Strategies in the treatment of pain….

make it 'scorable'

Policy Revision of

Pain Management Standard to

Require non pharm therapies

Arya Nielsen, PhD
Icahn School of Medicine at Mount Sinai
Mount Sinai Beth Israel

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Arya Nielsen, PhD

- American acupuncturist
- Taught in the classical lineage of Dr. James Tin Yau So

- Practitioner, teacher, author, and researcher

- Assistant Clinical Professor, Icahn School of Medicine at Mount Sinai
- Directs: Acupuncture Fellowship for Inpatient Care, MSBI

- Author: *Gua Sha, A Traditional Technique for Modern Practice* (trans. German and French) now in second edition.
- *Gua Sha: Step-by-Step a teaching DVD.*

- Online Courses with ProD Seminars: www.prodseminars.com
  - Gua sha Certification Course (50 PDA)
  - Professional Safety (Part I) and Ethics (Part II) in Acupuncture Therapy [8 PDA]
  - 'Acupuncture Therapies' for Inpatient and Hospital-based Care [~20 PDA]

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  - Arya Nielsen, PhD
  - PCOM Symposium, 2016
- This allows others to access the scholarly trail & source material

18th century: 'neuropathological revolution'

- Diseases were 'nervous' in nature
- Theory that 'nervous power' could be aided by judicious use of 'stimulants' and narcotics
- 'Stimulation' worked like gravity, a master principle in nature
- For patients, the most visible legacy of the 'neuropathological revolution' was the abandonment of bloodletting or "cupping" and the increasingly widespread use of opium and alcohol in medical treatments

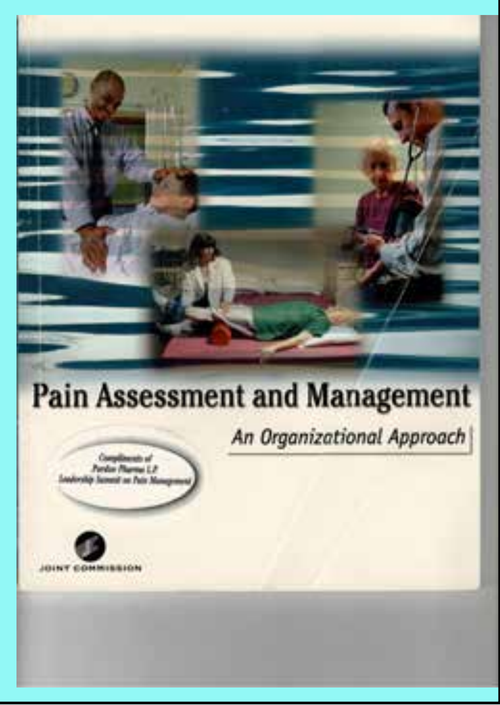
Vickers N. Opium as a Literary Stimulant: the Case of Samuel Taylor Coleridge. In: *International Review of Neurobiology*. Academic Press Inc. 1; 2015:327-338.

http://www.jointcommission.org/

- Independent, not-for-profit organization.
- Accredits hospitals, doctors offices, nursing homes, office-based surgery centers behavioral health treatment facilities and providers of home care services.
- Oldest and largest standards-setting and accrediting body in health care.
- recognized nationwide as a symbol of quality that reflects an organization’s commitment to meeting certain performance standards.

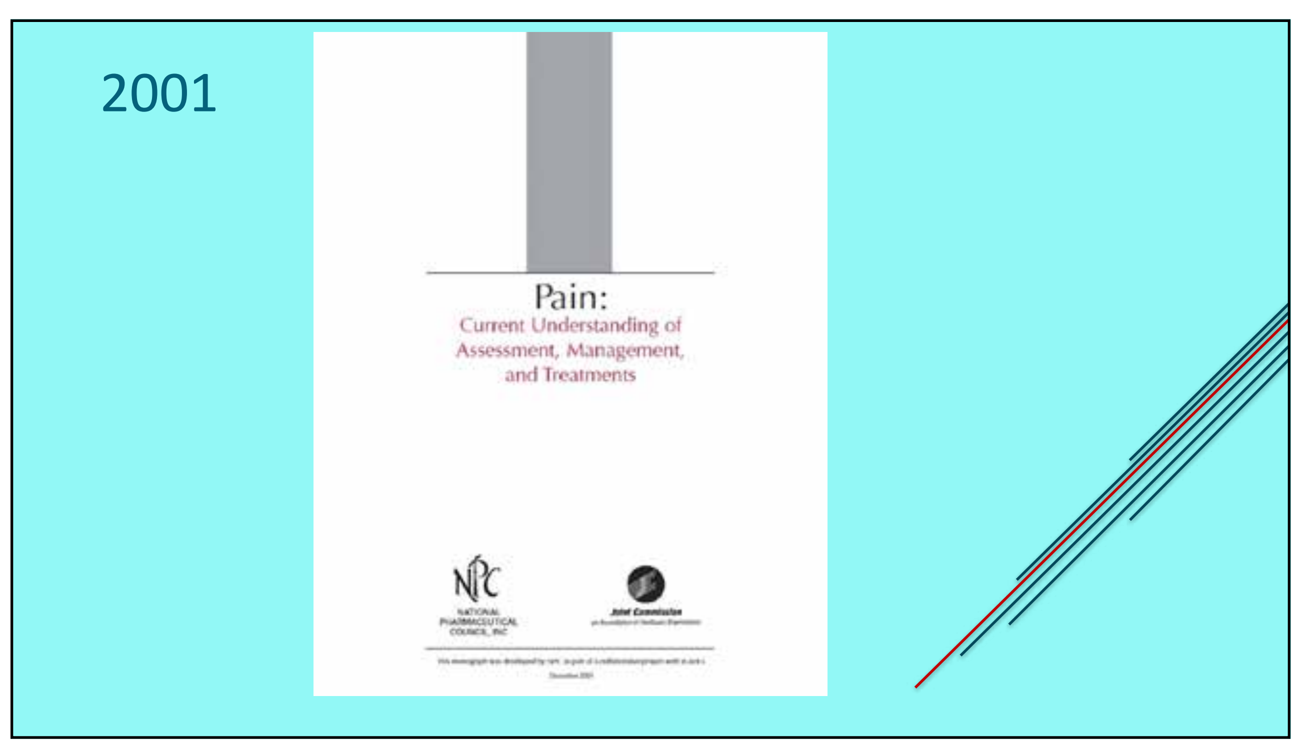
Pain mandate year 2000

- VA proposed pain as ‘fifth vital sign’ in 1999
- JCAHO adopted and required patients be asked about pain and rate it on scale 0-10 (or on face image scale).
- Mandate required pain be treated



JCAHO manual written with National Pharmaceutical Council

- Over represented position of pharma
- Companies pushed opioids to MDs
  - As non addictive in time release form
  - Without any supporting evidence
  - Exaggerated reports of NSAID risk
- Contributed greatly to opioid epidemic



Yet the origingal mandate included 'non pharm therapies'

- As part of a comprehensive strategy to address pain
- Emphasized creating a plan with a patient
- To include non pharm strategies along with pharm
- But no plan for how to gauge compliance
  - Ask about pain
  - Create a strategy with patient
  - Record

Barriers

- GAP analysis after mandate points to barriers
  - Lack of familiarity with non pharm therapies and providers
  - Lack of hospital credentialing for non pharm
  - Lack of reimbursement strategy

Intracultural bias

- General medical culture resistance and suppression of non conventional methods even when able to be performed by nursing
- Claims of 'lack of evidence'
- Disregard for evidence even as it accumulates
- Safety issue claims (suspect other)

Non pharm therapists & conventional medicine…

Have felt picked on
…held to a higher standard of proof…

'Say this stuff works…
one more time…'

Opioids

- As 4.6 % worlds population, US consumes 80% worlds opioid supply, 99% of global hydrocodone supply

Manchikanti L, Fellows B, Ailinani H, Pampati V. Therapeutic use, abuse, and nonmedical use of opioids: a ten-year perspective. *Pain Physician*. 2010;13(5) (October):401-435.

- Even with prescribed opioids, 70% of patients still complain of moderate to severe pain post-operatively (Pyati and Gan, 2007)

Pyati S, Gan TJ. Perioperative pain management. *CNS Drugs*. 2007;21(3):185-211.

2015 NIH Analysis: Americans in pain

- An estimated 23.4 million adults (10.3 percent) experience a lot of pain.
- An estimated 126 million adults (55.7 percent) reported some type of pain in the 3 months prior to the survey.
- Adults in the two most severe pain groups were likely to have worse health status, use more health care, and suffer from more disability than those with less severe pain.

https://nccih.nih.gov/news/press/08112015

- The number of opioid prescriptions per 100 persons increased by 35.2%, from 61.9 to 83.7
- The distribution of opioids to US pharmacies, in milligrams per 100 persons, increased by at least 100% for all selected opioids.
- The average size of an oxycodone prescription increased by 69.7% (from 923 MME to 1566 MME) during the same period
- The average size of a hydrocodone prescription increased by 69.4% (from 170 MME to 288 MME).
- The increase for fentanyl was smaller (20.9%) (from 4804 MME to 5809 MME).

Kenan K, Mack K, Paulozzi L. Trends in prescriptions for oxycodone and other commonly used opioids in the United States, 2000-2010. *Open Med*. 2012;6(2) (April 10):E41-e47

MME-Morphine milligram equivalents

In Guilty Plea, OxyContin Maker to Pay $600 Million

Photographs by Don Petersen for The New York Times
From left, Howard R. Udell, the top lawyer for ***Purdue Pharma;*** Dr. Paul D. Goldenheim, the company's former medical director; and Michael Friedman, Purdue's president.
By BARRY MEIER
Published: May 10, 2007

- Purdue Pharma acknowledged in the court proceeding today that "with the intent to defraud or mislead," it marketed and promoted OxyContin as a drug that was less addictive, less subject to abuse and less likely to cause other narcotic side effects than other pain medications.
- For instance, when the painkiller was first approved, F.D.A. officials allowed Purdue Pharma to state that the time-release of a narcotic like OxyContin "is believed to reduce" its potential to be abused.
- But according to federal officials, Purdue sales representatives falsely told doctors that the statement, rather than simply being a theory, meant that OxyContin had a lower potential for addiction or abuse than drugs like Percocet. Among other things, company sales officials were allowed to draw their own fake scientific charts, which they then distributed to doctors, to support that misleading abuse-related claim, federal officials said.
- Between 1995 and 2001, OxyContin brought in $2.8 billion in revenue for Purdue Pharma, a closely held company based in Stamford, Conn. At one point, the drug accounted for 90 percent of the company's sales.

No jail time
These offenders went on to other pharma boards

Photographs by Don Petersen for The New York Times
From left, Howard R. Udell, the top lawyer for ***Purdue Pharma;*** Dr. Paul D. Goldenheim, the company's former medical director; and Michael Friedman, Purdue's president.
By BARRY MEIER
Published: May 10, 2007

- Drug overdoses are the leading cause of injury deaths in the United States, at nearly 44,000 per year.
- Half of those are related to prescription drugs (22,000 yr).
- These deaths have more than doubled in the past 14 yrs.
- Overdose deaths now exceed motor vehicle-related deaths in 36 states and Washington, D.C

(Trust for America's Health & the Robert Wood Foundation 2015)

- Since 2003, more overdose deaths have involved opioid analgesics than heroin and cocaine combined (CDC MMWR 2012).
- By 2008, an American is as likely to die from a prescription opioid overdose as either suicide or a motor vehicle accident (CDC MMRR 2011).

- By 2010, narcotics were prescribed in the US at levels equivalent to medicating every single adult
- with a 5 mg hydrocodone taken every 4 hours for a month (CDC MMWR 2011).

- Opioid prescription drug epidemic has contributed to an increase in heroin use which has doubled in the last 7 years (Trust for America's Health 2015) as well as an increase in injection use of prescription opioids which have had a direct increase in HIV and HCV infection rate (CDC MMWR 2015)

- Heroin overdose deaths have quadrupled 2002-2013
- Those who use prescription opioids are 40 times more likely to use heroin.
- The odds of heroin abuse or dependence were highest among those who had abused or become dependent on opioids or cocaine –

Jones CM. http://www.pharmacytimes.com/news/heroin-related-deaths-on-the-rise

Dr. Thomas Frieden
Head of CDC

- '…more and more people are susceptible to heroin because they have been prescribed prescription opiates, like OxyContin.
- and …heroin itself has become cheaper and more widely available'
- Dec 14, 2015 CDC New Guidelines for Opioids (note)
  - Opioids unproven? [Frieden is quoted as saying]

Bingel et al. 2011

- Brain activity while subjected to 'heat pain' (fMRI)
- Administration of 'drug' (Remifentanil) with message
  - This drug will have no effect
  - This drug will diminish pain sensation
  - This drug will make your pain worse
- Results based on expectation
  - 'Drug will be effective': Twice as much relief than those 'expecting no effect'
  - Some relief even if 'expecting no effect'
  - 'Expecting pain will be worse': no improvement

fMRI brain activity

- 'Heat pain' activates so-called 'pain circuit'
- Expectation of increased pain
  - More neural activity in brain areas that mediate mood and anxiety than during expectation of relief
- Expectation of pain relief
  - Brain showed descending mechanism of pain inhibition

Bingel U, Wanigasekera V, Wiech K, Mhuircheartaigh RN, Lee M, Ploner MT I. The Effect of Treatment Expectation on Drug Efficacy: Imaging the Analgesic Benefit of the Opioid Remifentanil. *Sci Transl Med*. 2011;3(70ra14) (16 Feb).

Conclusion Bingel et al.

- A drug with true biological effect may appear to be ineffective to a patient conditioned to expect failure
- Authors suggest to shape patient's beliefs to maximize drug effectiveness
- A decades old reproach of

'alternative medicine'

Acupuncture vs IV morphine in ED

Grissa M, Baccouche H, Boubaker H et al. Acupuncture vs intravenous morphine in the management of acute pain in the ED. *Am J Emerg Med*. 2016;pii: S0735-6757(16) (July 20):30422-3.

300 patients	Acupuncture 150	IV morphine 150
Pain score reduction ≥50%	92% success	78% success
Resolution time	16±8 (8-24 minutes)	28 ±14 (14-42 minutes)
89 patients (29.6%) AE	4 (2.6%) AE	85 (56.6%) AE

In patients with acute pain presenting to the ED, acupuncture was associated with more effective and faster analgesia with better tolerance.

- Writing a pain mandate with the National Pharmaceutical Council has contributed to over and unnecessary prescribing of opioids
- A national epidemic of opioid abuse and deaths is declared by the CDC

- Ongoing use of opioids for pain that becomes chronic is associated overall with worse pain, higher health care utilization and lower activity levels
- Odds of recovering from chronic pain were four times higher among individuals not using opioids (Manchikanti et al. 2012)

Institute of Medicine

- 100+ Million People with Chronic Pain
- $560-$635 Billion in Annual Costs
- Untold Human Suffering

Institute of Medicine Report from the Committee on Advancing Pain Research, Care, and Education: Relieving Pain in America, A Blueprint for Transforming Prevention, Care, Education and Research. The National Academies Press, 2011. http://books.nap.edu/openbook.php?record_id=13172&page=1

Gov Peter Shumlin, VT

- …the governor went after the FDA and pharmaceutical industry in his State of the State address, saying Oxycontin "lit the match that ignited America's opiate and heroin addiction crisis."
- "Just a few months ago, the FDA approved Oxycontin for kids. You can't make this stuff up. The $11 billion a year opiate industry in America knows no shame," Shumlin said, adding that "opiate addiction is the one thing that could destroy Vermont as we know it."

We must flip the presumption that a patient needs opioids to manage pain.

http://abcnews.go.com/Health/vermont-governor-pushes-limit-prescription-painkillers-combat-opioid/story?id=42938840

Need more than…just say 'no'

- There are options for treating pain.
- There are therapies that are shown to be clinically effective.
- That are regulated by States
- Professionals working within their scopes of practice
- Who are diminished and marginalized under the terms Complementary and Alternative (CAM)

CAM as a brand

- CAM represents a grouping of approaches outside of surgery and pharmacy.
- Called CAM decades ago when there was little evidence
- Now: the evidence of effect in the treatment of pain has been established beyond placebo and beyond doubt
- We need to lead with the evidence
- Situate discourse with terms that engage the evidence

Need to…

- Change medical culture….one hospital at a time
- Revise Policy Standards with Regulatory Organizations

Our story

- How did the appeal to The Joint Commission happen?

Beth Israel Medical Center now Mount Sinai Beth Israel

- 2000 Center for Health and Healing
  - Credentialed Acupuncturists
  - Created Policy & Procedures
- 2008 became Integrative Medicine Dept
- 2008 Acupuncture Fellowship Inpatient Care
- 2010 Consult service Hospital-wide
- 2015 28 Fellows ~ 10,000 inpatients

Demonstrated

- Feasible to develop a training model for licensed acupuncturist as a strategy for integrating acupuncture to the inpatient setting.
- A safe record of inpatient acupuncture therapy has been established at Mount Sinai Beth Israel in NYC.

Process Required Presenting

- Literature reviews of evidence
- Department presentations 2008-2013 supported incorporation of practice
- Why not send to JCAHO?

Ben Kligler, MD
Research Director
MSBI Integrative Medicine
(then) Chair
Consortium of Academic Health Centers
for Integrative Medicine, USA

Marsha J. Handel, MLS

Informatics
Medical Librarian

Provided Literature Reviews Evidence and Safety Record

- Acupuncture therapy
- Massage therapy (with Janet Kahn, PhD)
- Relaxation Response (RR) therapies
- Note terms…consistent with NLM MeSH

We Request TJC Review of Pain Standard

1. evidence that management of pain has not been completely successful;
2. documented risks involved with increased use of opioids and their side-effects;
3. the amount of high quality research evidence that supports non-pharmacologic approaches to pain management as part of an interdisciplinary strategy.

Requested that

- Hospitals must not only offer information regarding non-pharmacological management of pain but
- Must offer 'in person' options for the therapies on-site: acupuncture therapy; relaxation/stress management therapies including meditation, yoga breathing, Reiki and Healing Touch; massage therapy and/or music therapy, among others.

Immediate response

- The Joint Commission never intended for our pain management standards to focus exclusively on pharmacologic treatments. In the greater than 10 years that this standard has been part of accreditation, it has been a persistent misperception that these standards applied exclusively to pharmacological treatments.
- The Joint Commission is in the process of exploring ways to both correct the misconceptions concerning our standards and also to investigate the need to modify these standards so as to keep them contemporary.
- We always look to the field to find expert opinion to assist us. If you would like to be a part of the process of updating The Joint Commission standards on pain management, please let us know.

Expert Panel

- Petition April 2013
- Expert panel 'pain specialists' convened Jan 13, 2014
- Decision Nov 12, 2014
- Effective Jan 1, 2015

Effective January 1, 2015: For ambulatory care, critical access hospital, home care, hospital, nursing care center, and office-based surgery accreditation programs.

Standard PC.01.02.07: The [organization] assesses and manages the [patient's] pain.
[Revised] Rationale for PC.01.02.07 [New for ambulatory care and office-based surgery practice]
The identification and management of pain is an important component of [patient]-centered care. [Patients] can expect that their health care providers will involve them in their assessment and management of pain. Both pharmacologic and nonpharmacologic strategies have a role in the management of pain. The following examples are not exhaustive, but strategies may include the following:

- Nonpharmacologic strategies: physical modalities (for example, acupuncture therapy, chiropractic therapy, osteopathic manipulative treatment, massage therapy, and physical therapy), relaxation therapy, and cognitive behavioral therapy
- Pharmacologic strategies: nonopioid, opioid, and adjuvant analgesics

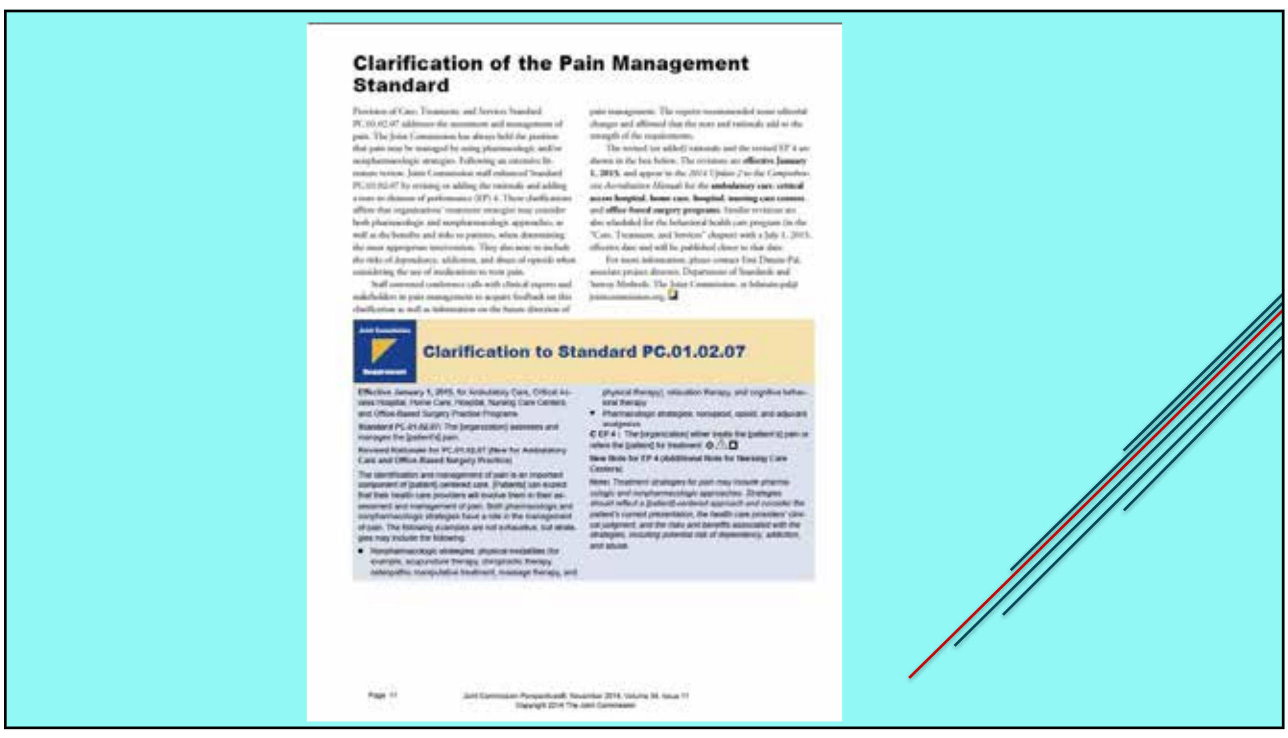
EP 4: The [organization] either treats the [patient's] pain or refers the [patient] for treatment.

[New] *Note: Treatment strategies for pain may include pharmacologic and nonpharmacologic approaches. Strategies should reflect a [patient]-centered approach and consider the patient's current presentation, the health care providers' clinical judgment, and the risks and benefits associated with the strategies, including potential risk of dependency, addiction, and abuse.*

www.jointcommission.org

Now in PDF

'Clarification of the Pain Management Standard'



Clarification of the Pain Management Standard

Clarification to Standard PC.01.02.07

Revisions to pain management standard effective January 1, 2015

- Accreditation
  - Revisions to the Provision of Care, Treatment, and Services standard PC.01.02.07 – which addresses pain management – will be effective January 1, 2015.
  - **Following an extensive literature review**, The Joint Commission revised the rationale and added a note to element of performance (EP) 4. Clinical experts in pain management provided feedback on these revisions and guidance on the future direction of pain management. The experts affirmed that treatment strategies may consider both pharmacologic and nonpharmacologic approaches. In addition, when

- considering the use of medications to treat pain, organizations **should** consider both the benefits to the patient, as well as the risks of dependency, addiction, and abuse of opioids. The revisions (below) will appear in the 2014 Update 2 to the accreditation manuals. Similar revisions are scheduled for the behavioral health care program (in the "Care, Treatment, and Services" chapter) with a July 1, 2015, effective date and will be published closer to that date.

Let's make it 'scorable....'

Revise the Pain Management Standard
Require non pharm options

Arya Nielsen, PhD
Mount Sinai Beth Israel
Department of Family Medicine & Community Heatlh
December 2015

Letters of Support

- Research supports non pharmacologic therapies are safe, feasible and therapeutic for pain.
- **The Academic Consortium for Integrative Medicine & Health** supports a revision of the Pain Management Standard to ***require*** provision of non pharmacologic strategies as an Element of Performance (EP) to the Standard Provision of Care (PC.01.02.07).

- 70 institutional members of the Academic Consortium for Integrative Medicine and Health (The Consortium). The Consortium is a 501(c)3 nonprofit organization comprised of highly esteemed academic medical centers and affiliate health care systems; Allina Health, Aurora Health Care, Scripps Health, and Sutter Health Care System (www.IMConsortium.org).

If you want to support here is the language:

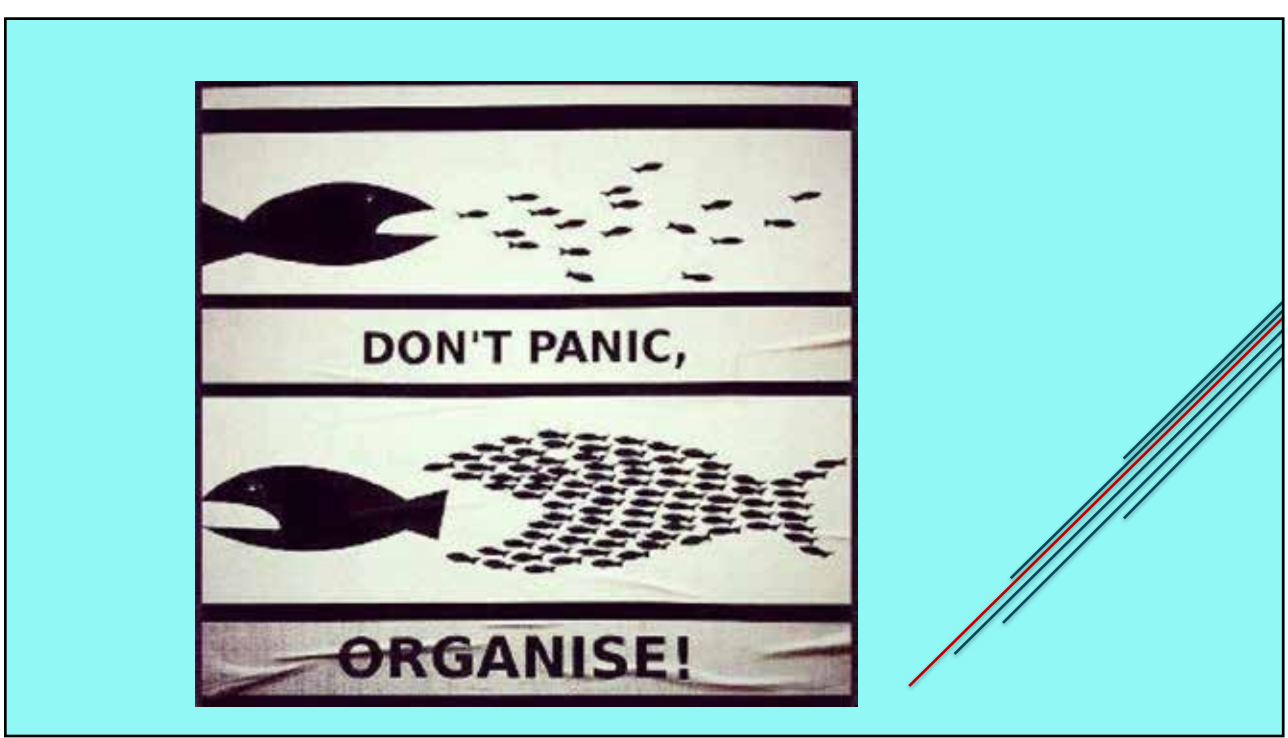
- a revision of the Pain Management Standard to make scorable
- ***To require*** provision of non pharmacologic strategies as an Element of Performance (EP) to the
- Standard Provision of Care (PC.01.02.07).

Other Organizations

- CMS.gov Centers for Medicare & Medicaid Services
- State Departments of Health
- Because not every hospital is accredited by JCAHO now known as The Joint Commission

The Joint Commission

- Typically creates a standard
- Floats it for a year
- Then makes it 'scorable'
- It has been 16 years that non pharm therapies have been part of TJC mandate on pain
- IT IS TIME



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Deaths from Injuries Up Significantly Over Past Four Years in 17 States; Majority of States Score 5 or Lower Out of 10 on Injury Prevention Report Card. Trust for America's Health and the Robert Wood Johnson Foundation June 17; 2015. http://healthyamericans.org/newsroom/releases/?releaseid=326 Accessed June 18, 2015.

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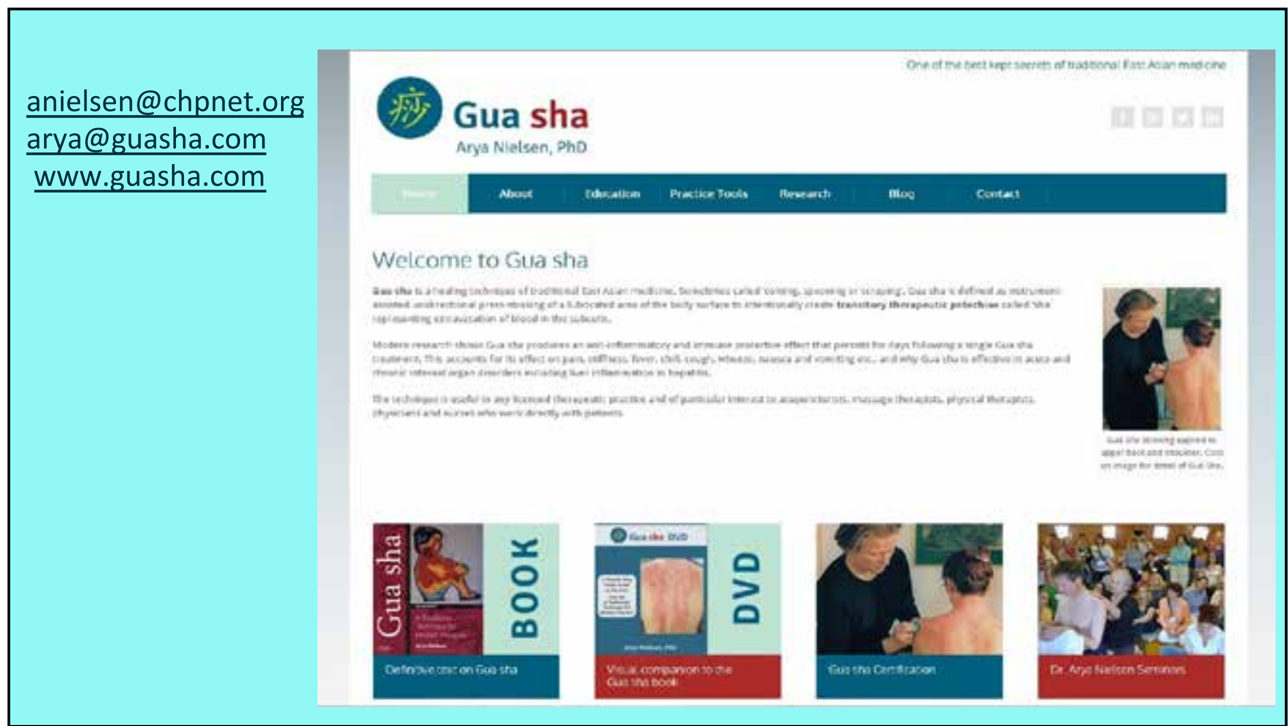
Afternoon session: Acupuncture therapy

- Evidence in the treatment of chronic pain
- Our trial treating chronic pain in underserved population
  - PCORI grant
  - Albert Einstein Medical College
  - Montefiore: the University Hospital
  - Mount Sinai
  - NYC Ring
  - PCOM (Beau Anderson co investigator)
- Evidence in acute care, inpatient setting

© Arya Nielsen, PhD
Assistant Clinical Professor
Icahn School of Medicine at Mount Sinai
Department of Family Medicine & Community Health

Director, Acupuncture Fellowship for Inpatient Care
Mount Sinai Beth Israel
New York, NY

anielsen@chpnet.org
www.guasha.com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arya@guasha.com
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