Device Evaluation and Coverage Policy in Workers' Compensation: Examples from Washington State

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Abstract

Workers' compensation health benefits are broader than general health benefits and include payment for medical and rehabilitation costs, associated indemnity (lost time) costs, and vocational rehabilitation (return-to-work) costs. In addition, cost liability is for the life of the claim (injury), rather than for each plan year. We examined device evaluation and coverage policy in workers' compensation over a 10-year period in Washington State. Most requests for device coverage in workers' compensation relate to the diagnosis, prognosis, or treatment of chronic musculoskeletal conditions. A number of specific problems have been recognized in making device coverage decisions within workers' compensation: (1) invasive devices with a high adverse event profile and history of poor outcomes could significantly increase both indemnity and medical costs; (2) many noninvasive devices, while having a low adverse event profile, have not proved effective for managing chronic musculoskeletal conditions relevant to injured workers; (3) some devices are marketed and billed as surrogate diagnostic tests for generally accepted, and more clearly proven, standard tests; (4) quality oversight of technology use among physicians may be inadequate; and (5) insurers' access to efficacy data adequate to make timely and appropriate coverage decisions in workers' compensation is often lacking. Emerging technology may substantially increase the costs of workers' compensation without significant evidence of health benefit for injured workers. To prevent ever-rising costs, we need to increase provider education and patient education and consent, involve the state medical society in coverage policy, and collect relevant outcomes data from healthcare providers.

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The delivery of healthcare benefits within state workers' compensation systems differs in several ways from the delivery of general health (non-workers' compensation) benefits (Table 1). Differences between the workers' compensation and general health systems are most acute when state workers' compensation benefits are compared with private health benefits for similar, particularly musculoskeletal, conditions in working age populations. These differences would be less apparent if benefits provided by state workers' compensation systems and public payers (eg, Medicare, Medicaid, and the Veterans Administration system) were compared for chronic systemic disorders, such as acquired immunodeficiency syndrome and diabetes. Chronic systemic disorders, however, are rarely encountered in worker's compensation systems, where musculoskeletal conditions predominate.

One difference between workers' compensation and general health systems is that the laws that govern workers' compensation health benefits are liberally construed. Workers gave up their right to bring civil suit against employers early in this century in exchange for "sure and certain" relief from injury and illness. Workers' compensation carriers pay for proper and necessary medical services. The assumption is that a procedure, drug, or device prescribed by the attending physician is proper and necessary unless specifically denied coverage by the workers' compensation carrier. General health systems, on the other hand, pay for services in a defined benefit plan but can add benefits to the plan as needed.

In the workers' compensation system, workers are compensated for lost work time (indemnity benefits) related to the injury or illness in addition to medical benefits. Indemnity benefits represent approximately 60% of total workers' compensation costs, with medical costs accounting for about 40%.[1] In other words, disability-related costs exceed associated medical costs for the conditions covered. In addition, disability-related costs are directly affected by the efficacy

Table 1. Workers' Compensation Versus General Health (Non-Workers' Compensation) Benefits

	Workers' Compensation	General Health
Duration of coverage	Life of claim until maximum medical improvement	Annual contract
Indemnity benefit	Yes	No
Return-to-work focus	Yes	No
Copays and deductibles	No	Yes
Worker contribution to premium	No*	Yes
Due process regarding disputes	Formal process	Informal process

*Washington state is a notable exception—50% of the medical aid fund is by worker contribution.

of the medical care received. Although some recent cost-benefit analyses of technologies have taken these additional costs into account,[2] others have not.[3]

In contrast to the general health system, the workers' compensation system focuses on returning the worker to work. Purely palliative treatments, with less impact on functional improvement, are therefore valued less than more curative treatments. Studies on the efficacy of new technologies must assess symptoms, functional status, and return to work as outcomes to provide reasonable guidance regarding the value of these technologies for injured workers. This is particularly important when evaluating medical devices used to treat workers with chronic pain of non-malignant origin.

With workers' compensation, workers have little economic incentive to seriously consider the costs and benefits of any given technology, including those that are expensive, unproved, or invasive. In most states, workers do not contribute to the employee-based premiums that fund workers' compensation benefits. In addition, workers' compensation benefits have no copayments or deductibles.

Workers covered by workers' compensation are entitled to receive medical, rehabilitation, and indemnity benefits until their condition reaches maximal medical improvement (ie, until no further medical treatment is likely to substantially improve the condition). General health benefits are limited to annual benefits that would not cover the condition beyond the yearly contract for coverage. The practical impact of this difference can be seen in the use of an implantable spinal cord stimulator, a technology that benefits no more than 50% of patients in which it is used.[4,5] Under general health benefits, the stimulator might be implanted for chronic pain. If the enrollee then lost his or her health coverage, no further expenses related to the stimulator (eg, replacement parts or reoperation to remove infected leads) would be covered beyond the end of the covered year. In workers' compensation, all expenses incurred after implantation would be covered as long as the device remained implanted. Instrumentation devices used to assist lumbar fusion (arthrodesis) are another example.[6] Workers' compensation would be liable for health benefits even if the device broke many years after implantation, including reoperation for removal and any lost time associated with the reoperation. Workers' compensation would also be liable for costs related to long-term disability if an ineffective device contributed to a poor health outcome that prevented the worker from returning to work.

Another difference is that outcomes of selected procedures in the workers' compensation system are worse than those in the general health system. Although this difference has been demonstrated for many procedures,[7-10] little similar data are available regarding technology use. In our review of more than 30 articles (published since 1985) on this issue, none specifically addressed medical devices. Although the reasons for the difference in outcomes are not entirely clear, they highlight the need for looking at outcomes appropriate to the injured worker population.

Finally, the extent of due process available in workers' compensation is far greater than that generally available in the general health system. Although disputes involving denial of a specific medical benefit are less common than are other types of medical disputes (eg, those regarding causality or impairment ratings), they may be on the rise. In Washington State, any provider (including manufacturers) can appeal an adverse decision to the Board of Industrial Insurance

Appeals. In a recent example, at least 10 denied claims for device payment were brought to the board by a distributor. These cases were dropped after the cases were consolidated into one appeal.

The unique characteristics of the workers' compensation system increase the importance of evaluating new and emerging (or controversial) medical devices for the purposes of making coverage decisions. To make these decisions, outcomes assessment into areas not typically considered in general health systems (eg, return-to-work outcomes) is needed, although concerns over disability-associated loss are becoming increasingly important in the general health arena as well.[11] In addition to the substantial differences between workers' compensation and non-workers' compensation healthcare, workers' compensation benefits also vary considerably within and between states. These inter- and intrastate differences include the extent of worker choice of provider, the mix of large versus small employers, and the interposition of third-party administrators in coverage decisions.

Policy makers found it nearly impossible to parse out the relative merits of one technology already in wide use versus those of the numerous other similar devices.

DEVICE EVALUATION PROBLEMS IN WORKERS' COMPENSATION

The ability to make sound policy decisions regarding workers' compensation coverage for medical devices is hampered by the paucity of efficacy data that exists for particular devices. For example, only one randomized, controlled clinical trial on external electrical bone growth stimulators as an adjunct to spinal fusion has been published to date,[12] yet the Food and Drug Administration (FDA) has approved the device and most states allow its use in the workers' compensation setting. This study,[12] however, is seriously flawed by the high number of patients who did not complete the study and the exclusion of data from these patients in the efficacy analysis. The policy-making process also is adversely affected by the lack of information sharing among providers, insurers, and state agencies. There also is no consensus about which outcomes (eg, time loss status, functional status, return to work) would be best to track in a longitudinal outcomes study.

Although the workers' compensation system in each state is unique, most of the refractory clinical problems and costs in all workers' compensation systems relate to the treatment of chronic pain for musculoskeletal conditions, including back and neck, shoulder and knee, and upper extremity cumulative trauma disorders.[13] Not only do these conditions account for most of the costs for workers' compensation, they also generate the greatest amount of lost productivity (Fulton-Kehoe D, Franklin GM, Weaver M, Cheadle A. Years of productivity lost among injured workers in Washington State: Modelling disability burden in workers' compensation. Submitted for publication). In Washington State, most medical technologies assessed and reviewed relate to the treatment of musculoskeletal conditions. However, many of these devices have limited evidence of efficacy or improved outcomes in injured workers with these conditions. Yet these technologies consume the greatest proportion of policy resources. Technologies established as effective, such as nerve conduction testing for carpal tunnel syndrome, are not at issue in terms of coverage policy.

Class III Devices Used for Off-Label Indications

Pedicle screw fixation devices for lumbar fusion have had a checkered history since their widespread use starting in the mid-1980s. The popularity of these devices among spine surgeons stemmed in large part from the promise that the rate of successful bony fusion would increase. Although these systems of rods and screws had proved successful when used in long bones, no randomized, controlled trials supporting their effectiveness when used in the lumbar spine were available at the time.

Not until 1994 did pedicle screw fixation systems gain partial FDA approval for a limited indication (grade 3-4 spondylolisthesis at L5-S1), one rarely seen in injured workers. By that time, population-based outcomes data from Washington State had demonstrated a doubling of reoperation risk among injured workers receiving instrumentation,[6] and multidistrict

litigation against manufacturers for instrumentation-related adverse events resulted in at least one out-of-court settlement.[14]

In response to these data, the Industrial Insurance Committee of the Washington State Medical Association recommended that the workers' compensation system continue to cover instrumented fusions, provided that patients received a consent form outlining the risks and potential outcomes (Figure 1). Recently, one instrumentation manufacturer sued the state of Washington in an attempt to stop the use of a patient consent form. Although the merits of the suit were debatable, it highlights a rather unique problem—a workers' compensation system wishing to educate patients on the state of the technology being attacked for doing so.[15]

In the fall of 1997, one pedicle screw system received a 510(k) approval for degenerative lumbar disk disease. However, recent studies[16,17] have further demonstrated that even though pedicle screw instrumentation may lead to higher fusion rates, it provides little clinical benefit. With its poor adverse event profile and substantially greater fusion cost, the use of pedicle screw instrumentation as an adjunct to lumbar spinal fusion may decrease.

Although the desirability of pedicle screw instrumentation may be declining, at least two new interbody devices have received FDA approval for lumbar spine implantation since September 1996.[18] Data from the Washington State worker's compensation system indicate that this new technology, heavily marketed to spine surgeons, has increased requests for lumbar fusion. Recent utilization review data show at least a 50% increase in fusion requests since the introduction of interbody fusion cages (Figure 2). As with the pedicle screw fixation de-

Figure 1. Lumbar Fusion Patient Consent Form

Lumbar Fusion Patient Consent Form
(To be reviewed with your physician)

The department has developed guidelines for various surgical procedures as part of its utilization management program. The guidelines for lumbar fusion require that your physician discuss the following information with you before surgery:

A recent study* at the University of Washington showed that in Washington workers:

- The chances of an injured worker being off of disability time loss 2 years after fusion are 32%
- More than 50% of workers who received lumbar fusion, in Washington's workers' compensation system, reported that both pain and functional recovery was no better or worse than expected after lumbar fusion.
- The overall rate of reoperation within 2 years, for all fusions, is approximately 23%. The use of instrumentation in Washington workers nearly doubled this risk of reoperation.

In addition:
Smoking at the time of fusion greatly increases the risk of fusion failure.
Pain relief after fusion, even when it occurs, is not likely to be complete.

My physician has discussed this information with me. I understand it and wish to proceed with the fusion. I understand that this information does NOT take the place of, and is separate and distinct from, the operative consent form that I will review before surgery.

_____ _____
Patient Physician

___/___/___ ___/___/___
Date Date

Adapted from reference 6.

Figure 2. Number of Lumbar Fusion Requests in the Washington State Workers' Compensation System

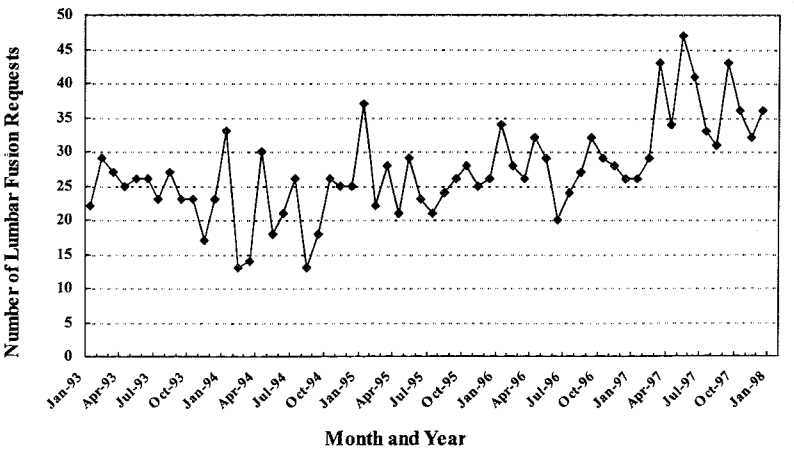

Figure 3. Request Form for Extended Use of Transcutaneous Electrical Nerve Stimulator

Dept of Labor & Industries
Health Services Analysis

TENS EXTENDED RENTAL OR PURCHASE RECOMMENDATION

Department of Labor and Industries policy allows up to three months of TENS therapy on a rental basis. For extended rental (limited to three additional months) or purchase of a TENS unit, this form must be completed and signed by the treating provider. Purchase will **not** be considered until after six months of rental.

The following information is required from the treating provider: For extended rental recommendations, complete and sign Box 1. For purchase, complete and sign Box 2. **Specific** documentation is required in the space given to demonstrate patient's improvement. Attach additional sheets or materials if necessary.

Send the form to: Performance Modalities, Inc., 25530 74th Ave S, Kent, WA 98032-6014. Phone the vendor @ (800) 999-TENS or, if questions arise or additional information is needed, call the L&I Provider Hotline @ (800) 848-0811. The VENDOR is responsible for forwarding extended rental and purchase recommendations to L&I. Sending requests to L&I directly may result in delays in processing.

Claimant's name (Last, First, MI)	Claimant's SSN (for ID only)	L&I claim number

Claimant date of injury	Date of initial TENS prescription	Name of treating provider (print)

TENS Extended Rental Recommendation

1. Medical support/reason for continuing TENS therapy for up to an additional three months:

- ☐ Patient has been able to return to work because of TENS therapy
- ☐ Reduction in pain medication resulting from TENS therapy
- ☐ Patient has demonstrable functional improvement from use of TENS
- ☐ Other demonstrable improvement (such as a vocational program) from use of TENS

Please provide evidence/detail for the box (es) checked: _____

Physician's Name, Address and Phone:	Date / Physician's signature
	Date / Verification of Vendor receipt

TENS Purchase Recommendation

2. Medical support/reason for purchasing a TENS for this injured worker:

- ☐ Patient has been able to return to work because of TENS therapy
- ☐ Reduction in pain medication resulting from TENS therapy
- ☐ Patient has significant functional improvement from use of TENS
- ☐ Other demonstrable improvement (such as a vocational program) from use of TENS

Please provide evidence/detail for the box (es) checked: _____

Date / Physician's signature	Date / Vendor's verification of receipt signature

DEPT USE ONLY

Concur with recommendation? ☐ Yes ☐ No — Date / L&I Medical Consultant signature

Reason(s):

F245-038-000 TENS extended rental/purchase rec 1-97

SCAN Index: MED

Figure 4. Request Form for Medical Device Coverage

MEDICAL DEVICE COVERAGE REQUEST

Information provided will be used by the Office of the Medical Director in evaluating the medical device.

Your Name:	Company Name:
Mailing Address:	Date
City State ZIP + 4	FAX Number: ( )
Telephone Number: ( )	E-Mail Address:
Name of Device:	Manufacturer of Device:

Please provide answers on a separate sheet. Number answers to correspond to numbered questions.

1 a. Why do you believe this device merits consideration and review by the Office of the Medical Director?
b. What is the device intended to do?

2 a. What published, peer-reviewed literature documents the efficacy of this device or the science that underlies it?
Please enclose articles or a bibliography
b. Specify which, if any, of the enclosed articles look at the clinical effectiveness of the device and its impact on return to work of injured workers.
c. Are there any other sources that would provide useful information?
Please enclose or provide bibliography

3. FDA approval:
a. Does the device have FDA approval?
b. When was the device approved?
c. For what indications is the device approved for by the FDA?
d. What approval process was employed (e g , 510(k), PMA, IDE)?
If approved under the 510(k) process, what device is it substantially equivalent to?
Please include approval letter and other relevant supporting documents to or from the FDA.

4. How is this device (1) different from and (2) more efficacious than devices that currently address the medical conditions for which this device has been approved?

5. How is this device (1) different from and (2) more efficacious than current medical treatment procedures or diagnostic alternatives for this type of injury?

6. Total cost for the device:
a. What is the total cost for the device for which the Department of Labor and Industries will be charged?
b. What are the on-going costs associated with the device during the patient's use?
c. How does this cost compare with other medical treatment procedures or diagnostic alternatives for this type of injury?

7. How would this device increase the quality of care the Washington State workers would receive?

8. How would this device return Washington State workers to work more quickly than existing devices and medical treatment procedures currently do?

9. Which State Workers' compensation programs reimburse for use of this device?
Please provide contact names and phone numbers

10. Which private insurers reimburse for use of this device?
Please provide contact names and phone numbers

11. Have any relevant medical organizations (e g , AMA) expressed an opinion on this device?
If so, please provide verification documents and contact names and numbers if possible.

12. What safety and efficacy issues does use of this device raise?

For OMD Use	Date Received:	OMD Personnel
Action:		Submitter Advised/Date:
Comments:		

vices, the Washington State workers' compensation program will be assessing outcomes, including functional status, related to this new technology. Although the new interbody cage devices are not being used "off label," their rapid dissemination in the face of limited efficacy data warrants close monitoring for adverse events and should stimulate outcomes studies in this population.

Looking to other major insurers for guidance on coverage of class III devices used for off-label indications may not be fruitful. Although the Health Care Financing Administration makes many national coverage decisions for Medicare based on the best available scientific evidence, decisions regarding off-label uses in general are left to the regional medical directors. Thus no national coverage policies regarding off-label uses of technologies are available.

Marketing Similar Devices Within Broad Indication Categories

Many therapeutic devices, although not harmful, have not been proved beneficial to injured workers. For example, transcutaneous electrical nerve stimulation (TENS) is used to treat a variety of painful musculoskeletal disorders. Although TENS is commonly used in patients with low back pain, at least one clinical trial found that this treatment offered no substantial benefit to these patients.[19] In recent years, an explosion of nerve stimulator "look-alike" devices has occurred, including microcurrent TENS, neuromuscular electrical stimulation, interferential current therapy, percutaneous electrical stimulation, and electroceutical stimulation. Most of these devices have received FDA approval for marketing based on 510(k) equivalency.[20] However, the 510(k) approval process provides no substantive evidence of a device's efficacy.

As for crafting worker's compensation coverage decisions, policy makers found it nearly impossible to parse out the relative merits of one technology already in wide use (TENS) versus those of the numerous other similar devices. Again relying on the recommendation of the Industrial Insurance Committee of the Washington State Medical Association, policy makers decided to allow short-term use of TENS. Because of the lack of evidence supporting the long-term benefits of TENS, long-term rental (>3 months), and particularly purchase, of a TENS device requires clear documentation of functional improvement or return to work related to use of the requested device. The physician requesting long-term use of TENS must complete a form specifying the type of improvement the patient is experiencing (Figure 3). The device vendor reviews requests for a second 3-month rental period, but a medical consultant must approve the reason for a purchase. To date, medical providers have not been able to adequately justify the purchase of a TENS device in most cases. Correspondingly, the number of requests for purchase has decreased considerably.

Needling procedures provide a second example of the confusion caused by similar technologies with broad indications. One approach to treating tender areas of muscle spasm has been to inject anesthetic or anti-inflammatory agents into those areas (trigger-point injections). The workers' compensation system of Washington State allows three such injections in one area, followed by an additional three injections if benefits can be documented. Recent requests for "dry needling," that is, needling without the therapeutic injection, were difficult to classify. Because acupuncture is not covered by Washington State workers' compensation, the procedure was initially denied as being somewhat similar. However, review of the clinical trials of dry needling revealed it to be more similar to trigger-point injection than to acupuncture.[21] Obtaining this type of information from the requesting provider (or manufacturer) through a formal request for information (Figure 4) places the burden on the requester to supply information critical for coverage policy.

Ersatz Technologies and Exaggerated Claims of Effectiveness

The workers' compensation system in Washington State has encountered a number of examples of technology use in which a standard test has been replaced by a new, unproven test. For example, electromyographic scanning, a computerized method of testing muscle activity using surface electrodes, has been billed under the needle electromyographic codes (CPT 95860 - 95872) for diagnosing neuromuscular conditions. Similarly, screening quantitative (psychophysical) sensory tests, such as neurometry, have been billed in place of standard nerve conduction velocity tests (CPT 95900 - 95904). Neither of these two new technologies has the specificity or localizing value of the standard tests and would not be recommended as replacements for them.[22-24] Furthermore, in the Washington State workers' compensation system, scanning electromyography and numerous computerized strength and motor assessment technologies, have been used by some providers to predict the duration of impairment in patients with musculoskeletal injuries. Such prognostication is not supported by the scientific literature and provides the injured worker with invalid information about his or her condition.

PHYSICIAN EXPERTISE AND QUALITY OVERSIGHT

Another concern, beyond whether a technology is effective or should be covered, relates to who is using and billing for the technology. Physician oversight of both accepted and questionable technologies has, at times, been a problem.

One quite contorted example of poor physician oversight of an accepted technology relates to the use of intraoperative spinal cord monitoring by evoked potentials.[25] The manufacturer of the technology contracted with a local hospital to conduct intraoperative testing, and the manufacturer's technician oversaw the conduct of the test. The operating neurosurgeon included the results of spinal cord monitoring as related by the technician in his operative report but had no particular expertise in interpreting the test results. Quality oversight was entirely between the manufacturer and the technician, even though the operating surgeon billed for the test's interpretation. After a departmental audit of the surgeon's billing behavior, and a stern letter to the hospital, the practice stopped and the surgeon moved to another state.

In the Washington State workers' compensation system, many unproven technologies have been used by attending physicians who do not have the training or expertise to conduct more standard tests. A small number of primary care physicians with large practices aimed at injured workers conduct and bill for electromyographic scanning, quantitative sensory tests, and computerized muscle testing, for example, rather than referring patients to a specialist who can conduct more standard (and proven) tests, such as nerve conducting testing and electromyography.

A recent example provides a new twist on these themes. A company expanding nationally offers a battery of tests to primary care physicians and chiropractors by mobile van. These tests include most or all of the following: ergometric muscle testing, quantitative sensory testing, nerve conduction velocities, a test for thoracic outlet syndrome, and isometric strength testing. Medical quality oversight is limited, and the average bills received per patient are approximately $1,000. A marketing brochure states, "in many cases, nothing is more important than an objective medical evaluation." The evaluation is touted as allowing "healthcare providers to establish the exact extent of injury. This gives everyone a frame of reference to monitor progress during the course of treatment and best determine when the patient has reached maximum medical improvement." None of the tests in this battery has been validated to accomplish these stated objectives.

CONCLUSION

Although we do not have an accurate estimate of the impact of emerging technologies on escalating costs in workers' compensation systems, the examples presented here suggest that the use of both invasive and noninvasive technologies may substantially increase costs. More important, few data support the widespread use of most technologies marketed for the diagnosis, prognosis, or treatment of workers with chronic, painful disorders of the musculoskeletal system. The workers' compensation system in Washington State has adapted an information gathering tool similar to that proposed by Ramsey et al[20] to gather key data from healthcare providers requesting coverage for new technologies (Figure 4). This process helps determine whether enough information exists to justify coverage and whether a full technology assessment is appropriate. The key data required for this process are initially formally requested from the appropriate provider or manufacturer. The focus is on availability of efficacy data that support a significant beneficial effect on workers' ability to function or return to work. At each stage, input from community physicians helps inform the coverage decision-making process. The decision-making process also is usually overseen by a statutory labor-management committee.

Beyond the data and policy analysis required for technology coverage decisions, additional efforts may prove useful. These include increased provider education and patient education and consent, formal mechanisms for required physician advice and consent, and collection of relevant outcomes data from providers. At a regulatory level, increasing the rigor with which devices are evaluated, with a clearer focus on patient-centered clinical outcomes, is desirable.[20] In the meantime, better postmarketing data collection, particularly of important clinical effectiveness outcomes and adverse events, would greatly help in determining coverage policy. Data-sharing arrangements between large insurers and between insurers, the FDA, and other public payers, are also needed.

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