

Evidence Based Approaches to Chronic Pain Management: Time to Reconsider the Benefit of Technophilism?

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Disclosure

Dr. Schatman serves as a consultant to Kaleo



Learning Objectives

- Define the concept of technophilism as it relates to pain medicine
- Describe the problems with the evidence-bases of the technophilic approaches to pain management that are currently overutilized
- Employ a plan for more rational specialist referral

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Original AMA Code of Ethics (1847)

- "From the age of Hippocrates to the present time, the annals of every civilized people contain abundant evidences of the devotedness of medical men to the relief of their fellow-creatures from pain and disease....."
- Is this the case in American pain medicine?
- If not, have we become "uncivilized"?
- I believe so.....



Spurious Symbolic Measures to Improve Pain Management in the US

- Congressional declaration of "Decade of Pain Control and Research" (HR3244)
- Initiative to treat pain as the "5th vital sign"
- The National Pain Strategy....?

"The silence on the failure of caregivers to adequately address pain in the clinical setting has been deafening"

Rich BA. J Med Humanit. 1997;18:233-259.

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Reasons for Inadequate Treatment of Pain and Suffering

- Lack of interest by many physicians
- Approximately 8000 board certified "pain specialists" in the US
- American Board of Pain Medicine. Frequently Asked Questions. Available at: <u>http://www.abpm.org/fag</u>.
- Training in pain management in med schools and residency programs is highly inadequate

Loeser JD, Schatman ME. Postgrad Med. 2017;129:332-335. Zoberi K, Everard KM. Fam Med. 2018;50:22-27.

Concerns regarding professional sanctions and legal action relating to opioid prescription

Webster LR. Pain Med. 2014;15:345-346.



Reasons for Inadequate Treatment of Pain and Suffering (cont'd)

Insurance industry's and hospital administrations' concerns with costcontainment and profitability as opposed to quality of care

Schatman ME. Pain Med. 2011;12:415-426.

 Insurance companies' refusal to pay for interdisciplinary programs has resulted in a decrease from over 1000 programs in the US to fewer than 90 outside the VA and military

Anooshian J, et al. Psychosomatics 1999;40:226-232. Schatman ME. Pain Clin Updates 2012;20(7):1-5.

TECHNOPHILISM

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Technophilism

• Defined as portraying all problems as want of technical know-how Sorenson RA. Pseudo-Problems: How Analytic Philosophy Gets Done. New York: Routledge; 1993.

- Definition as applied to chronic pain management:
 - A reliance upon medications, procedures, and surgical approaches in lieu of treatment of the person, thereby ignoring his/her phenomenological existence

Schatman ME. J Pain 2007;8(Suppl.):S86.

 Derived from what Hans Lenk referred to as the "technocratic imperative" the perceived need to put into use any and all technologies (and techniques) simply because "we can"

Lenk H. Notes on extended responsibility and increased technological power. In: Durbin PT, Rapp F (eds.). Philosophy and Technology (pp. 195-210). Dordrecht, Holland: D. Reidel Publishing Company;1983.



Technophilism (cont'd)

- What drives technophilism in pain medicine?
- Is it simply obsession with all things technological?
- Perhaps if you ask my 19-year-old son....



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Cause of Technophilism in Pain Medicine

It's actually all about the \$\$\$\$\$....

• Jim Giordano, the leading critic of technophilism in pain medicine Giordano J. Technology in pain medicine: research, practice, and the influence of the market. Practical Pain Manag. 2008;8(3):56-58. Giordano J, Benedikter R. Pain Med. 2011;12:406-414.

- Notes that the Hippocratic Oath "calls for the clinician to be prudent regarding using any and all treatments, so as to adhere to, and maximize the ends of the practice"
- The technocratic imperative prizes speed and efficiency



Cause of Technophilism in Pain Medicine (cont'd)

- But do speed and efficiency necessarily maximize the ends of pain medicine?
- Not necessarily.....
- And they may actually impede the ideal ends of pain medicine....
- The market economy under which most pain medicine is practiced in the US causes us to equate speed and efficiency with increasing economic gains and minimizing loss

Herlinger RE. Market Driven Healthcare: Who Wins, Who Loses in the Transformation of America's Largest Service. Perseus Books. New York;1999.

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Commodification of Pain Medicine

- Thus, it's not technology, per se, but the commodification of pain medicine that has driven it into the toilet
- As pain research has become all about the money, too, we're seeing "pseudoscience-fueled neuromysticism" subverting the knowledge of physicians and compromising their abilities to adequately care for their patients

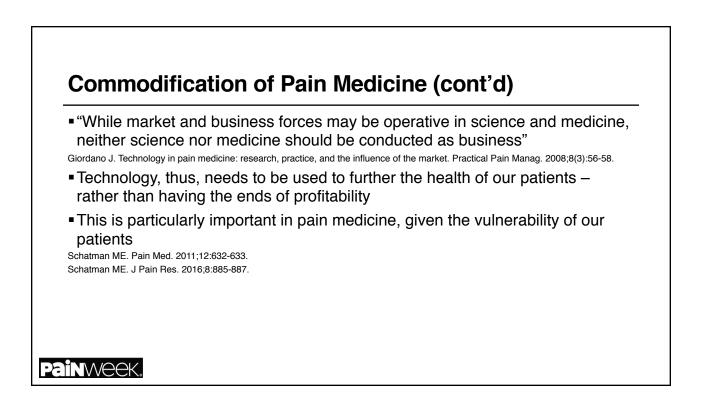
Atkinson TJ, Schatman ME, Fudin J. J Pain Res. 2014;7:265-268.

"...many sly people make money out of ignorance of the rest while endangering the health of innocent patients who, one way or the other, must pay…"

Valentinuzzi ME. Magnetotherapy, alternative medicines, Hippocratic oath. BioMedical Engineering OnLine. 2008. 7(1).



Commodification of Pain Medicine (cont'd) Second practicing pain physicians Second practicing pain physicians



Bad Segue



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(Lack of) Empirical Support for Technophilic Approaches

- Opioids
- Spine surgery
- Intrathecal opioid delivery systems
- Spinal cord stimulators*
- Other interventional approaches



Opioid Analgesics

- Difficult topic for me.....
- Few would argue that opioids should be considered a first-line approach to chronic pain

Fudin J, Pratt Cleary J, Schatman ME. J Pain Res. 2016;9:153-156.

- Although our society has thrown the baby out with the bathwater
- Another day, another lecture....
- Jane Ballantyne is certainly technically-correct

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Opioid Analgesics (cont'd)

 Current knowledge of long-term analgesic efficacy comes from surveys, case series, and open-label follow-up studies rather than RCTs of sufficient length
 Ballantyne JC. Problems with chronic opioid therapy and the need for a multidisciplinary approach. In: Schatman ME, Campbell

Ballantyne JC. Problems with chronic opioid therapy and the need for a multidisciplinary approach. In: Schatman ME, Campbell A (eds.). Chronic Pain Management: Guidelines for Multidisciplinary Program Development. New York: Informa Healthcare. 2007;49-64.

Maximum length of a published RCT is 32 weeks

Ballantyne JC. Chronic opioid therapy: the argument for caution. In: Schatman ME (ed.). Ethical Issues in Chronic Pain Management. New York: Informa Healthcare. 2007;121-141.

• Weighted mean duration of opioid RCTs is approximately 5 weeks Turk DC. Clin J Pain 2002;18:355-365.



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Bottom Line on Opioids

These are very imperfect drugs...yet sometimes the only option

The pendulum has clearly swung awry....

Schatman ME, Darnall BD. Pain Med. 2013;14:617-620. Atkinson T, Fudin J, Schatman ME. J Pain Res. 2014;7:265-268.

- We can't ignore an important caveat
- Irrespective of a lack of evidence basis for efficacy and potentially brutal iatrogenic complications, sometimes the "wrong answer" is the "only answer".....

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Bottom Line on Opioids (cont'd) 9.0% of the American population live in medically underserved areas Mathematical Health Association. Health Care Workforce Distribution and Shortage Issues in Rural America, 2012. Available at: www.uralhealthweb.org/index.cfm? 9.000 luck finding any chronic pain treatment resources other than PCPs in these communities 9. Ethical question: Assuming a lack of aberrancy and genuine informed consent around iatrogenic complications of opioids, should these medications be considered an option?



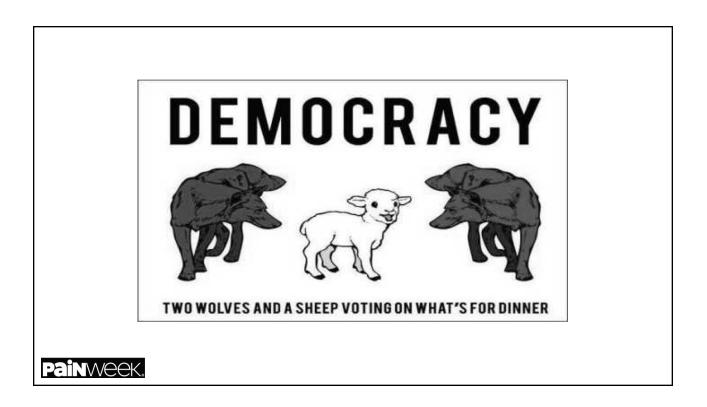
Bottom Line on Opioids (cont'd)

- The "tyranny of the majority" seems overwhelming...
- 2015 study found that long-term opioid therapy relieves chronic pain in "only" 20% of women

LeResche L, et al. J Womens Health 2015;24:629-635.

- Considered "more evidence" against COT
- If opioids work for only 20%, they must be "ineffective"
- The "evidence basis" is sometimes overrated....
- Perhaps 1000 studies with an "n of 1" needed

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(Spinal) Surgery-Efficacy and Safety

Vastly over-performed

Berenson RA, Docteur E. Timely Analysis of Immediate Policy Issues (RWJF/Urban Institute), January 2013 . Available at: <u>http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2202879</u>.

• Evidence-basis for many surgeries is woefully poor Deyo RA, et al. J Am Board Fam Med. 2009;22:62-68.

 Limited number of RCTs and meta-analyses make establishing evidencebases difficult

Gnanalingham KK, et al. Br J Neurosurg. 2013;27:152-155.

Iatrogenesis of spinal surgery – problematic

Deyo RA, Mirza SK. Eur Spine J. 2009;18(Suppl 3):S331-337.

 Incidental dural tears occur in 3%-16% of spine surgeries, and are associated with worse outcomes

Baker G, et al. Spine J. 2012;12:121-126.

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Spine Surgery—Evidence and Risks

-10.8% undergoing anterior cervical surgery develop dysphagia Kalb S, et al. World Neurosurg. 2012;77:183-187.

-Surgical site infection rates as high as 10.4% identified for certain fusions Abdul-Jabbar A, et al. Spine 2012;37:1340-1345.

 Adjacent segment degeneration occurs in 29.3% following spinal surgery (systematic review and meta-analysis)

Xia XP, et al. Spine 2013;38:597-608.

-30-day readmission rates of 7.9% after cervical surgery and 7.3% after lumbar surgery identified

Wang MC, et al. Spine J. 2012;12:902-911.

A lot of these problems may relate to increasing obesity, as increased BMI predicts surgical failure

Bono OJ, et al. Spine J. 2017[Epub ahead of print].



Spine Surgery—Evidence and Risks (cont'd)

- Feeling safe?!?!?!
- Irrespective of negative evidence-bases and risk data, spine surgery rates continue to increase

-Increasing rates of fusions for lumbar isthmic spondylolisthesis Thirukumaran CP, et al. Spine 2016;41:490-501.

-Increasing rates of spinal fusions, generally Rajaee SS, et al. Spine 2012;37:67-76.

-Increasing rates of complex fusion procedures for spinal stenosis Deyo RA, et al. JAMA 2010;303:1259-1265.

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Spine Surgery—Evidence and Risks (cont'd)

 Increasing rates of cervical surgeries – mainly due to significant increases in anterior fusions

Oglesby M, et al. Spine 2013;38:1226-1232.

- Why the increase in fusions?
- Are outcomes improving?
- Are iatrogenic complications decreasing?
- Are fusions by far the most expensive spinal procedures?

What a surprise!!!!!

Weiss AJ, et al. Healthcare Cost and Utilization Project, Statistical Brief #170. Available at: <u>http://www.hcup-us.ahrq.gov/reports/statbriefs/sb170-Operating-Room-Procedures-United-States-2011.pdf</u>.



Bottom Line on Spine Surgeries

- No one will argue that spine surgeries are not sometimes necessary
- But to what extent are elective surgeries driven by profit motivation?
- Deyo and colleagues have noted that elective surgeries are becoming progressively more complex
 - -Resulting in progressively more iatrogenic complications
- Sound pain practice does <u>not</u> entail referring our refractory patients for elective surgery due to our own frustrations!

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Intrathecal Opioid Delivery Systems (IODS)

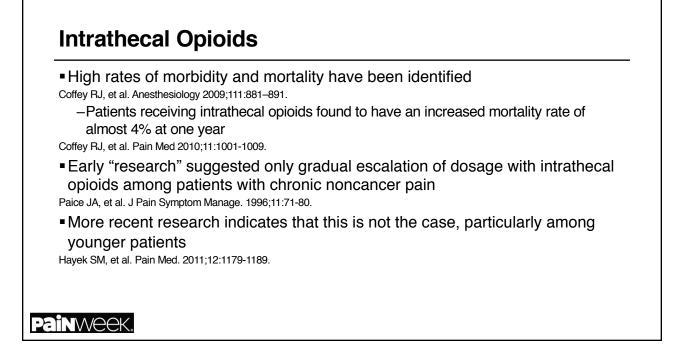
 Modest efficacy established for analgesia among cancer patients – although with substantial risks

Smith TJ, et al. J Clin Oncol 2002;20:4040-4049.

- Among patients with noncancer pain....not so much
- Not a single RCT (other than one with an n of 8) performed for noncancer pain since the pumps were introduced in 1991 – called an "embarrassing situation"
 Harden RN, et al. Pain Med. 2014;15:1823-1824.

Data aren't encouraging for long-term outcomes
Bennett G, et al. J Pain Symptom Manage 2000;20:S37–43.
Turner JA, et al. Clin J Pain 2007;23:180–195.
Knight KA, et al. Croatian Med J. 2007;48:22-34.





Intrathecal Opioids (cont'd)

• OIH has been established experimentally with intrathecal opioids Ferrini F, et al. Nat Neurosci. 2013;16:183-192.

 Endocrinopathic changes occur with long-term intrathecal opioid use – just as is the case with oral opioids

Abs R, et al. J Clin Endocrinol Metab 2000;85:2215-2222.

 Catheter malfunctions are common, occurring in 15%-25% of patients implanted

Hayek SM, Hanes MC. Curr Pain Headache Rep. 2014;18:388.



Intrathecal Opioids (cont'd)

Catheter malfunctions include:

-Occlusion

-Leakage

-Migration

-Dislodgement

-Kinking

–Puncture

-Shearing

Hayek SM, Hanes MC. Curr Pain Headache Rep. 2014;18:388.

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Intrathecal Opioids (cont'd)

 A case report of nerve root entrapment due to intrathecal coiling recently appeared in the literature

Han JL, et al. Pain Physician 2016;19:E499-E504.

Infection rates of 5% have been identified

Kamran S, Wright BD. Neuromodulation 2001;4:111-115.

Costs

-Average lifespan prior to explantation for battery replacement is 5.4 years

-75% of patients require more than one pump implantation

-Among patients who completed the study, overall costs ranged from \$5.29 to \$2973.10/day for single pumps (mean=\$10.30/day), with mean cost of second or later pumps=\$10.73/day (\$4000/year)

Bolash RB, et al. Neuromodulation 2015;18:150-155.



Intrathecal Opioids (cont'd)

 There's a serious problem with the research and the consensus guidelines – generally published by investigators on industry payrolls
 Deer TR, et al. Neuromodulation 2012;15:467-482.

 We have to remember that consensus guidelines and evidence-based guidelines are not the same – particularly when guideline writers are paid by the leading manufacturers of the equipment that they're evaluating Shaneyfelt TM, Centor RM. JAMA 2009;31:868-869.

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Bottom Line on Intrathecal Opioids

 Conclusion: "there is still a scarcity of rigorous evidence to guide its integration into clinical practice"

Smyth C, et al. Drugs 2015;1957-1980.

- But it's so damn high-tech that it must be good....
- Or so the manufacturers of intrathecal hardware and the opioids that they use will tell us...
- Insurers have become reluctant to pay for intrathecal opioids Pope JE, et al. Pain Pract. 2016;[Epub ahead of print].
- Nice to see them get something right in pain medicine.....
- Most malpractice claims relating to implantable devices for chronic pain relate to intrathecal pumps

Abrecht CR, et al. Anesth Analg. 2017;24:1304-1310.



Spinal Cord Stimulators First published clinical report of SCS dates back half a century Shealy CN, et al. Anesth Analg. 1967;46:489–491. Systematic reviews determined that SCS was moderately effective for pain clief for some types of neuropathic pain Taylor RS. J Pain Symptom Manage. 2006;31:S13-S19. Simson EL, et al. Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin: systematic review and economic evaluation. In: NIHR Health Technology Assessment Programme: Executive Summaries. Southampton (UK): NIHR Journals Library; 2009. Chou R, et al. Spine 2009;34:1078-1093. Grider JS, et al. Pain Physician 2016;9:E33-54. Although reviews of SCS determined weak evidence for efficacy in other conditions. Tey ME, et al. Pain Physician 2009;12:379-397.

Spinal Cord Stimulators (cont'd)

 With no evidence for greater efficacy compared to other treatments found in a workers compensation population

Turner JA, et al. Pain 2010;148:14-25.

- Why do the "accepted indications" for treatments like SCS increase without empirical support?
- Cost-effectiveness has been established only for failed back surgery syndrome and CRPS

Taylor RS, et al. Clin J Pain 2010;26:463-469. Kemler MA, et al. Value Health 2010;13:735-742.

 Traditional tonic, low frequency SCS can be effective for radicular pain, but does little for axial back or neck pain
 Van Buyten JP, et al. Neuromodulation 2013;16:59-65.



Complications of SCGS "The long-term success of spinal cord stimulation is impeded by the high incidence of adverse events" Over a quarter of patients over a 10-year period experienced adverse events – most involving hardware Kumar K, et al. J Neurosurg Spine 2006;5:191-203. Hean complication rates as high as 42% have been identified in reviews ten Vaarwerk IA, Staal MJ. Spinal Cord 1998;36:671-682. Pisk of spinal cord injury is 0.5% Chan AK, et al. J Neurosurg Spine 2016;25:31-38.

Complications of SCS (cont'd)

Unit discomfort and/or migration are the most common complications (11.1%)

- Followed by lead migration (8.5%)
- Other common complications include infection and paresthesia/dysesthesia
- Revision or explantation each occurred in 24% of patients

-Loss of therapeutic effect was the most common reason for explantation Hayek SM, et al. Neuromodulation 2015;18:603-609.



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Costs of SCS

• Average 2-year total costs determined to be >\$80,000 Lad S, et al. Spine 2014;39:E719-E727.

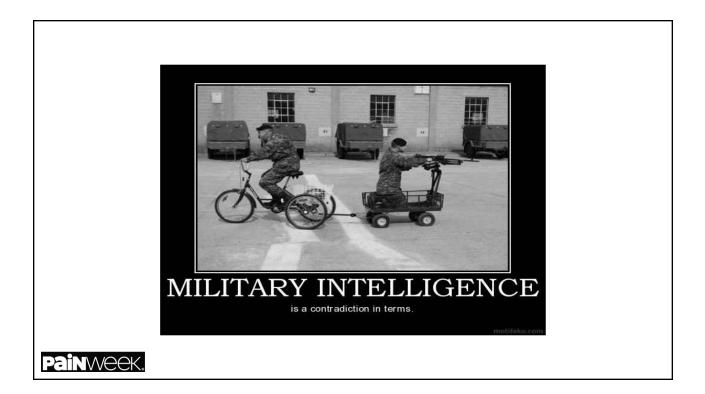
Complications are frequent and expensive

-Average cost of addressing complications >\$7,000 (2006 Canadian dollars) Kumar K, et al. J Neurosurg Spine 2006;5:191-203.

Batteries are either nonrechargeable or rechargeable

• Nonrechargeable units require surgical replacement every 4 years or less Taylor RS, Et al. Clin J Pain 2010;26:463-469.

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New SCS Technology

 High frequency SCS (10-kHz) provides analgesia without causing the paresthesias associated with traditional SCS

Song JJ, et al. Pain Physician 2014;17:235-246.

 Importantly, the new technology is effective for axial pain as well as radicular symptoms

Kapural L, et al. Anesthesiology 2015;123:851-860.

- Can be used while driving and sleeping
- Empirically established as improving insomnia associated with chronic pain Ramineni T, et al. Neurmodulation 2016;19:477-481.
- Found to significantly reduce axial back pain in patients who never underwent surgery for 36 months....and counting
 Al-Kaisy A, et al. Pain Med. 2018;19(6):1219-1226.

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Bottom Line on SCS

- The process of trialing SCS makes the approach potentially the least destructive of the technophilic treatments
- Still very expensive
- Historically utilized for conditions without evidence-basis
- New high frequency SCS broadens appropriate applications and ongoing research will broaden them further
- Perhaps the greatest innovation in pain medicine I've seen



Other Interventional Approaches

Reasonable evidence-basis for acute pain Anuj B, et al. Anesth Analg. 2016;122:857-870.

• For chronic pain, efficacies depend upon whom you ask....

 2009 update of a Cochrane Review: "There is insufficient evidence to support the use of injection therapy in subacute and chronic low-back pain"
 Staal JB, et al. Spine 2009;34:49-59.

 Bottom line – interventional techniques are not a panacea for most types of chronic pain

• "Interventional pain management....will probably suffer the most under the new affordable health care law and regulatory burdens"

Manchikanti L, et al. Pain Physician 2012;15:E27-E52.

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Other Interventional Procedures

• Vastly overutilized in the US due to profit motivation Epstein NE. Surg Neurol Int. 2015;6(Suppl 14):S383-387.

Evidence-basis of many interventional approaches for chronic pain is limited

Armon C, et al. Neurology 2007;68:723-729. Parr AT, et al. Pain Physician 2009;12:163-188. Staal JB, et al. Spine 2009;34:49-59. Rhee JM, et al. Spine 2013;38(22 Suppl 1):S55-67. Poetscher AW, et al. Spine 2014;39:E842-849.

 Unless they're based on reviews done by interventional pain management societies, in which case they're generally methodologically flawed and selfserving

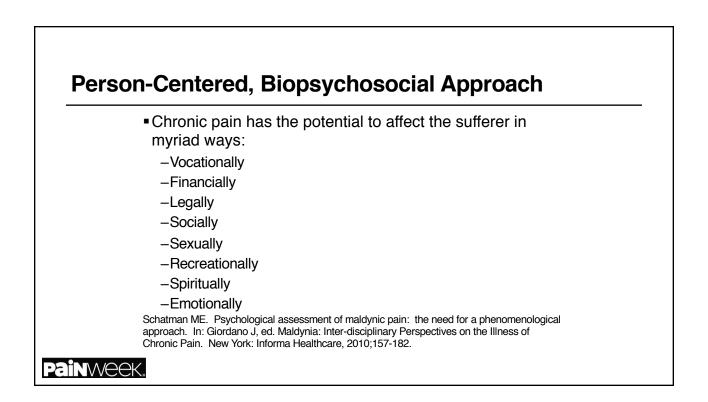
Chou R, et al. J Pain 2011;12:833-839.



So What Is the Answer?

- We need to become more person-centered in treating chronic pain!
- We need to become more biopsychosocial....and less technophilic
- "Chronic pain" is not synonymous with "persistent pain"
- Chronic pain is a "disease of the person"
- Schatman ME. Pain: Clin Updates 2012;20(7):1-5.
- How is the "person" compromised by chronic pain?

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Person-Centered, Biopsychosocial Approach (cont'd)

- Patients with chronic pain need to be considered <u>phenomenologically</u>, with each of these areas addressed
- Technophilic approaches are about as nonphenomenological as we can get!
- "The history of pain medicine is replete with failures of the biomedical model" Gallagher RM. Med Clin N Am. 1999;83:555-583.
- Yet it's so profitable....

Schatman ME, Lebovits AH. Pain Med. 2011;12:403-405.

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Treating the Person

- Through person-centered approaches, we have the opportunity not only to reduce chronic pain, but to reduce <u>suffering</u> as well
- "Tendencies toward overspecialization, overreliance on technology, and loss of humanitarian concern have constituted the dark side of modern medicine's stunning achievements"

Leder D. Theor Med. 1990;11:9-24.



Treating the Person (cont'd)

 Although the biomedical model may be an effective approach to disease states in which the cause is clearly defined, it is not appropriate for conditions such as chronic pain

Steen E, Haugli L. Theor Med. 2000;21:581-599.

- The "maldynic" quality of most types of chronic pain already marginalizes the patient
- Does subjecting a patient to unnecessary technophilic approaches further marginalize him/her?

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What Can the Primary Care Provider Do?

- Treating patients with chronic pain is frustrating..... and time-consuming
- Do these patients actually want referral to a specialist?
- Perhaps early on.....
- Yet patients with pain become frustrated by failure, too...
- How many specialists should a patient see?
- Do patients with chronic pain ultimately lose faith?



Referral to Specialists

• "Referrals to specialists...by the primary care physician should reflect the prudent judgment that more advanced consultation, if not treatment, is required"

Giordano J, Schatman ME. Pain Physician 2008;11:775-784.

- Is this why referrals of chronic pain patients are generally made?
- Or is it done out of frustration?
- How often does this backfire....?

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Referral to Specialists (cont'd)

- Do patients referred to interventionalists ever not receive at least one injection?
- If a patient allows it, does he/she generally receive 3 ESIs....irrespective of the outcomes of the first 2?
- How often does an interventionalist or a surgeon change a patient's medications or recommend an evidence-based therapy?
 - A lack of collaboration or "ownership" of chronic pain patients by specialists is a source of frustration for PCPs

Lincoln LE, et al. J Palliative Care Med. 2013;S3:001.



Strategy for Success

- Rarely should an interventionalist or a surgeon be the first line of referral
- Consider the physician who practices most biopsychosocially
- Consider a physiatrist!

Approach is more biopsychosocial than other pain specialists Stanos SP, et al. Sem Pain Med. 2004;2:186-196.

 Possess tools including medication, physical therapies, assistive technologies, education programs, and others
 von Groote PM, et al. J Rehabil Med. 2011;43:869-875.

Often specialize in treating injured workers

Chamblin D. Phys Med Rehabil Clin N Am. 2015;26(3):xi-xiii.

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Physiatrists

Broadest armamentaria of conservative treatment approaches

-The emphasis of treatment is on functional outcomes, not just "pain scores" Akuthota V. PM&R 2012;4:545-547.

"...physiatry is specifically geared toward the provision of holistic care and rehabilitation over time"

Gonzalez JG, Zotovas A. PM&R 2014;6:184-187.

- Top-notch diagnosticians
 - –Fellowships in sports, spine, pain, and general musculoskeletal medicine have increased in popularity among PM&R residents

Button JH, et al. Am J Phys Med Rehabil. 2007;86:926-934.

They know <u>When</u> to refer....and to whom



Physiatrists (cont'd)

 Numerous practice applications in PM&R have been empirically established as cost-effective

Cardenas DD, et al. Arch Phys Med Rehabil 2001;82:711-719.

 Biopsychosocial physiatrists question the benefit of the explosion in the rates of interventional approaches

Bagnall DL. PM&R 2010;2:3-5.

- Although many have become experts in regenerative therapies Mascarinas A, et al. Phys Med Rehabil Clin N Am. 2016;27:1003-1017.
- Mandatory physiatric consultation found to result in reduced rates of surgery for back pain, with high patient satisfaction

Fox J, et al. Spine 2013;38:E178-E184.

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Summary and Conclusions

- Irrespective of what our adolescent kids tell us, technology is not the answer to all of our problems...including chronic pain
- Finding "quick and easy" answers is alluring yet impossible
- We have to remember that chronic pain is a "disease of the person"....and thus the whole of the person must be addressed
- We've all learned our lessons about opioids being a "quick fix"



Summary and Conclusions (cont'd)

- We need to beware of those claiming that surgery, intrathecal opioids, spinal cord stimulation, and endless injections are the "answer"
 - -These technophilic approaches are far more financially-motivated than evidence-based
 - -With the possible exception being the new high frequency SCSs
- Primary care providers are under the gun to find quick and easy ways to treat patients with chronic pain

-Treating them biopsychosocially is indeed time-consuming

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Summary and Conclusions (cont'd)

- - -Knee-jerk referrals will generally frustrate your patients....and you!
- Physiatrists are generally the best physicians to whom to refer patients with chronic pain when your own treatment armamentarium becomes exhausted
 - Find a good one who believes in a biopsychosocial approach, not one who has become a full-time interventionalist
- Doing so will help your patients immensely....and allow you to feel good about providing sound and ethical treatment



THANK YOU

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