
 - Washington State Department of Labor & Industries (2002)
- Evidence relied upon not explicit/variable quality

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Discography Guidelines

- No guideline recommends discography as stand-alone preoperative diagnostic test
- MRI is recommended as diagnostic test of choice
- Three guidelines indicate that discography be reserved for patients with equivocal or inconclusive MRI findings
- WLDI does not recommend use at all
- AANS recommends against surgery where MRI normal, even if positive discography
- Wa L&I does not consider positive discography a definitive indication for fusion

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Step Three: Committee Decision

Lumbar Fusion and Discography

- **National Medicare Coverage:**
 - CMS has no national medicare coverage policy on spinal fusion or discography
 - CMS Medicare Coverage Advisory Committee considered lumbar fusion for treatment of DDD in Medicare enrollees over 65 on Nov 2006 but issued no coverage decision
 - Commissioned AHRQ evidence report
 - No RCT addressed over 65 population;
 - Four RCT on middle age population failed to demonstrate clinically meaningful improvement on ODI; 2 studies should statistically significant benefit of less than 15 point difference which is generally accepted minimum clinically meaningful difference
- <http://www.cms.hhs.gov/determinationprocess/downloads/id41ta.pdf>


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Lumbar Fusion and Discography

- **State Agency Policy**
 - Medicaid, and UMP currently cover Lumbar Fusion and Discography (no indication restrictions)
 - Labor and Industries covers Lumbar Fusion under certain criteria based on Industrial Insurance Medical Advisory Committee guideline (2001)
 - Requires prior authorization for fusion;
 - Approval for fusion only if either 1) measurable instability present, and/or 2) objective evidence of neurological impairment associated with DDD/bony deformity.
 - Considers relative contra-indications to fusion (smoking, multi-level DDD, significant psyche factors, no improvement from prior spine surgery).


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Lumbar Fusion and Discography

- **State Agency Policy: Alternatives**
 - The agencies cover fusion surgery alternatives, including but not limited to (singly or in combination):
 - Cognitive behavioral therapy
 - Medications (anti-depressant, Acetaminophen, NSAID)
 - Rehabilitation
 - Psychological
 - Exercise, education
 - Interdisciplinary Rehabilitation
 - Spinal Manipulation
 - The agencies cover discography alternatives, including:
 - Physical examination
 - MRI
 - Plain Radiograph (x-ray)

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Step Three: Committee Decision Lumbar Fusion and Discography

Labor And Industries (SFY06)

Lumbar Fusion Surgery		
Clients	Professional and Facility	Average Cost
435	\$16.1 million	\$37,200
*Discography prior to fusion		
137	\$305,000	\$2,230

* A total of 358 discographies were done. Of these, 221 injured workers did not go on to have fusion

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Step Three: Committee Decision
Lumbar Fusion and Discography

Uniform Medical Plan Utilization (SFY06)

Lumbar Fusion Surgery		
Clients	Professional and Facility	Average Cost
122	\$4.2 million	\$34,500
*Discography prior to fusion		
4	\$8,800	\$2,200

* A total of 15 discographies were done. Of these, 11 members did not go on to have fusion

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Step Three: Committee Decision
Lumbar Fusion and Discography

DSHS Utilization (SFY06)

Lumbar Fusion Surgery		
Clients	Professional and Facility	Average Cost
175	\$3.6 million	\$21,000
*Discography prior to fusion		
7	\$9,800	\$1,400

* A total of 45 discographies were done. Of these, 38 clients did not go on to have fusion



Step Three: Committee Decision

Lumbar Fusion and Discography

Washington State Agency Outcome Experience

Labor and Industries 1994 Study

- Peer reviewed and published in Spine 20: 1897-1903
 - Reviewed 388 clients that received fusion from 1986-87
- Outcomes
 - 68% Total Disability at 2 years
 - 23% more surgery by 2 yrs
 - Instrumentation doubled risk of reoperation
 - Surgical experience didn't matter
- WC fusion outcomes far worse than previously reported from surgical case series

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Step Three: Committee Decision

Lumbar Fusion and Discography

Washington State Agency Outcome Experience

Labor and Industries 2006 Study

- Peer reviewed and published in 2006 Study: Spine 31: 2715-23
- **Design:** Retrospective population-based cohort study.
- **Scope:** All injured WA workers 18-80 who underwent lumbar fusion
 - Almost 2000 cases (n= 1950)
 - Seven year period: 1994-2001
 - Excluded: Index LF for removal or reinsertion of instrumentation, self-insured, rejected claims, scoliosis, spinal inflammatory, infectious or neoplastic diagnoses.

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Step Three: Committee Decision Lumbar Fusion and Discography

Washington State Agency Outcome Experience

Labor and Industries 2006 Study

- Disability Status
 - 2-yr disability rate-63.9%
 - 11.3% with total permanent disability (N=214)
 - No change in outcome by receipt of instrumentation or cages

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Step Three: Committee Decision Lumbar Fusion and Discography

Washington State Agency Outcome Experience

Labor and Industries 2006 Study

- Safety Profile: Post Operative Complications
- 11.8 % postoperative complications
 - N=75 post-op infections
 - N=62 DVTs
 - N=70 anesthetic complications
 - N=7 neural injuries
 - N=4 pulmonary emboli

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Step Three: Committee Decision Lumbar Fusion and Discography

Washington State Agency Outcome Experience

Labor and Industries 2006 Study

- Safety Profile: Re Operations
- 22% reoperation within 2 years
- Average time to reoperation 11 months
 - 50% repeat fusion
 - 28% instrumentation removal
 - 21% both

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Step Three: Committee Decision Lumbar Fusion and Discography

Multi-Disciplinary Pain Clinic with CBT

- 8 centers including Tacoma, Seattle, Redmond, Spokane, Portland, OR and Boise, ID
- Must be accredited by CARF-Commission on Accreditation of Rehabilitation Facilities-a high bar
 - All cognitive-behavioral based
- All intensive, 6-8 hrs/daily, up to 18 days consecutive
 - Plus 5 follow up days over 3 months post-discharge,
 - and 10 more days if needed
- Approximately 1000 workers/yr evaluated/treated
- \$7 million/yr (average approximately \$7,000/case)

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Lumbar Fusion/Discography

Questions