Journal of Manual & Manipulative Therapy

ISSN: 1066-9817 (Print) 2042-6186 (Online) Journal homepage: https://www.tandfonline.com/loi/yjmt20

The cost impact of a quality-assured mechanical assessment in primary low back pain care

Ronald Donelson, Kevin Spratt, W. Steve McClellan, Richard Gray, J. Mark Miller & Eric Gatmaitan

To cite this article: Ronald Donelson, Kevin Spratt, W. Steve McClellan, Richard Gray, J. Mark Miller & Eric Gatmaitan (2019): The cost impact of a quality-assured mechanical assessment in primary low back pain care, Journal of Manual & Manipulative Therapy, DOI: 10.1080/10669817.2019.1613008

To link to this article: https://doi.org/10.1080/10669817.2019.1613008

Published online: 19 May 2019.

JOURNAL OF MANUAL & MANIPULATIVE THERAPY
https://doi.org/10.1080/10669817.2019.1613008

The cost impact of a quality-assured mechanical assessment in primary low back pain care

Ronald Donelson[a], Kevin Spratt[b,c], W. Steve McClellan[d], Richard Gray[d], J. Mark Miller[d] and Eric Gatmaitan[e]

[a]SelfCare First, LLC, Hanover, NH, USA; [b]Geisel School of Medicine Department of Orthopaedics, Lebanon, NH, USA; [c]Dartmouth Hitchcock Medical Center, Lebanon, NH, USA; [d]Integrated Musculoskeletal Care, Tallahassee, FL, USA; [e]AppliedIE, Kalamazoo, MI, USA

ABSTRACT

Objectives: The escalating cost of low back pain (LBP) care has not improved outcomes. Our purpose: to compare costs between LBP care guided by a quality-assured mechanical assessment (MC) and usual community care (CC).

Study Design: Administrative claims data analysis.

Methods: Employees and dependents of a large self-insured manufacturer seeking care for LBP in 2013 chose between the company's primary care clinic (where MC was delivered) and community care.

The claims of 5,036 were analyzed for one year following subjects' initial evaluation excluding only those with diagnostic codes for fractures, dislocations, or infections. MC included an advanced form of Mechanical Diagnosis & Therapy (MDT). CC varied based on each subjects' selection of providers. Primary outcome measure: one-year cost of each subject's care. Secondary: number of MRIs, spinal injections, and lumbar surgeries undertaken. The payer's proprietary risk-adjustment algorithm was utilized.

Results: After risk adjustment, the average cost per MC subject was 51.48% lower than the CC average cost ($p < .0279$). The utilization of MRIs, injections, and surgeries was lower with MC by 49.75%, 39.44%, 78.38% with relative risks of 1.99, 1.64, and 4.73, respectively.

Conclusions: This 51.5% cost-savings reflects the substantial reduction in downstream care-seeking with MC, including lower utilization of MRIs, injections, surgeries, and downstream care after six months from the initial visit. It is well documented that the MDT clinical examination typically elicit patterns of pain response that in turn identify how most can rapidly recover with self-care with no need for other intervention.

Level of Evidence: 1b.

KEYWORDS
Low back pain; cost-savings; Mechanical Diagnosis & Therapy; risk-adjustment; observational longitudinal cohort; quality-assured

Introduction

Disorders causing low back pain (LBP) occur in the great majority of humans worldwide. Determining effective treatment is a challenge since the specific nociceptive source cannot be identified in most leaving them classified as having so-called 'non-specific low back pain' [1].

For this reason, identifying and validating LBP subgroups has been reported as the top LBP research priority [2,3]. The Cochrane Back Review Group wrote that determining 'which interventions are most effective for which patients' represents a 'Holy Grail-type' research question [4].

The effectiveness of most non-surgical paradigms is unproven. Further, spine fusions and disc arthroplasties are often performed on non-specific axial pain based on equally non-specific degenerative disc MRI findings that are well documented as being false-positive in many asymptomatic individuals [5,6].

One way to identify and validate LBP subgroups is to define them based on specific patterns of symptom response revealed in a unique form of mechanical history and physical exam. That examination is summarized in an Addendum. These patterns must be identified with good inter- and intra-examiner reliability and then followed by identifying subgroup-specific treatments that demonstrate value and effectiveness by improving clinical and/or cost outcomes for that subgroup [7].

The use of beneficial patterns of pain response or pain provocation to mechanical testing is common across musculoskeletal (MSk) care for diagnostic purposes. Pseudo-claudication and nerve tension signs are but two pain response patterns that directly reflect the underlying spinal pathology. In contrast, clinical testing that excludes the monitoring of pain response, e.g. palpation, has been largely shown to have poor inter-examiner reliability [8–10].

Experiencing progressive increases in its costs of treating employees' musculoskeletal conditions, a large Global 500 self-insured manufacturer conducted in 2012 its own internal comparison of the costs of care of their employees and dependents with painful musculoskeletal

CONTACT Ronald Donelson donelson@selfcarefirst.com SelfCare First, LLC, 13 Gibson Road, Hanover, NH 03755, USA
The manuscript has been read and approved by all authors.

disorders. They determined a substantial benefit (cost-savings, high subject satisfaction with care) utilizing an outcomes-accountable version of 'Mechanical Diagnosis & Therapy' (MDT) [11] compared with local 'usual' community care (CC). The employer consequently contracted with this MDT network (Integrated Musculoskeletal Care – IMC) to expand its services across the employer's other U.S. facilities.

The primary purpose of this study was to compare one-year costs for employees and dependents of this same manufacturer with LBP who either received this form of mechanical care (MC) delivered in the company's primary care clinic vs. that delivered in the community (CC). Our hypothesis was that MC would generate substantial savings by avoiding many expensive downstream procedures.

Methods

Institutional review board exemption

As an administrative data analysis, the Florida A&M University Institutional Review Board determined this project was exempt from Institutional Review Board review according to federal regulations.

Target population

The total population of subjects was limited to those presenting with LBP if their first visit for LBP was in 2013 with no LBP visits within 6 months prior to that first visit. Subjects who met these inclusion criteria were free to choose either CC or care in one of the employer's in-house primary care clinics where MC was provided. Each subject's LBP diagnosis was initially established by the International Classification of Diseases, Ninth Clinical Modification (ICD-9) codes assigned by their referring primary care physician. Fractures, dislocations, or infections were the only exclusions.

The company attempted to steer subjects to their internal clinic even prior to the availability of this MC care. When MC became available, subjects were informed of this new MSk program but were provided no information about how this care might differ from what they would encounter in the community.

Study design

This research was designed as an observational, patient-preference, longitudinal cohort study. The primary outcome was the cost of CC and MC care for subjects with LBP until one-year post-treatment. Secondary outcomes included determination of counts, percentage change, and relative risks of imaging, injections, surgery events, and rates of downstream care for six months after the initial visit by treatment group.

Four covariates were included (age, sex, prospective and retrospective risk) to compare unadjusted and adjusted differences in costs of CC and MC care using the same model. Follow-up visits past 365 days were excluded.

Data sources

The employer provided four silos of claims data: inpatient services, outpatient services, professional services, and pharmacy as well as data generated from proprietary risk-adjustment algorithms utilized by the third-party-administrator [12]. Because the claims data structure did not designate which medications were directly related to LBP care, the pharmacy cost data were excluded from these analyses.

Interventions

CC varied based on which clinician(s) in the community each subject chose for care. No CC clinician had undergone the MC training described below and was therefore unable to deliver the MC type of care.

MC consists of a standardized, quality-assured form of Mechanical Diagnosis & Therapy (MDT) that was based on IMC's proprietary protocols for treating a wide range of patho-mechanical diagnoses. All patient outcomes are determined and then evaluated to continuously improve the quality of the MC's outcomes. A detailed description of MC management is described in the Addendum.

Like physical therapists delivering CC, MC clinicians were licensed physical therapists. But MC clinicians also completed 96 h of post-graduate MDT education [11]. Many underwent an additional 350 h of one-on-one clinical tutoring in the application of MDT. All then completed 7½ hours of IMC's Outcomes Accountable Clinician (OAC) online training in musculoskeletal patient management. They then passed the OAC written examination with a 75% or higher grade and were enrolled in IMC's proprietary data-enabled quality assurance program.

All MC patients self-report joint-specific data at the outset of care and on their third visit. Most patients demonstrate favorable patterns of pain response, like directional preference (DP) and/or pain centralization (PC), during their assessment and then routinely recover rapidly (see Addendum). But based on IMC's benchmarks, if insufficient improvement occurs by visit #3, that patient is flagged and discussed at a weekly online conference of IMC clinicians including one with more advanced training in this patient management processes. The patient's next best course of action is determined by this group while all clinicians in attendance benefit from this learning process.

MC's cost-of-service was based on the prevailing rates in the community. Therefore, MC's fees did not contribute substantially to cost-savings.

Potential differences in the MC and CC subgroups are further discussed below. It is important to note that MC and CC would both have distributions of easy and difficult patients in some proportion. When comparing the proportion of cases that did not escalate beyond the primary care level, we see that by definition all MC patients self-escalated to seek MC care which was at a level of physical therapy. By IMC policy, any patient presenting with conditions that were best managed at the primary care level (i.e. they would self-resolve in a short duration) would not proceed to MC. Alternatively, only 23.1% of CC patients did not escalate beyond primary care. An additional 6.9% did not escalate beyond an X-ray.

Cost allocation rules

There were four separate patterns of care that determined to which treatment group each subject's claims were allocated: (1) 'CC Exclusive' and (2) 'MC Exclusive', for subjects that started and finished their care in that same group. (3) Since published data document the need for at least three MDT assessment sessions to fully evaluate a patient's pain response patterns [13], the employer and the MC network agreed that subjects who had only one or two MC visits before themselves choosing CC did not receive MC's full assessment. MC should therefore not be held responsible for their CC costs which were instead allocated to CC minus the initial MC charges [4]. Three or more MC visits were interpreted as an adequate trial of MC care. Any subsequent CC costs of any such subjects who pursued subsequent CC, either of their own volition or because MC referred them, were allocated to MC.

Determining group-differences

The absence of clinical baseline data for the CC subjects limited our ability to assess certain differences between the CC and MC cohorts. Covariates of interest such as height, weight, smoking status, symptom duration, and location were unavailable either as part of the claims data or because of no access to CC patients' clinical records.

However, available within the claims data were subjects' age, gender, and the retrospective and prospective risk scores provided by the Optum algorithms that included co-morbidities and other risk-predictors [12]. Each subject's risk of health-related costs over the previous year (2012), i.e. retrospective, and the current calendar year (2013), i.e. prospective, were estimated using these algorithms. Lower scores from these algorithms reflect less risk. Due to the proprietary nature of these algorithms, we're unable to validate them [12].

Statistical analysis

Subject demographics

Subject demographics were compared between the two treating groups. CC and MC differences for gender were evaluated using Chi-square tests; continuous variables (age, prospective risk, and retrospective risk) were evaluated using the general linear model.

The primary independent variable was the treatment group. The primary outcome or dependent variable was the cost of care for each treatment group across the follow-up year. The analysis used the general linear model. Adjusted mean differences in cost of care used the same model but added four covariates: age, sex, prospective and retrospective risk.

Primary outcomes

Each subject's service dates and charges identified their total costs as well as their procedure codes (e.g. imaging, injections, and surgery) which were rolled up within each subject's identification code across their 365 days of care. Also, available were the age, gender, retrospective and prospective risk as independent variables.

The primary independent variable was the treatment group. The primary outcome or dependent variable was the cost of care for each treatment group across the follow-up year. The initial analysis used the general linear model. Adjusted mean differences in cost of care used the generalized linear model (GLIMMIX) because of both fixed and random effects associated with the added covariates: age, sex, prospective and retrospective risk with the two risk factors specified as random effects. These adjusting methods have been demonstrated to provide similar results compared with matching and/or propensity methods with the advantage of no loss of data points.

Secondary outcomes

Counts of imaging, injections, and surgery procedures were secondary outcomes of interest. Associated procedure codes, e.g. surgical trays for a surgical procedure, were not counted as individual procedures but simply linked to each 'main' procedure code and claim. Only the main procedure codes were then counted, including multiple main procedure codes if they occurred on a single date.

Since the imaging, injections, and surgery procedures and the care-seeking counts were defined as dichotomous count variables, the differences in counts between the two treating groups were analyzed as relative risks generated with the frequency procedure in all analyses done using in SAS 9.4 (SAS

Institute, Cary NC), running under the Windows 7 64-bit OS (Microsoft, Redman WA).

Claims-based quality measure(s)

With no availability of CC patient-reported data with which to compare available MC data, any quality of care comparison was limited to our claims-data set. As a measure of quality, we arbitrarily chose a 6-month cut-off after subjects' baseline evaluation and determined how many were still care-seeking thereafter.

Results

Claims data for 6,065 subjects were screened and 1,029 were found to be ineligible due to having LBP services within 6 months of their 2013 enrollment. The remaining 5,036 patients (4,602 CC and 434 MC subjects) all had initial visits in 2013. Everyone started care with either MC or CC and most (92%) remained there over the next year. The remaining 8% shifted between allocation categories as described in Methods.

While the CC subset was much larger than the MC subset, both are adequately large to ensure that valid estimates are possible [13].

The comparison of demographic data showed an average age of 43 years, 46% of subjects being female, and both groups had low average risk scores. The CC group was somewhat younger, had a greater number of females, and higher risk scores (Table 1).

Overall model test statistics for the unadjusted cost estimates revealed that treatment differences were significant, p < .002. The effects of the adjusted model, including treatment and the four covariates, reveals that treatment type (MC vs. CC) and age both demonstrated statistically significant effects: p < .03 and .0002, respectively (Table 2). There was a trend toward significance for an effect for the prospective risk factor, p < .06.

With MC's cost-of-service based on the prevailing rates in the community, the major contributors to cost-savings, as hypothesized, were MC's avoidance of unnecessary downstream procedures and their high costs.

The unadjusted average total cost of care in the CC group was $1,791.14 per subject vs. $791.09 for MC (p < .02) (Table 3). This unadjusted difference of $1,000.05 demonstrated a 55.83% lower cost for the MC group vs. CC. When adjusted for age, gender, retrospective, and prospective risk scores, the mean difference changed to a 51.48% savings for the MC group compared to the CC group.

Table 2. Adjusted model with Treatment and Age demonstrating statistically significant effects, with the prospective risk factor trending similarly.

Source	DF	Mean Square	F Value	P <
Treatment	1	332,505,293.5	4.84	0.0279
Age	1	931,659,377	13.55	0.0002
Retrospective Risk	1	5,588,363.1	0.08	0.7756
Prospective Risk	1	240,272,294.5	3.49	0.0616
Gender	1	5,995,568.9	0.09	0.7678

The rates in imaging, injections, and surgery utilization were lower with MC by 49.75%., 39.44%, and 78.38%, respectively (Table 4). The relative risks (RRs) for both surgical and imaging rates were both statistically significant with surgeries being 4.7 times more likely in the CC group compared to the MC treatment group and imaging nearly twice as likely (1.99). The 1.64 RR for injections was not statistically significant (p < .06) but trended in the same direction.

Only 8% of MC subjects were still generating claims 6 months after their care began compared with 30% of CC subjects. This indicates that CC subjects were 4.49 times more likely than MC subjects to seek downstream care 6 months after their initial visit (Table 4).

Six months before this study's intake, 24% of all subjects had undergone CC and met inclusion criteria. The care of 23.1% of CC patients never escalated beyond primary care while 100% of MC patients started care at the physical therapy level.

Discussion

The primary findings were: 1) the adjusted average cost of MC cases was 51.48% lower than the average cost of CC cases; 2) the utilization of MRIs, injections, and surgeries was lower with MC by 49.75%, 39.44%, 78.38% with relative risks of 1.99, 1.64, and 4.72, respectively; and 3) CC and MC subjects' care-seeking after 6 months from initial visit were 4.49 times more likely with CC compared with MC.

These reductions with MC-related care argue in favor of the value of implementing this standardized mechanical assessment (see Addendum) that reliably classifies most LBP cases that in turn guide treatment selection.

Table 1. Demographics for Treating Groups and Overall.

	Treatment groups/N Counts						
	CC N = 4,602		MC N = 434			Overall N = 5036	
Variable	Mean	Std Dev	Mean	Std Dev	P[1] <	Mean	Std Dev
Age (yrs)	42.96	16.12	45.32	13.22	0.004	43.18	15.89
Retrospective RISK	2.45	2.98	1.79	1.73	0.0001	2.39	2.89
Prospective RISK	2.20	2.27	1.75	1.26	0.0001	2.15	2.2
Gender (0/1 F/M)	0.46	0.5	0.54	0.5	0.002	0.47	0.5

1. P value reflects the differences in CC and MC means for each demographic variable

Table 3. Summary of differences in CC and MC average costs per subject over the course of 365 days.

	Treat	Cost/ Subject	95% CI LB[1]	95% CI UB[1]	p <	Pct Savings[2]
UNADJUSTED	CC	$1,791.14	$1,550.21	$2,032.07	0.0169	−55.83%
	MC	$791.09	$86.53	$1,575.65		
ADJUSTED	CC	$1,786.50	$1,546.14	$2,026.85	0.0279	−51.48%
	MC	$866.89	$83.87	$1,649.92		

1. LB = lower bounds; UB = upper bounds
2. Percent savings = 100 x (MC costs − CC costs)/CC costs = 100 x (791.09–1,791.14)/1,791.14 = −55.83%

Mean differences between adjusted costs for the CC and MC were statistically significant with the magnitudes being clinically relevant (MC vs CC adjusted values). Mean differences between CC and MC use of 'high' cost treatments (i.e. imaging, injections, and surgery) were statistically and clinically different demonstrating lower costs for imaging and surgery with injections close behind (Table 4).

The unadjusted and adjusted cost data demonstrated that the demographic covariates minimally reduced the differences between the CC and MC groups, while the MC average cost per subject was significantly lower than CC average cost (Table 1).

Access to claims data

This cost-comparison analysis was only possible because of the employer's willingness to share its claims data. Claims data captures all care and costs over the duration of any study regardless of what providers subjects choose to see. In contrast, when RCT subjects don't return for follow-up, their outcomes are often unobtainable. Typical of most claims databases, these data were limited to a common group of variables consisting of subjects' age, gender, and retrospective and prospective risk scores.

Study design comparison

Every study design has its strengths and limitations. Claims data analyses typically include a large number of subjects with few, if any, lost to follow-up. Unfortunately, claims databases typically contain no clinical data and that limits the ability to risk-adjust. In contrast, cost–effectiveness studies contain both clinical and cost data but the study sample is usually much smaller. RCTs are highly desirable but are expensive to perform, typically have much lower subject numbers that are more easily lost to follow-up. Also, most RCTs have no access to cost data.

Relevant external literature

MRI utilization

Regardless of the form of physical therapy (PT) delivered, early PT referrals for LBP have been shown to reduce the frequency of MRI acquisition by 30–35% and consequently surgery frequency and costs [14–16]. Alternatively, early MRI acquisition has been shown to lead to an 8-fold increase in the risk of surgery [17]. It's been further reported that the rates of spinal MRI use explained 22% of the variability in spine surgery rates which is more than twice the predictive power of individual patient characteristics [18]. In comparison, this study's data show that MC reduced MRI utilization by 49.75% and lumbar surgeries by 78.38%.

Table 4. Counts, percentage change, and relative risks of imaging, injections, surgery events, and downstream care after six months from the initial visit by treatment group.

Domain	Treat	Event Yes[1]	Event No	Total	Rates	% Change[2]	RR[3]	95% CI[4] LB	95% CI[4] UB	p[5] <
Imaging	MC	13	1266	1279	0.0102	-49.75%	1.99	1.156	3.498	0.0110
	CC	726	35078	35804	0.0203					
Injections	MC	14	1266	1280	0.0109	-39.44%	1.64	0.987	2.781	*0.0611*
	CC	643	35147	35763	0.0180					
Surgery	MC	2	1278	1280	0.0016	-78.38%	4.73	1.179	19.00	0.0153
	CC	265	35569	35834	0.0074					

1. Yes means that these services were provided.
2. % change is calculated as 100 x (.0102 - .0203)/.0203 = -49.75% reflecting 49.75% less imaging for MC.
3. RR or relative risk is the ratio of CC/MC where, for example, 0.0203/0.0102 = 1.99, which indicates that imaging was 1.99 times more likely for CC subjects relative to MC subjects.
4. 95% confidence interval (CI) shows the lower and upper bounds (LB and UB) for relative risks.
5. p < values reflecting the likelihood of rejecting the null hypothesis (Ho) of no differences in CC & MC risks.

Domain	Treat	Event None[1]	Event Some	Total	Rates	% Change[2]	RR[3]	95% CI[4] LB	95% CI[4] UB	p[5] <
DownStream Care	MC	35	1511	1546	0.0226	-77.72%	4.49	4.44	4.54	0.0001
	CC	399	3527	3926	0.1016					

1. None means that these no services were necessary after 6 months of care from baseline. 2. %change is calculated as 100 x((0.0226 - 0.1016)/0.1016) = -77.72% reflecting less care after 6 months for MC.
3. RR or relative risk is the ratio of CC/MC where, for example, 0.1016/0.0226 = 4.49, which indicates that downstream care was 4.49 times more likely for CC subjects relative to MC subjects.
4. 95% confidence interval (CI) shows the lower and upper bounds (LB and UB) for relative risks.
5. p < values reflecting the likelihood of rejecting the null hypothesis (Ho) of no differences in CC & MC risks.

Surgery and injection reduction

A substantial reduction in lumbar surgeries as a result of the MDT assessment/treatment paradigm has been previously documented beyond the primary care setting [19–22]. Three studies reported on subjects for whom disc surgery was being contemplated who, at that late date in their care, were given the opportunity to undergo an MDT assessment pre-operatively [19,20,22]. In all three, 50% were found to have a directional preference (DP), pain centralization (PC), or both. Two studies additionally reported a 50% reduction in surgery [20,21] consistent with the findings in other cohort [19,20,23–35] and randomized studies [36–43] that all report the excellent prognosis for subjects found to have a baseline DP, PC, or both.

The findings in all these studies indicate that a large percentage of lumbar disc surgeries appear to be unnecessary and are identifiable *before surgery* by this dynamic mechanical evaluation. These data reveal that 50% of surgical candidates have a previously undiscovered directional characteristic to their disorder that enables it to be corrected non-surgically utilizing this MC form of care.

Finally, a Dutch research team studied 77 sciatica subjects who failed conservative care, had no DP or PC during their MDT assessment, and were therefore considered surgical candidates [44]. They then underwent an average of two trans-foraminal epidural steroid injections (TESIs). A subsequent second MDT re-examination revealed one subgroup of 14 (11%) that had fully resolved their disorder with the TESI's alone. A second subgroup of 37 (48%) were now found to have a DP and PC and recovered fully with MDT treatment. These two subgroups had one-year recoveries of 100% and 92%, respectively. In non-DP patients, this study reveals the benefit of epidural steroids in transforming a non-DP pain-generator into one with a DP with an excellent prognosis.

Explanations for savings?

A primary consideration is whether these two groups were different or similar. If similar, then the difference in cost must be due to MC patients' greatly reduced downstream care-seeking related to their satisfaction with their MC outcomes.

The employer had implemented no other cost-saving tactics during this study period.

How different or similar were the cohorts?

Age and gender were comparable across the two groups. The proprietary risk-adjustment algorithms from Optum [12] revealed small differences which were accounted for in the cost-savings determination. It would be hard to argue that these cost-savings are largely related to group differences.

The company made a general announcement to employees of the introduction of his new form of low back care in their in-house clinic. Employees and beneficiaries self-selected their care paths. Some might speculate that those with mild or simpler LBP might be attracted to the convenience of the company clinic while viewing seeking CC as a hassle. Alternatively, more complex patients who had done poorly with CC in the past might be attracted to this new program.

Indeed, 24% of all subjects that had undergone CC six months before this study's intake was very likely dissatisfied with their persistent pain and therefore attracted to this new MC option. Our claims data are unable to shed additional light on differences between the cohorts. The simplicity of 23.1% of CC patient disorders never escalated them beyond primary care while 100% of MC patients started their care at the physical therapy level.

A true cost–effectiveness study that includes the collection of clinical baseline and follow-up outcomes data for all subjects would be required to answer this question.

Differences between the two clinical approaches

The lack of clear evidence of differences between subjects in the two groups may indicate that the diagnostic and treatment differences offer a stronger explanation for differences in outcomes.

Our analysis concludes that CC subjects were 4.49 (relative risk) times more likely than MC subjects to seek downstream care six months after their initial visit. The 49.75%, 39.44%, and 78.38% reductions in downstream MRIs, spinal injections, and lumbar surgeries would seem to reflect the effectiveness of MC's care that routinely includes teaching subjects effective secondary prevention strategies. Another explanation for MC patients' lower care-seeking is their satisfaction with their MC outcomes.

CC typically provides highly variable treatment paradigms largely unsupported by reliable diagnostic components needed to identify effective patient-specific care. Such variability across providers often results in ineffective, expensive care [45].

In contrast, MC's treatment decisions are based on the findings of a standardized, dynamic mechanical evaluation as the initial step in MDT care. The two patterns of symptom response, 'directional preference' (DP) and 'pain centralization' (PC), are reliably elicited in 70–91% of acute patients [24,25,27,29,31,32] and in 45–50% of chronic or pre-surgical LBP patients [19,20,22]. To our knowledge, such unanimity across so many studies is unique in low back care.

The ability to reliably identify those findings is again documented unanimously and establishes a patho-mechanical diagnosis [31,34,46–51] at the outset of care as well as routinely identifying predictably-effective treatments. Directional self-treatment informed by these two clinical findings achieves good-to-excellent, usually rapid, outcomes as reported in many prospective cohort studies [23–29,31,32,34,35,52,53], RCTs [36–41,54,55], and systematic reviews [56–58]

Given the lack of evidence of differences between subjects in the two treatment groups, coupled with an absence of any concurrent employer payment denial policies or other cost-influencing factors, this study's significant cost-savings may reflect the value of basing treatment decisions on assessment findings that identify a reliable mechanical diagnosis and, in most cases, a predictably effective treatment [11,59].

Study limitations

With only access to claims data, the value equation (value = quality/cost) cannot be calculated [60] nor could we determine symptom duration, intensity, or location of each subject's pain. Of course, it would be ideal to have comparable clinical benchmarks for both groups. Instead, we analyzed a proxy quality measure by arbitrarily choosing a 6-month cut-off after subjects' baseline evaluation and determined that the relative risk of CC subjects seeking care was 4.49 greater than MC subject.

Further MC cost-savings

Independent of this claims analysis, the employer reported that the average duration of short-term disability with MC was 50% lower than CC [61]. Such a difference in indirect costs produces substantial cost-savings for the employer well beyond the direct care savings determined in our claims data analysis. Unfortunately, we had no access to these actual indirect cost data. We hope to acquire those data from this employer for a future analysis.

As stated, we were unable to analyze any pharmaceutical differences in the treatment of these two cohorts. But it is noteworthy that patients under MC care, being predominately treated by physical therapists, would never be prescribed any medications.

Conclusions

This 51.48% savings appears to largely be due to a substantial decrease in MC's downstream utilization of expensive interventions. In the absence of any other employer cost-saving measures, it appears that MC's diagnostic and treatment model is the most likely explanation for these substantial savings. A fully funded cost-effectiveness analysis would accurately determine the source of these savings.

Funding

Partially funded by The International Mechanical Diagnosis & Therapy Foundation, No. M022013.

Notes on contributors

Ronald Donelson, is a board-certified orthopedic surgeon who specialized in and researched non-operative spine care for 30 years. He earned his Diploma in Mechanical Diagnosis & Therapy in 1990 and a Master of Science degree from The Dartmouth Institute in 1999. He founded and is the President of SelfCare First, LLC whose mission is to globally improve the quality and cost of care for individuals seeking help for painful low back, neck, and all other musculoskeletal disorders. He has published many research studies, chapters, review articles and presented over one hundred research papers, conference workshops, courses, and symposia in more than 15 countries. He published two books about precisely diagnosing and treating individuals with low back pain. Donelson has no consulting, equity, or advisory role with Integrated Musculoskeletal Care (IMC) and received no funding from either IMC or the International Mechanical Diagnosis & Therapy Research Foundation (IMDTRF) for leading this project.

Kevin Spratt, earned his Ph.D. at the University of Iowa (UI) as a methodologist, a statistician and psychometrician. At the UI College of Education and the Department of Orthopedics, he focused on reliability and validity research in school achievement testing and patient self-reported health states. He has published over 100 research articles, won prestigious awards including the Kappa Delta Award, 3 Volvo Awards, and two North American Spine Society best paper awards; authored six book chapters, been a deputy editor for Spine for more than 30 years and regularly reviews articles in the European Spine and the Spine Journals. Retired in 2017, he continues to mentor medical students and residents understanding research methods and being critical evaluators of clinical research.Spratt has no financial and/or business interests related to this study. He was funded by the IMDTRF as statistician, experimental design, data cleaning, analysis, and interpretation. He signed a confidentiality agreement with the Fortune 500 company prohibiting the sharing of this study's data without their permission.

W. Steve McClellan earned his MS in Quantitative Analysis in the College of Social Science at Florida State University. He then developed and analyzed products and services for national markets as well as financial analysis and management at Florida State. He joined Integrated Musculoskeletal Care (IMC) in 2015 to help define and launch their product and service offerings utilizing predictive analytics for musculoskeletal health. McClellen was an employee of IMC during this project.

Richard Gray graduated from Florida A&M University in 1994, earned a Mechanical Diagnosis and Therapy credential from the McKenzie Institute International in 2002, served on the Board of McKenzie Institute U.S.A., taught Accountable Community Development, and has been a clinical practitioner for two decades. He is presently the CEO of Integrated Musculoskeletal Care focused on innovations in musculoskeletal diagnostics, health care and self-care. He is a thought and practice leader in group health, workers' compensation, and disability outcomes optimization. He is a regular speaker at national orthopedic conferences and a guest lecturer in a broad range of clinical education settings. Gray is the Chief Executive Officer of IMC.

J. Mark Miller graduated from the University of Toronto in 1987 and co-developed the McKenzie Institute International's North American clinical residency program. He has been a clinical practitioner for 27 years and is a widely recognized health industry. He is Co-Founder and currently serves as Vice President of Clinical Operations for Integrated Musculoskeletal Care (IMC) with a focus on optimizing musculoskeletal outcomes. He has served on the faculty of the McKenzie Institute International and U.S.A. for over 20 years teaching over 270 continuing education courses in Mechanical Diagnosis and Therapy (MDT) to physicians, chiropractors, physical therapists and others worldwide. Miller is the Vice President of Clinical Operations for IMC.

Eric Gatmaitan earned a bachelor of science degree in industrial engineering with a minor in mechanical engineering from De La Salle University followed by an MBA in business information systems from Western Michigan University. He authored four books: Manager's Guide to Lean and Performance, Lean and Performance Driven, Building a Citadel, and Beginner's Guide to Crystal Reports and was a faculty member at Western Michigan University teaching computer technology application and programming. In industry, he served as an industrial engineer, production supervisor, plant manager, and chief operating officer. Now working for an industrial engineering and consulting firm, he leads projects and conducts training in business process optimization, quality management systems, and performance management systems. He was a data consultant with Integrated Musculoskeletal Care.

ORCID

J. Mark Miller http://orcid.org/0000-0002-9372-6083

References

[1] Hartvigsen J, Hancock M, Kongsted A, et al. What low back pain is and why we need to pay attention. Lancet. 2018;391:2356–2367.
[2] Borkan J, Koes B, Reis S, et al. A report from the second international forum for primary care research on low back pain: reexamining priorities. Spine. 1998;23(18):1992–1996.
[3] Costa L, Koes B, Pransky P, et al. Primary care research priorities in low back pain: an update. Spine. 2013;38:148–156.
[4] Bouter L, Pennick V, Bombardier C. Cochrane back review group. Spine. 2003;28(12):1215–1218.
[5] Boden S, Davis D, Dina T. Abnormal magnetic-resonance scans of the lumbar spine in asymptomatic subjects: a prospective investigation. J Bone Joint Surg. 1990;72:403–408.
[6] Jensen M, Brant-Zawadski M,N, Obuchowski O, et al. Magnetic resonance imaging of the lumbar spine in people without back pain. N Engl J Med. 1994;331:69–73.
[7] Spratt K. Statistical relevance. In: Fardon DF ea, editor. Orthopaedic knowledge update: spine 2. Orthopaedic knowledge update: spine 2. 2nd ed. Rosemont, Illinois: The American Academy of Orthopaedic Surgeons; 2002. p. 497–505.
[8] Gonnella C, Paris S, Kutner M. Reliability in evaluating passive intervertebral motion. Phys Ther. 1982;62:437.
[9] Matyas T, Bach T. The reliability of selected techniques in clinical arthrometrics. Aust J Physiother. 1985;31(5):175–199.
[10] Potter N, Rothstein J. Intertester reliability for selected clinical tests of the sacroiliac joint. Phys Ther. 1985;65 (11):1671–1675.
[11] McKenzie R, May S. Mechanical diagnosis and therapy. 2nd ed. Waikanae, New Zealand: Spinal Publications New Zealand Ltd.; 2003.
[12] Symmetry episode risk groups white paper 2018. Available from: https://www.optum.com/content/dam/optum3/optum/en/resources/white-papers/Symmetry_ERG_White_Paper_July181.pdf
[13] Werneke M, Hart D, Cook D. A descriptive study of the centralization phenomenon: a prospective analysis. Spine. 1999;24:676–683.
[14] Childs J, Fritz J, Wu S, et al. Implications of early and guideline adherent physical therapy for low back pain on utilization and costs. BMC Health Serv Res. 2015;15:150.
[15] Pham H, Ginsburg P, McKenzie K, et al. Redesigning care delivery in response to a high-performance network: the virginia mason medical center. Health Aff (Millwood). 2007;26:532–544.
[16] Fuhrmans V. A novel plan helps hospital wean itself off pricey tests: it cajoles big insurer to pay a little more for cheaper therapies. Wall Street J. 2007.
[17] Webster B, Cifuentes M. Relationship of early magnetic resonance imaging for work-related acute low back pain with disability and medical utilization outcomes. J Occup Environ Med. 2010;52:900–907.
[18] Lurie J, Birkmeyer N, Weinstein J. Rates of advanced spinal imaging and spine surgery. Spine (Phila Pa 1976). 2003;28:616–620.
[19] Donelson R, Aprill C, Medcalf R, et al. A prospective study of centralization of lumbar and referred pain: A predictor of symptomatic discs and anular competence. Spine. 1997;22(10):1115–1122.
[20] Kopp J, Alexander A, Turocy R, et al. The use of lumbar extension in the evaluation and treatment of patients with acute herniated nucleus pulposus, a preliminary report. Clin Orthopedics. 1986;202:211–218.
[21] Rasmussen C, Nielsen G, Hansen V, et al. Rates of lumbar disc surgery before and after implementation of multidisciplinary nonsurgical spine clinics. Spine. 2005;30:2469–2473.
[22] Laslett M, Öberg B, Aprill C, et al. Centralization as a predictor of provocation discography results in chronic low back pain, and the influence of disability and distress on diagnostic power. Spine J. 2005;5:370–380.
[23] Donelson R, Grant W, Kamps C, et al. Pain response to repeated end-range sagittal spinal motion: a prospective, randomized, multi-centered trial. Spine. 1991;16(6S):206–212.
[24] Franz A, Lacasse A, Donelson R, et al. Effectiveness of directional preference to guide management of low back pain in Canadian Armed Forces members: a pragmatic study. Mil Med. 2017;182:e1957–66.
[25] Karas R, McIntosh G, Hall H, et al. The relationship between non-organic signs and centralization of symptoms in the prediction of return to work for

patients with low back pain. Phys Ther. 1997;77 (4):354–360.
[26] Larsen K, Weidick F, Leboeuf-Yde C. Can passive prone extensions of the back prevent back problems? A randomized, controlled intervention trial of 314 military conscripts. Spine. 2002;27:2747–2752.
[27] Long A. The centralization phenomenon: its usefulness as a predictor of outcome in conservative treatment of chronic low back pain. Spine. 1995;20 (23):2513–2521.
[28] Snook S, Webster B, McGorry R, et al. The reduction of chronic nonspecific low back pain through the control of early morning lumbar flexion: a randomized controlled trial. Spine. 1998;23:2601–2607.
[29] Sufka A, Hauger B, Trenary M, et al. Centralization of low back pain and perceived functional outcome. J Orthopedics Sports Phys Ther. 1998;27(3):205–212.
[30] Werneke M, Hart DL. Centralization phenomenon as a prognostic factor for chronic low back pain and disability. Spine. 2001;26(7):758–765.
[31] Werneke M, Hart DL, Cook D. A descriptive study of the centralization phenomenon. A prospective analysis. Spine. 1999;24(7):676–683.
[32] Donelson R, Silva G, Murphy K. The centralization phenomenon: its usefulness in evaluating and treating referred pain. Spine. 1990;15(3):211–213.
[33] Oliver D, May S. An observational study of centralization and directional preference in older patients with back pain. Int J Mech Diagn Therapy. 2010;5:3–5.
[34] Spratt K, Weinstein J, Lehmann T, et al. Efficacy of flexion and extension treatments incorporating braces for low-back pain patients with retrodisplacement, spondylolisthesis, or normal sagittal translation. Spine. 1993;18(13):1839–1849.
[35] Williams M, Hawley J, McKenzie R, et al. A comparison of the effects of two sitting postures on back and referred pain. Spine. 1991;16(10):1185–1191.
[36] Brennan G, Fritz J, Hunter S, et al. Identifying subgroups of patients with acute/subacute "nonspecific" low back pain. Results of a randomized clinical trial. Spine. 2006;31:623–631.
[37] Browder D, Childs J, Cleland J, et al. Effectiveness of an extension-oriented treatment approach in a subgroup of patients with low back pain: a randomized clinical trial. Phys Ther. 2007;87(12):1–11.
[38] Fritz J, Delitto A, Erhard R. Comparison of classification-based physical therapy with therapy based on clinical practice guidelines for patients with acute low back pain: a randomized clinical trial. Spine. 2003;28(13):1363–1371.
[39] Guzy G, Franczuk B, Krakowska A. A clinical trial comparing the McKenzie method and a complex rehabilitation program in patients with cervical derangement syndrome. J Orthop Trauma Surg Rel Res. 2011;2:32–38.
[40] Kilpikoski S, Alen M, Paatelma M, et al. Outcome comparison among working adults with centralizing low back pain: secondary analysis of a randomized controlled trial with 1-year follow-up. Adv Physiother. 2009;1:1–8.
[41] Long A, Donelson R, Fung T. Does it matter which exercise? A randomized controlled trial of exercise for low back pain. Spine. 2004;29(23):2593–2602.
[42] Petersen T, Larsen K, Nordsteen J, et al. The effect of the McKenzie method as compared with that of manipulation when used adjunctive to information and advice for patients with clinical signs of disc-related peristent low back pain. A randomized controlled trial.. Spine. 2011;36:1999–2010.
[43] Schenk R, Jazefczyk C, Kopf A. A randomized trial comparing interventions in patients with lumbar posterior derangement. J Manipulative Physiol Ther. 2003;11(2):95–102.
[44] van Helvoirt H, Apeldoorn A, Knol D, et al. Transforaminal epidural steroid injections influence Mechanical Diagnosis and Therapy (MDT) pain response classification in candidates for lumbar herniated disc surgery. J Back Musculoskelet Rehabil. 2016;29:351–359.
[45] Wennberg J, Thomson P. Time to tackle unwarranted variations in pract¡ce. BMJ. 2011;342:d1513.
[46] Clare H, Adams R, Maher C. Reliability of the McKenzie spinal pain classification using patient assessment forms. Physiotherapy. 2004;90:114–119.
[47] Clare H, Adams R, Maher C. Reliability of McKenzie classification of patients with cervical and lumbar pain. J Manipulative Physiol Ther. 2005;28(2):122–127.
[48] Kilby J, Stigant M, Roberts A. The reliability of back pain assessment by physiotherapists, using a "McKenzie algorithm". Physiotherapy. 1990;76 (9):579–583.
[49] Kilpikoski S, Airaksinen O, Kankaanpää M, et al. Interexaminer reliability in low back pain assessment using the McKenzie method. Spine. 2002;27:E207–14.
[50] Razmjou H, Kramer J, Yamada R. Inter-tester reliability of the McKenzie evaluation of mechanical low back pain. J Orthopedic Sports Phys Ther. 2000;30(7):368–383.
[51] Wilson L, Hall H, McIntosh G, et al. Intertester reliability of a low back pain classification system. Spine. 1999;24(3):248–254.
[52] Delitto A, Cibulka M, Erhard R, et al. Evidence for an extension-mobilization category in acute low back syndrome: a prescriptive validation pilot study. Phys Ther. 1993;73(4):216–228.
[53] Erhard R, Delitto A, Cibulka M. Relative effectiveness of an extension program and a combined program of manipulation and flexion and extension exercises in patients with acute low back syndrome. Phys Ther. 1994;74:1093–1100.
[54] Petersen T, Kryger P, Ekdahl C, et al. The effect of McKenzie therapy as compared with that of intensive strengthening training for the treatment of patients with subacute or chronic low back pain: A randomized controlled trial. Spine. 2002;27:1702–1709.
[55] Schenk R., Jozefczyk C.Kopf A. 2003. A randomized trial comparing interventions in patients with lumbar posterior derangement. Journal Of Manual & Manipulative Therapy 11 (2):95-102. doi:10.1179/106698103790826455.
[56] Clare H, Adams R, Maher C. A systematic review of efficacy of McKenzie therapy for spinal pain. Aust J Physiother. 2004;50:209–216.
[57] Aina S, May S, Clare H. The centralization phenomenon of spinal symptoms - a systematic review. Manual Ther. 2004;9:134–143.
[58] Cook C, Hegedus E, Ramey K. Physical therapy exercise intervention based on classification using the patent response method: a systematic review of the literature. J Manipulative Physiol Ther. 2005;13:152–162.
[59] Donelson R. Rapidly reversible low back pain: an evidence-based pathway to widespread recoveries and savings. Hanover, NH: SelfCare First, LLC; 2007.

[60] Porter M. What is value in health care? N Engl J Med. 2010;363:2477–2481.
[61] Mattern C. A strategy for addressing muscuolskeletal disease through integrated mechanical care. Integrated Mechanical Care: An Update Austin, TX. 2012 Oct 5

Addendum
A Description of Mechanical Care (MC)

MC clinicians perform a detailed history of pain location and duration, any consistent pattern of pain reproduction, relief, and functional gain or loss related to daily positions, movements, and activities. Patients are assisted to recognize patterns and associations between them.

The physical examination then assesses the immediate symptom and functional responses to specific, repeated, end-range joint-loading tests that determine/confirm relationships, or lack thereof, between any patterns of symptom or functional response.

One very common pattern of symptom response during or as a result of testing is called 'pain centralization' (PC). That refers to the patient describing that the pain location is retreating back toward the lumbar midline, usually as a result of performing repeated end-range movements in a single direction of spinal bending. PC is a very reliable sign that something beneficial is occurring to the pain generator. That single direction of beneficial testing is referred to as the pain generator's 'directional preference' (DP). Lumbar extension is the most common DP revealed during this mechanical assessment.

Combining the historical and clinical information enables sub-grouping the patient's condition. This precisely determines and then drives patient-specific treatment movements and exercises that eliminate most subject's pain as well as those that reproduce and aggravate it.

Patients are then coached to make subsequent clinical decisions by frequently performing those movements that eliminate and then prevent the return of their pain while temporarily avoiding positions and movements that reproduce the pain.