

## **Response to Blue Cross Blue Shield of Vermont's Report to the Vermont General Assembly: Insurance Coverage for Acupuncture**

In January of 2017 Blue Cross Blue Shield of Vermont (BCBSVT) filed a report to the Vermont Legislature entitled, "Report to the Vermont General Assembly: Insurance Coverage for Acupuncture." This report was filed to comply with Section 15 of Act No. 173, 2015 (Adj. Sess.), *An act relating to combating opioid abuse in Vermont*, directing BCBSVT to:

evaluate the evidence supporting the use of acupuncture as a modality for treating and managing pain in its enrollees, including the experience of other states in which [acupuncture] is covered by health insurance plans [and report] its assessment of whether its insurance plans should provide coverage for acupuncture when used to treat or manage pain.

Note: Prior to submitting this response to the legislature, it was forwarded as a courtesy to the Chief Medical Officer at BCBSVT. It is our understanding that BCBSVT intends to file an amended report with the legislature which will correct some of the errors identified below. We appreciate this correction to the record.

**Several serious problems have been identified in the BCBSVT report.** These problems are summarized as follows:

**1) The report understates the benefits of acupuncture in the following ways:**

- a. **The report cites 2005 data to suggest that acupuncture is unproven for the treatment of low back pain and other pain conditions while totally omitting recent high quality literature supporting the efficacy of acupuncture for low back pain and a range of other pain conditions.**

Regarding low back pain, the report states, "*The evidence is insufficient to determine the effects on health outcomes.*" To support this, the report cites a 2005 Cochrane review including trials covering 2861 patients, but omits a high quality 2006 low back pain trial with over 11,000 patients that concluded "Acupuncture plus routine care was associated with marked clinical improvements in these patients and was relatively cost-effective."<sup>1</sup> Furthermore, data was totally omitted from a landmark 2012 meta-analysis which included only the highest quality trials, examining data from nearly 18,000 patients who received acupuncture for chronic pain conditions including back and neck pain, osteoarthritis, chronic headache, and shoulder pain. The data indicated that, "Acupuncture is effective for the treatment of chronic pain and is therefore a reasonable referral option. Significant differences between true and sham acupuncture indicate that acupuncture is more than a placebo."<sup>2</sup>

- b. **The report suggests that acupuncture's effects are short-lived while failing to cite relevant evidence regarding the persistence of acupuncture's effects after a course of treatment.**

In multiple instances, the report highlights phrases in bold to suggest the effects of acupuncture may not be lasting. However, the report totally omitted a recent paper analyzing high quality trials specifically around the question of persistence of acupuncture effects for pain patients. The analysis included data from 6376 patients and suggests that about 90% of the benefit of acupuncture relative to pragmatic controls would be sustained at 12 months.<sup>3</sup>

**c. The report acknowledges that acupuncture is beneficial for migraines and tension-type headaches but concludes that no coverage is warranted for these conditions.**

The data suggest that a benefit for the treatment of headaches would benefit a large group of patients and could therefore impact the utilization of the ER and the use of opioids:

14.2% of US adults 18 or older reported having migraine or severe headache in the previous 3 months. Headache or pain in the head was the fourth leading cause of visits to the emergency department (ED) in 2009-2010, accounting for 3.1% of all ED visits. In 2010, opioids were administered at 35% of ED visits for headache.<sup>4</sup>

**2) The report asserts that an acupuncture benefit would create “undue administrative burden” and “excessive costs” without offering any data or quantification to support the claim.**

The report states *“Developing and supporting an appropriate infrastructure to manage an acupuncture benefit would create undue administrative burden to providers and excessive costs to the health care system....”* However no cost estimates or estimates of administrative burden are provided. A cost/benefit argument against the use of acupuncture that fails to quantify cost is useless.

BCBSVT has not provided any acupuncture administrative impact or cost data to the legislature, but we do know the following:

- Regarding infrastructure, BCBSVT already has an existing network of Licensed Acupuncturists who serve patients employed by the State of Vermont and the University of VT Medical Center. Presumably, this same infrastructure could be used to service patients statewide without any additional implementation costs and very little administrative burden.
- Regarding costs, published evidence from other states indicates that an acupuncture benefit costs less than \$1 per member per month and remains stable.<sup>5,6</sup>

**3) The report includes pilot data in a sloppy and irregular manner and uses this to falsely suggest there may be potential harm in using acupuncture.**

The phrase “possibility of harm” or “potential harm” is repeated at least three times in the report, including prominently in the introduction and conclusion. There is nothing in the cited data, nor is there anything in the broader body of literature, so far as we are aware, that would support the assertion that there are any significant potential harms associated with the use of acupuncture. This is well documented on

an absolute basis (see point 6 below). It is also true on a relative basis, when compared with potential harms associated with commonly used and reimbursed surgical and pharmacological treatments for pain.

The prominent use of the words “harm” and “harmful” in the report are not appropriate for the following specific reasons:

- 1) The study cited is a pilot, including 35 patients.<sup>7</sup> In order to be adequately powered to detect differences in treatment effect between real and sham acupuncture needling, the most experienced acupuncture clinical trialists tell us that a study needs over 1000 patients. The authors of the study explicitly state that they failed to accrue as many patients as planned and that it is underpowered to properly detect differences. Usual professional standards would preclude underpowered pilot data from being considered when drawing conclusion for a report such this.
- 2) Even if these pilot results had been derived from a properly powered trial, the results would not justify the conclusion that acupuncture was associated with patient harm. In the pilot study cited, baseline medication use for “true” electroacupuncture recipients was 461 units, decreasing to 281 after 8 weeks of treatment. Subsequently, after 12 weeks of no treatment, medication use increased to 345 units. One could argue that the treatment effects weren’t lasting after treatment was ceased, but there is no justification to say that these patients were harmed. They still used less opiates than they had been using at the beginning of the trial. One would expect methadone users to regress if they stopped using methadone after a few weeks, but it would be incorrect to claim that they had been harmed by the methadone. The fact that sham electroacupuncture patients (who had needles inserted at non-classical acupuncture points but no electricity applied) regressed less than “true” electroacupuncture recipients could simply be interpreted as showing that manual acupuncture’s effects last longer than electroacupuncture’s. Of course, this is hypothetical because the pilot was grossly underpowered and we cannot pretend that any real difference between the two groups existed.

#### **4) The report fails to appropriately weigh the value of pragmatic vs. explanatory trials for the purpose of making clinical and policy decisions**

Pragmatic trial designs are more appropriate for understanding what works in the “real world” than are explanatory trial designs and should be weighted accordingly when making policy decisions. To understand this, it is important to understand some differences in methodology and purpose between explanatory trials and pragmatic trials. Explanatory trials, which were disproportionately cited in the BCBSVT report, are designed to test whether the effects of a given therapy have a physiological basis beyond placebo effects. In order to draw firm conclusions, such trials use strict controls and designs that artificially maximize their internal validity. For example, many patients who see their health care providers for chronic pain would be excluded from a typical explanatory trial due to strict inclusion/exclusion criteria that provide the homogeneity necessary for definitive conclusions. Additionally, practitioners in explanatory trials are usually restricted by treatment protocols that inhibit replication of usual care. While explanatory trials help us understand mechanisms of action and

serve a necessary gate-keeping function, they are neither designed nor well-suited for making clinical and policy decisions.<sup>8</sup> Pragmatic trials, in contrast, 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.<sup>9,10</sup> For example, most pragmatic trials study a therapy in the context it is actually practiced (rather than an artificially restricted or controlled setting) in a population that health providers actually see. Therefore, pragmatic trials deliberately include participants who reflect the heterogeneity and co-morbidities commonly seen in clinical practice. While these participants would not be appropriate in an explanatory trial; in a pragmatic trial, they provide evidence of the real-world impacts of a proposed therapy or policy decision.

The BCBSVT report correctly noted that, “*Assessment of the efficacy of a therapeutic intervention involves a determination whether the intervention improves health outcomes compared with available alternatives.*” However, rather than cite pragmatic trials which directly compare acupuncture with available alternatives, the report states that since pain conditions “*may be particularly susceptible to placebo effects... sham-controlled trials are essential to demonstrate the clinical effectiveness of acupuncture compared with alternatives, e.g. continued medical management.*” Unfortunately the report does neither, as it failed to consider recent sham-controlled acupuncture trials demonstrating the superiority of acupuncture to sham acupuncture for chronic pain while also failing to consider trials which compare acupuncture to available alternatives. Pragmatic trials are designed to directly compare an intervention with available alternatives. Pragmatic trials overwhelmingly favor the effectiveness of acupuncture over usual care, wait list, and no treatment controls. Explanatory trials are important but should not be over-weighted in the context of coverage decisions.

#### **5) The report fails to apply consistent coverage decision standards**

If BCBSVT insists that explanatory placebo controlled trials form the basis for coverage decisions, why do they allow coverage for steroid injections and most surgical procedures? With the exception of knee pain and pain from vertebral fractures, we are not aware of a sham-controlled evidence basis for most commonly reimbursed surgical procedures.

Additionally, acupuncture has a similar effect size for pain<sup>9</sup> as NSAIDS<sup>10</sup> when compared to placebo controls, yet BCBSVT’s policy is to reimburse for NSAIDS and not for acupuncture.

#### **6) The report fails to consider acupuncture coverage in the context of risk, alternatives, and integrated interdisciplinary care**

The BCBSVT report was commissioned by the VT legislature in the context of the opioid bill, an effort to deal with harms created in part by prescription opioids which are reimbursed by BCBSVT. It is appropriate to consider risk when considering which treatments are appropriate and worthy of reimbursement. The report made no mention of the excellent safety profile of acupuncture,<sup>13,14,15</sup> nor did it mention that several of the most common treatments reimbursed by BCBS for the treatment of pain, for example opioids and NSAIDS, carry significant risks. For example, the CDC reports that opioid overdose deaths have quadrupled in the US in the period between 1999 and 2015. Nearly half of these cases involved a prescription opioid.<sup>16,17</sup> NSAID drugs include

prescription and over-the-counter drugs such as ibuprofen and naproxen. A systematic review of 17 prospective observational studies found that 11% of preventable drug-related hospital admissions could be attributed to NSAIDs.<sup>18</sup> Some estimates suggest that each year more than 100,000 patients are hospitalized for NSAID-related GI complications alone, with direct costs ranging from \$1800 to \$8500 per patient per hospitalization. Moreover, it has been reported that 16,500 persons die annually from these complications. In the elderly, the medical costs of adverse GI events associated with NSAID use likely exceed \$4 billion per year.<sup>19</sup>

The Joint Commission, a certification body that accredits hospitals, has clarified that “*both pharmacologic and non-pharmacologic approaches, as well as benefits and risks to patients*” should be considered when determining the most appropriate intervention. Joint Commission standard PC.01.02.07 goes on to specifically cite acupuncture therapy as an example of a non-pharmacologic therapy that should be considered for pain.<sup>20</sup>

A recent article in the Journal of the American Medical Association (JAMA) entitled, “As Opioid Epidemic Rages, Complementary Health Approaches to Pain Gain Traction,” notes that “A recent review of clinical evidence published in Mayo Clinic Proceedings by National Institute of Health researchers suggests that complementary health techniques have a legitimate place in a physician’s pain relief toolkit.” The article cites the evidence-based use of acupuncture for back pain and osteoarthritis of the knee. The paper quotes Dr. Madhu Singh, a physical medicine and rehabilitation orthopedic physician who points out that “many of these [physical medicine] approaches aren’t feasible for patients because insurance companies often don’t cover them,” noting that “physicians are often backed into a corner when dealing with a patient’s pain”, referring to the tendency to default to medications. The article also cites the 2011 Institute of Medicine Report on “Relieving Pain in America” which emphasizes “integrated, interdisciplinary pain assessment and treatment that includes complementary and alternative medicine and recommended that reimbursement policies should be revised to accommodate this approach.”<sup>21</sup>

## **7) The report fails to consider physicians’ clinical judgment and experience along with patient preferences**

David Sackett, considered the “father” of evidence-based medicine said, “Evidence-based medicine is the integration of the best research evidence with clinical expertise and patient choice.”<sup>22</sup> There is a well-documented demand by physicians and patients in Vermont for acupuncture services for patients with pain. A 2009 UVM College of Medicine survey of health care providers in Chittenden County documented a robust referral network between primary care doctors and acupuncturists. In a 2015 UVMMC survey of medical staff, 72% (126) of respondents said they would be interested in referring patients to acupuncture if it were available in the medical center. Of course, the largest barrier to offering acupuncture in this setting is the lack of widespread insurance coverage for the procedure.

## **8) Failure to cite relevant acupuncture recommendations by professional organizations in the supplemental section of the report**

Acupuncture is recommended by the following organizations for a variety of pain conditions:

- American College of Physicians and the American Pain Society - Low Back Pain<sup>23</sup>
- American Association of Family Practitioners – Low back pain, shoulder pain, neck pain, headache, migraine, knee osteoarthritis, fibromyalgia, temporomandibular joint pain, postoperative pain<sup>24</sup>
- American College of Chest Physicians – uncontrolled pain, post-thoracotomy pain<sup>25</sup>
- California Workers Compensation Medical treatment guidelines - “Acupuncture” is used as an option when pain medication is reduced or not tolerated, it may be used as an adjunct to physical rehabilitation and/or surgical intervention to hasten functional recovery. Acupuncture can be used to reduce pain, reduce inflammation, increase blood flow, increase range of motion, decrease the side effect of medication-induced nausea, promote relaxation in an anxious patient, and reduce muscle spasm.<sup>26</sup>
- American College of Occupational and Environmental Medicine – chronic moderate to severe neck pain, chronic myofascial pain, chronic low back pain, osteoarthritis of the hip or knee, adhesive capsulitis, lateral epicondylitis, migraines.<sup>27</sup>
- American College of Obstetricians and Gynecologists – Chronic pelvic pain<sup>28</sup>

**This report was prepared on behalf of the Vermont Acupuncture Association by Robert Davis, MS, Vermont Licensed Acupuncturist; Research Chair – UVM Program in Integrative Health; Co-President – Society for Acupuncture Research**

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