

Medicaid Acupuncture Pilot Project Outcomes Report

Report to the House Committees on Health Care and on Human Services; Senate Committee on Health and Welfare Pursuant to Act 173 of 2016, Sec. 15a

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Acupuncture for Chronic Pain in the Vermont Medicaid Population Final Report

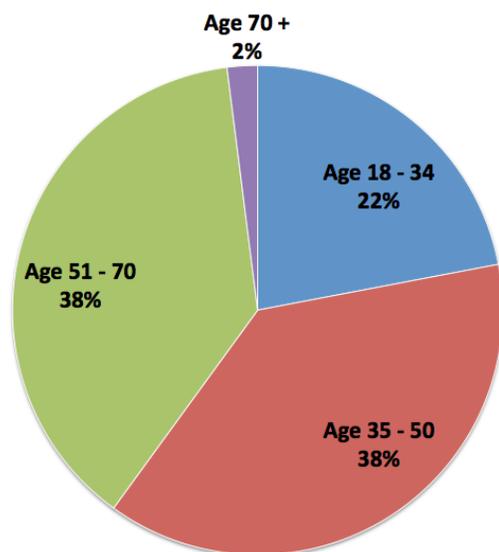
Background: In seeking to address issues related to the opioid crisis, Vermont legislators acknowledged that non-pharmacologic treatments have been recognized as an important strategy in the management of pain.¹⁻⁶ An advantage of this approach is the avoidance of serious adverse events associated with opioids and other medications commonly used to treat or manage pain.⁷⁻¹⁴ The efficacy of acupuncture for the treatment of common chronic pain conditions has been documented in randomized controlled trials.¹⁵ The safety of acupuncture is also documented.¹⁶⁻¹⁸ The 2016 Vermont Legislature appropriated \$200,000 to fund a pilot study to assess acupuncture as an adjunct therapy for the treatment of chronic pain in the Vermont Medicaid population.¹⁹

Research Design and Description: A pilot-level prospective pragmatic intervention trial design was chosen as the most appropriate approach for this project after a thorough analysis of the legislative goals, resources, and timeline provided by Act 173, along with a review of the existing scientific literature. Several acupuncture trialists considered to be subject-matter experts by their peers were consulted in order to confirm the soundness of this approach. Qualitative interviews were also utilized to understand the experience from the patients' perspective. Pragmatic trials are designed to answer questions useful to clinicians and policy makers because they aim to maximize external validity and generalizability to a real-world setting.²⁰⁻²¹ This pilot included a heterogeneous group of chronic pain patients that were treated by Vermont-licensed acupuncturists who provided treatment in their private clinics in line with their standard practice. This design was intended to reflect what would happen if acupuncture reimbursement were offered for local chronic pain patients by the local population of acupuncturists. As a Phase 1 uncontrolled pilot, this study was designed to provide qualitative and implementation data that may help policy-makers. The Department of Vermont Health Access (DVHA) decided this was the best research design available in the short timeframe. A thorough description of the rationale for this approach is described in the Progress Report to the Legislature²² and a journal article published on this topic²³.

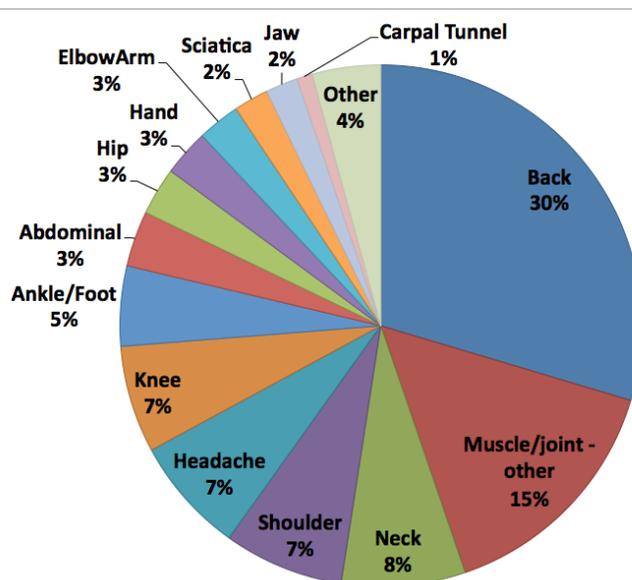
Protection of Human Subjects – This project was approved by the Agency of Human Services Institutional Review Board (IRB) in order to assure compliance with applicable standards protecting the safety and privacy of human subjects during research. No members of vulnerable populations (e.g. children, prisoners, institutionalized patients) were included in this trial.

Population: 156 adult Vermont Medicaid patients were consented and enrolled (211 patients screened, 174 met eligibility criteria) from referrals and advertisements in three counties: Chittenden, Washington and Windsor. Participants were screened to ensure a minimally qualifying pain score for at least 15 out of the past 30 days and for at least the past 3 months. Patients were excluded if they had started a new treatment for pain or had received any acupuncture treatment within the 4 weeks prior to the onset of treatment in this trial. 29% of patients were male and 71% were female.

Participant Age Distribution in Years



Participant Chief Pain Complaints



Intervention: Participants were eligible to receive up to 12 acupuncture visits within a 60 day period at no charge. Treatments were administered in the offices of 28 participating Licensed Acupuncturists. 1274 treatments were delivered during the course of the study. The mean number of treatments received was 8.17 per patient. Twenty patients (13%) received zero visits. Sixty patients (38%) received all 12 visits. 72% of patients received at least 6 visits.

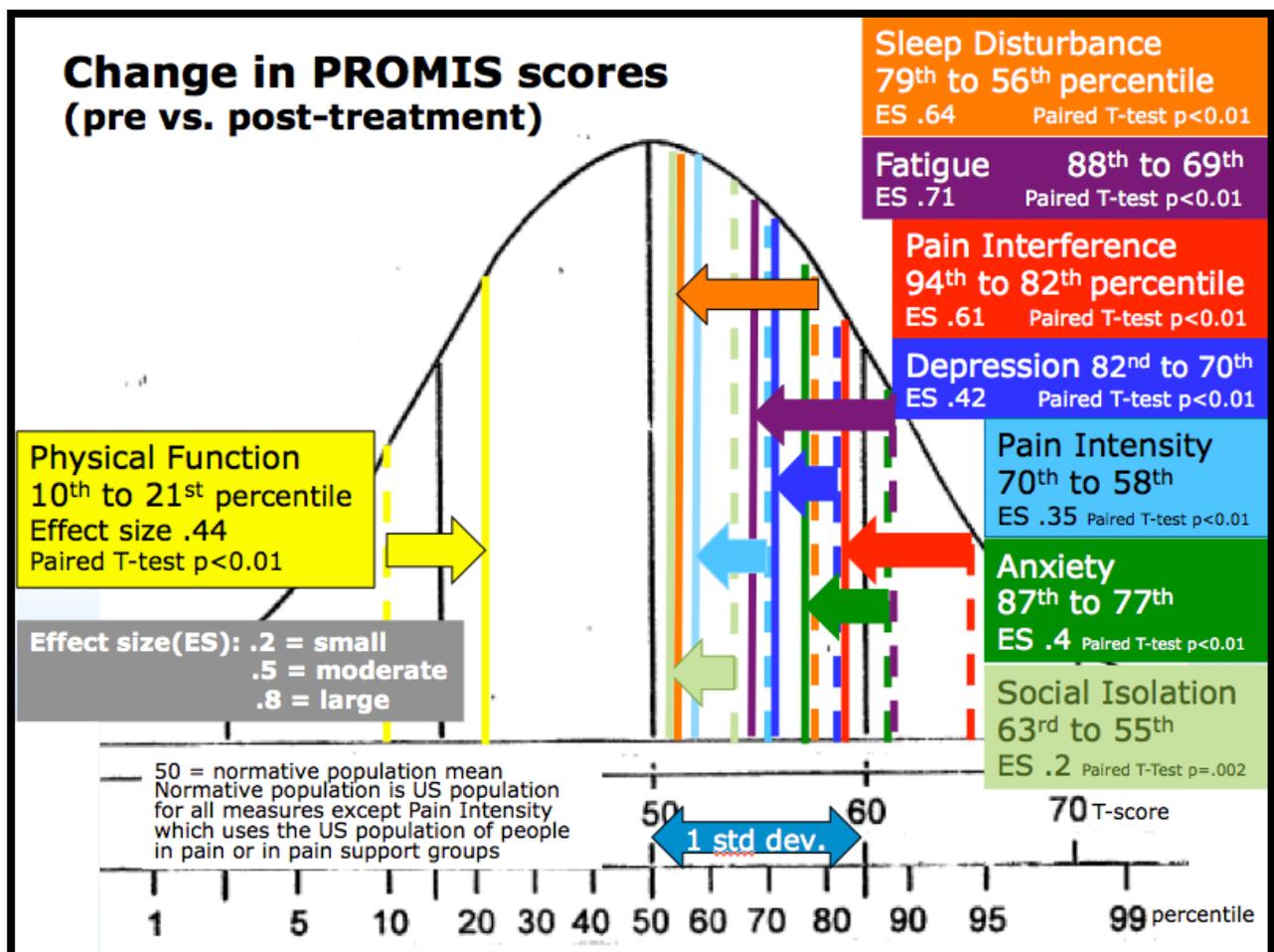
Comparison: This was an uncontrolled, non-blinded trial comparing Pre- and Post-treatment outcome measures.

Outcome Measures: a) NIH-developed and validated PROMIS® (Patient-Reported Outcomes Measurement Information System) questionnaires in eight domains – pain intensity, pain interference, physical function, fatigue, anxiety, depression, sleep disturbance, and social isolation; b) open ended questionnaires assessing medication use, occupational status, and subjective impressions; c) descriptive data – total visits used, main and secondary complaints; d) DVHA utilization analyses assessing medical utilization before, during and after treatment

Results:

PROMIS Questionnaires – patients demonstrated clinically meaningful+ improvements in seven of eight domains and statistically significant# improvements in all eight domains over the course of their 60 day treatment period.

<u>Domain</u>	<u>Improvement in Percentile Score</u>
Sleep Disturbance	23 points (Paired T-test p<0.01) #+
Fatigue	19 points (Paired T-test p<0.01) #+
Pain Interference	12 points (Paired T-test p<0.01) #+
Depression	12 points (Paired T-test p<0.01) #+
Pain Intensity	12 points (Paired T-test p<0.01) #+
Physical Function	11 points (Paired T-test p<0.01) #+
Anxiety	10 points (Paired T-test p<0.01) #+
Social Isolation	8 points (Paired T-test p<0.01)



Open Ended Questionnaires –

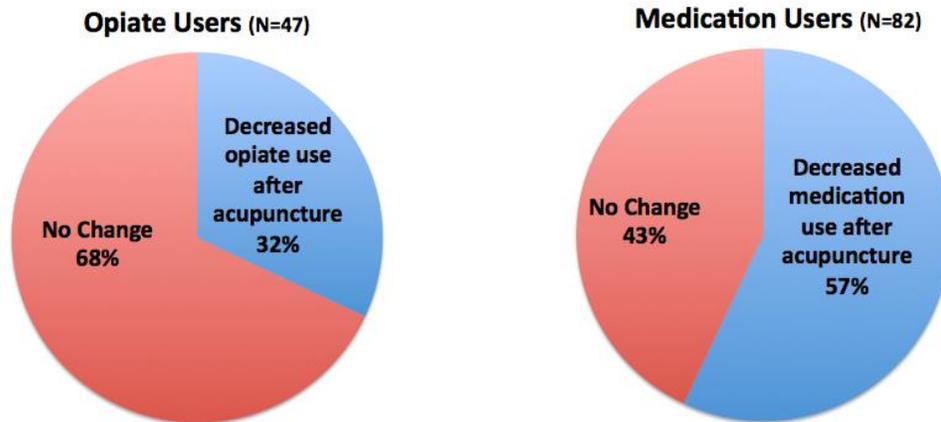
Medication Use

Prior to acupuncture:

- 72% of respondents reported using medications to manage their pain.
- 43% of medication users reported experiencing unwanted side effects (e.g. upset stomach, nausea, drowsiness, constipation, fatigue, dry mouth, grogginess, loppiness, forgetfulness.)

After acupuncture:

- 57% of medication users reported a decrease in their medication use.
- 32% of opiate users reported a reduction in their opiate use.



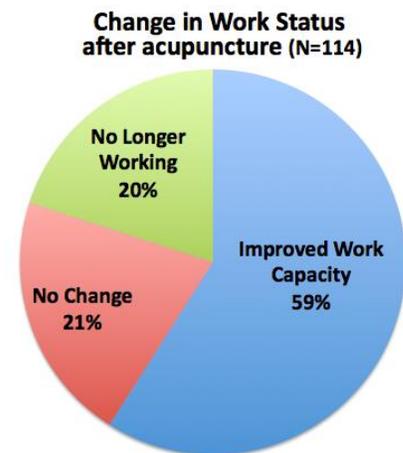
Work Status

Prior to acupuncture:

- 97% of respondents said their pain had negatively impacted their work.

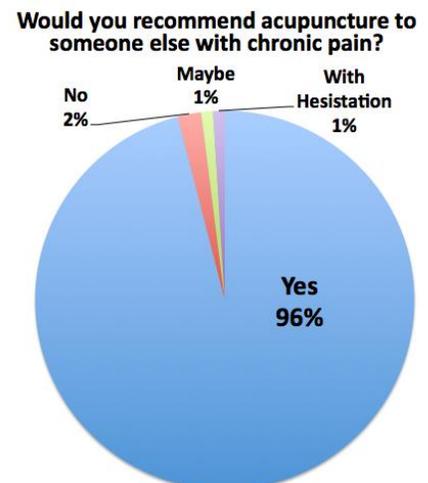
After acupuncture:

- 59% of respondents reported an improvement in their work capacity.
- 21% reported no improvement in work capacity.
- 20% not applicable – no longer working.



Would you recommend acupuncture to someone else with chronic pain?

- 96% – “Yes”
- 2% – “No”
- 1% – “Maybe”
- 1% – “With hesitation”



Is there anything else you would like Vermont health care policy makers to know about your experience with acupuncture?

- 91% of respondents commented on perceived qualitative improvements from acupuncture, most notably in the following areas:
 - Physical – 31% of comments (e.g. pain reduction, other positive physical changes)
 - Functional/Behavioral – 29% of comments (e.g. improved activities of daily living, improved energy, reduced use of other medical services)
 - Psycho-emotional – 24% of comments (e.g. improved sense of wellbeing, positive changes in emotional state, increased ability to relax, increased options and hope)
 - Other – 11% of comments (e.g. wished acupuncture could continue, felt listened to by acupuncturist)
- 8% of respondents reported no notable changes from acupuncture.
- 1% (1 patient) reported a flare in pain after the second treatment.

Please see Appendix A for representative quotes on medication use and work status after acupuncture treatment, as well as general comments from pilot participants.

Medicaid Claims Demographic Information and Utilization Analysis:

The Department of Vermont Health Access (DVHA) conducted an analysis of pilot participants' medical and pharmacy utilization in the 60-day period prior to beginning acupuncture treatment, and the 60-day period after treatment ended. Utilization during the 60-day treatment period was not included in the analysis. A substantial number of the original 156 participants were excluded from the medical claims and pharmacy utilization analysis (n=30) due to receiving no acupuncture treatments or having gaps in complete medical/pharmacy coverage in this timeframe. Summary demographic information based on information collected during the study are provided in Table I.1 and Table I.2 for the remaining participants (see Appendix B). The majority (60%) of the participants with one or more acupuncture treatments completed the entire 12 treatment regimen. Fifty-five percent of the participants were age 45 and over, 73% were female, and 71% had only Medicaid coverage and no Medicare coverage.

Services utilization was examined for participants who received four or more acupuncture sessions as reported by the acupuncture practices (n = 109) as there was an assumption during the study that four or more treatments were required for a substantial benefit due to acupuncture. Though some pre and post changes in services utilization after four or more acupuncture treatments were fairly substantial there were no findings identified as statistically significant. As such the utilization data itself cannot validate the efficacy of acupuncture in this pilot in terms of clinical outcomes or cost-effectiveness.

Several service categories had decreases in average cost of care among the participants with four or more acupuncture treatments. These were outpatient emergency department (ED), PCP office visits, opioid pharmacy, diagnostic laboratory, and chiropractic services (see Table I.3 in Appendix B). For Outpatient ED there were the same number of participants with one or more ED visits (Table I.4 in Appendix B) during the pre and the post acupuncture treatment periods, but the costs decreased. PCP office visits decreased both in number of participants and costs and had the lowest observed levels of significance due to the high frequency of utilization. Opioid pharmacy costs decreased substantially but there were only 11 participants in both the pre and post acupuncture periods with opioid pharmacy claims.

The services that increased in cost were total pharmacy and physical therapy. Since both pharmacy and physical therapy showed a decline in participants with one or more services and costs increased, the intensity or unit cost of pharmacy and physical therapy were driving an increase in cost.

Observations from the Pilot Lead Investigator:

- Recruitment and enrollment goals were achieved more quickly and with less effort than anticipated based on the norm for clinical trials. This may or may not suggest that there is demand for acupuncture amongst Vermont Medicaid patients.

- One of the reasons for the volume and speed of recruitment is that a majority of patients were referred by physicians. Whether that indicates the demand for and acceptability of acupuncture by the Vermont physician community in Vermont is high cannot be stated.
- Recruiting acupuncture providers to participate in the study was not an issue. This could suggest that a significant proportion of the workforce of approximately 200 Licensed Acupuncturists in Vermont would be willing to serve this population if the reimbursement and administrative requirements were similar to pilot levels.

Discussion:

- Evidence from this study suggests that Vermont patients who self-select acupuncture for the treatment of their chronic pain would benefit physically, functionally, psycho-emotionally and occupationally.
- This study did not confirm the efficacy of acupuncture in treating chronic pain in the general population (i.e. those who do not self-select).
- The relative ease of recruitment and waiting list for this study may suggest there is a demand for these services from patients (as a treatment option) and health care professionals (as a referral option).
- A growing number of professional clinical guidelines recommend acupuncture and other non-pharmacological treatments for chronic pain.¹⁻⁶ Lack of insurance reimbursement for acupuncture may be a barrier for successful adoption of these guidelines. This may be especially relevant for the Medicaid population.
- Analysis of Medicaid claims data led to no findings of statistical significance possibly due to the small sample size.

Strengths:

- Uses validated patient-centric outcome measures referenced to appropriate normative US populations.
- Qualitative data may provide important insight into patient values and experiences not captured elsewhere. Pragmatic Design – provides high confidence that results would generalize to Vermont health care system (VT Medicaid patients, VT Licensed Acupuncturists and VT referral sources).
 - Naturalistic enrollment mimics current acupuncture insurance coverage practices.
 - “real world” patient diversity – non-restrictive and heterogeneous pain diagnoses and complicated co-morbidities allowed
 - Geographic diversity (treatments in three counties, patients from 11 counties)
 - Practitioner diversity (not “cherry-picked” for experience or style of practice). Average duration of Vermont acupuncture license = 9.67 years, range = 8 months to 21 years
 - Patients allowed to choose their own provider

Limitations:

- This study was not designed to make direct comparisons between the use of acupuncture and opioids for chronic pain.
- This study in isolation is not able to rule out that observed changes could be due to non-acupuncture variables.
- This pilot does not provide data regarding the long-term effects of acupuncture on our patients.
- Any study conducted by a group that would potentially benefit from the outcomes has an inherent bias.
- No conclusion can be reached whether acupuncture would be any more effective than any other non-pharmacologic therapy not currently covered by Medicaid such as massage or yoga.
- No Strength of Recommendation (SOR) designation that the current emphasis on evidenced-based medicine demands can be assigned to this pilot for all of the above reasons.

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APPENDIX A

Representative quotes re: medication use after acupuncture:

- “less oxycodone and ibuprofen”
- “50% less hydrocodone”
- “much less Tramadol and no Tizanadine since acupuncture”
- “only 1 pill of muscle relaxer instead of 2”
- “has not taken any oxycodone since treatment”
- “less morphine, docs taking me down on oxys slowly”
- “off tramadol and aleve/tylenol/ibuprofen used half as often as before”
- “less lyrica, tramadol as needed but haven’t needed it”

Representative quotes re: work status after acupuncture:

- “don’t work, but helped with household chores.”
- “can work 30 hrs a week and was working none before!”
- “quality of work increased- much more settled and engaged”
- “added 10 hrs per week!”
- “no improvement, but I only had one treatment.”
- “more focused”
- “can work more, more focus, feel clearer/more productive”
- “been out with severe headaches less now “
- “can stand for multiple 9 hr shifts in a row, less pain after work “
- “could previously only give 2 massages/day but can go back to 3/day now“
- “got a job!”
- “I work a physically demanding job, and I have been able to return to work”

Representative general comments:

- "My acupuncture was life changing... I saw and felt and continue to feel a marked difference in my pain and mental clarity. I believe it saved my life."
- "Acupuncture helped me to get my life back."
- "I was very skeptical about this treatment being effective. As the weeks went by, I noticed different changes taking place in my body: my digestive system functioned much better, so my diet improved; I required less sleeping medication because my sleep was better; my pain level was much decreased; I had more genuine energy; and most especially, I had better mobility. The mobility change enabled me to walk more in fresh air and increased my good energy level. A circle of reinforcements that has made my life much better, more productive and happier. It has cut down my need for other medical interventions like physical therapy and medications for various ailments. People have noticed the outward improvement."
- "I went to a regular doctor for over six years and my pain only became more intense and more frequent. This is the longest I've gone without pain or medication in well over a year."
- “this is a very necessary way to treat pain. I am very allergic to many medications and during the study I was able to walk and do more without an allergic reaction.”
- "I would consider the acupuncture treatment I received to be the most effective of every treatment option I've ever tried in my life at reducing my pain and increasing my quality of life, as well as the quickest in producing results. I was able to stop taking all my pain medications while receiving acupuncture and was even able to try a few physical activities (such as yoga) that have caused me pain in the past. I only wish I could continue to receive acupuncture as I believe it's the one treatment with results that would allow me to work full time... if I was able to continue treatments if/when my pain flared up again."
- "I literally went in there day one thinking it was quack science and now I desperately miss it."
- “Gained 2 hours of sleep a night from the acupuncture because it helped me relax. 100% would recommend to anybody with pain.”

- "I have received acupuncture before but it was the consistent treatments that I felt a shift happen in my healing process."
- "It has somewhat improved my quality of life. It has significantly reduced the frequency of migraine headaches and helped to reduce arthritis pain in my neck and shoulders. Was not effective for osteoporosis back pain or peripheral neuropathy in hands and feet pain."
- "Makes huge difference in well being, physical and mental. Helps with pain, sleep, cognition."
- "If it had been covered, I may not of gotten [sic] so many scripts of narcotics and gotten addicted to opiates."

APPENDIX B

Medicaid Claims Demographic Information and Utilization Data

Table I.1 Number of Participants by Number of Treatments Received, Opioid Self Report, and Location of Acupuncture Practice

Number of Acupuncture Treatments Per Person		
	#	%
1 to 3	17	13.5%
4 to 6	11	8.7%
7 to 9	22	17.5%
10 to 12	76	60.3%
Total	126	100.0%
Opioid User Self Report		
	#	%
No	90	71.4%
Yes	36	28.6%
County of Acupuncture Site		
	#	%
Chittenden	60	47.6%
Washington	54	42.9%
Windsor	12	9.5%

Table I.2 Number of Participants by Age, Gender, and Dual Medicaid & Medicare Coverage

Age	#	%
18-34	28	22.2%
35-44	28	22.2%
45-54	32	25.4%
55+	38	30.2%
Gender	#	%
Female	92	73.0%
Male	34	27.0%
Medicaid and Medicare Coverage		
	#	%
Medicaid only	89	70.6%
Both	37	29.4%

Table I.3 Service Allowed Amounts (30-day rate) During the Baseline and Post Acupuncture

	<u>Baseline</u>	<u>Post</u>	<u>Δ%</u>	<u>p</u>[‡]
Outpatient ED	\$32	\$16	-51%	0.59
PCP Office	\$75	\$65	-14%	0.14
Specialty Office	\$16	\$13	-19%	0.51
MH/Psychiatry	\$208	\$191	-8%	0.24
Total Pharmacy	\$108	\$189	74%	0.32
- Opioids Rx	\$4	\$2	-53%	0.15
Diagnostic Radiology	\$28	\$35	23%	0.82
Diagnostic Laboratory	\$43	\$24	-44%	0.16
Physical Therapy	\$34	\$46	35%	0.96
Chiropractic	\$8	\$7	-21%	0.56

[‡] Significance levels based on Wilcoxon signed rank test. No changes in median allowed charge amounts were found significant at the alpha < 0.05 level.

Table I.4 Presence of Services During the Baseline and Post Acupuncture

	<u>Baseline</u>	<u>Post</u>	<u>Δ%</u>	<u>p</u>[†]
Outpatient ED	9	9	0%	1.00
PCP Office	80	72	-10%	0.23
Specialty Office	25	29	16%	0.52
MH/Psychiatry	57	58	2%	1.00
Total Pharmacy	63	59	-6%	0.48
- Opioid Rx	11	11	0%	1.00
Diagnostic Radiology	29	31	7%	0.86
Diagnostic Laboratory	46	44	-4%	0.86
Physical Therapy	28	25	-11%	0.71
Chiropractic	17	16	-6%	1.00

[†] Significance levels based on McNemar paired test. No changes in service utilization were found significant at the alpha < 0.05 level.