Maintaining Balance Among Compassionate Prescribing, Ethical Clinical Strategies, and Societal Obligations

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Dr. Schatman: Disclosures

- Dr. Schatman has no conflicts of interest to disclose

The contents of this activity does include discussion of off-label or investigative drug uses. The faculty is aware that is their responsibility to disclose this information.

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Target Audience

• The overarching goal of PCSS-O is to offer evidence-based trainings on the safe and effective prescribing of opioid medications in the treatment of pain and/or opioid addiction.

• Our focus is to reach providers and/or providers-in-training from diverse healthcare professions including physicians, nurses, dentists, physician assistants, pharmacists, and program administrators.

Educational Objectives

• At the conclusion of this activity participants should be able to:
  • Identify the stakeholders and recognize their influence on prescribing chronic opioids in American pain management.
  • Recognize how lack of understanding of the importance of pain management throughout the healthcare system, restrictions of insurance coverage and payment policies, pharmaceutical and medical device industries, regulatory and law enforcement policies, clinical practice guidelines, and news and information media, may all abandon chronic pain patients without appropriate opioid therapy.
  • Examine and review the practice of risk mitigation strategies for all physicians prescribing these drugs including mandatory use of UDT, prescription drug monitoring programs (PDMPs) and physician education in opioid safety.

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…”

• American pain medicine has come a long way but there is concern that recent changes will reverse that progress.
Attitudes Toward Opioid Analgesia

- American society has been labeled with many negative terms
- Among the least flattering are:
  - Absolutist
  - “Pendulumistic”
  - Agenda-driven (as opposed to data driven)
  - Disingenuous
  - Financially-driven
- These descriptors can be used for attitudes and policies regarding opioid analgesia

Problems with Chronic Opioid Therapy

- Lack of a long-term evidence of efficacy
- Opioid-induced hyperalgesia
- Possibility of:
  - Abuse
  - Addiction
  - Overdose
  - Diversion
  - Death
- Opioid-induced endocrinopathy
- Opioid-induced mood disorder

Relationship of Opioids Prescribed to Opioid-Related Deaths
Efficacy of Chronic Opioid Therapy

- “No evidence of benefit” is not the same as “evidence of no benefit”
- Current knowledge comes from:
  - Surveys
  - Case series
  - Open-label follow-up studies
  - Anecdotal evidence
- “Like any clinical therapy, some patients seem to do very well with chronic opioid therapy while others do not.”
- 2013 study: non-placebo-controlled, demonstrated sustained relief over 52 weeks

Opioid Pendulum

- The US went through a period of indiscriminate prescribing, causing misery on both individual and societal levels
- Opioids for chronic pain is becoming a thing of the past as arguments are being made that analgesia should not be the ends of pain medicine
- Now the pendulum has swung awry...to opiophobia
- Opiophobia -> Oligoanalgesia
- Have patients lost their voice in this debate?
- Has respect for patient autonomy been lost?

We Must Find A Middle Ground

- In our current healthcare system finding “balance” will be difficult
- The opioid debate is complicated and many of us are directly involved
- There are many stakeholders in American pain medicine:
  - Insurance companies
  - Health systems
  - Pharmaceutical industry
  - Law enforcement (federal, state, local)
  - Government health agencies
  - Media
Insurance Company Impact

- Profound impact on many levels
- For years, most types of chronic pain could be treated through interdisciplinary treatment programs
- Functional restoration was important; so was reducing reliance upon opioids
- Evidence-bases for cost-efficiency as well as for clinical efficacy were established


The Fall of Interdisciplinary Pain Clinics

- Over 1,000 programs in the 1990’s
- Decreased to fewer than 90 today
- ≥100 million Americans with chronic pain
- This leaves 1 program for every 1.1 million patients


International Perspective

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Abuse-Deterrent Coverage

- Abuse-deterrent and tamper-resistant formulations are not perfect but do help reduce abuse.
- Increase physician confidence in prescribing opioids.
- Not available as generics so are more expensive.
- Due to cost, insurers often do not cover them.

Insurers: “Just Say No”

- Many for-profit insurers now limit opioid prescriptions due to fear of addiction and its associated costs.
- Their focus is on cost-containment and profitability rather than obligation to the chronic pain patient.
- Adds more complications and limits to effective pain care.

Health Systems Adopt No-Opioids Policy

- Began with anecdotal reports.
- Now beyond anecdotal:
  - “Prescription drug crackdown making it hard for some to obtain needed pain pills.”
  - “Tennova Healthcare to stop prescribing opiates for long-term care.”
- Research describes health system programs to reduce opioid doses in patients on chronic opioid therapy:
  - Demonstrated large decreases in mean daily doses
  - Did not mention patient responses to dosage decreases.
- It is distressing that researchers did not recommend alternative treatments that are evidence-based and accessible.
Health Systems Prescription Problems

The “chilling effect” is also having an adverse impact on primary care systems’ willingness to prescribe

**RX: Opioids**

- Physicians are abruptly discontinuing chronic opioid therapy in adherent patients
- Particularly problematic as many pain specialists have become less likely to prescribe opioids than PCPs
- Of great concern, state guidelines such as Washington’s require a referral to a “pain specialist” for high-dose opioid prescribing


Pharma Influence on Prescribing

- Certain pharmaceutical companies played a role in the formation of the opioid crisis
  - Misleading marketing statements created a sense of false security in opioid prescribing
- Though marketing practices have changed, Pharma still influences prescribing:
  - Paying the IMMPACT Group co-chairs up to $50,000 each to facilitate drug approval meetings with the FDA
  - Engaging in questionable "enriched enrollment randomized withdrawal (EERW)" methods in clinical trials in order to fast-track opioid analgesics


Pharma Marketing Strategy

- Yet their greatest influence is probably through legal marketing
  - Many non-CME presentations are infomercials
  - Pharma-sponsored and -conducted opioid research is published in the same issues of journals in which they advertise
- Some have called for prohibition of opioid marketing, particularly for chronic pain
- The AMA has proposed a ban on direct-to-consumer Pharma marketing

Pharma’s Fight for Abuse-Deterrence

- Developing improved tamper-resistant products
- Some groups oppose approval because they are not yet completely “abuse-proof”
- Yes, they are trying to make money and make opioid prescribing safer but are frustrated by insurers’ refusal to pay for these new formulations

DEA and Government Crackdown

- DEA started the opioid war offensive
  - Pill mills clearly had to be shut down
  - Now shifted from focusing on preventing diversion, abuse, overdoses, and deaths to investigating well-intentioned physicians for prescribing practices
- State governments also involved, at times with questionable legality
  - 2010 – Florida state agencies and law enforcement partnered with the federal government to shut down pill mills
  - Massachusetts attempted to make Zohydro® illegal – which a federal judge quickly overruled
- State and local law enforcement have also been involved with roles varying from town to town

Physicians Fear Prescribing Opioids

- Physicians’ primary fear seems to be regulatory scrutiny/sanction
  - Almost half of primary care physicians expressed such fear in a recent study
  - Training on regulatory tracking compliance did not reduce fear

The 2013 Federation of State Medical Boards Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain addressed physician fears
Federation of State Medical Boards
Model Policy

- The policy states physicians should not fear prescribing under the following conditions:
  - For a legitimate medical purpose
  - In the usual course of professional practice
  - Based on accepted scientific knowledge or sound clinical grounds
  - Based on clear documentation
  - In compliance with applicable state or federal law

- Is this true today…is it becoming less so?

Restrictive Prescribing Regulations

- The public's (and physicians') confusion regarding "addiction" vs. "dependence" on opioids has had an impact on prescribing practices
- Restrictive prescribing regulations are unethical in two ways:
  - Scare physicians into not prescribing opioids
  - Reinforces misconceptions, further marginalizing already stigmatized patients

Federal Registrant Actions Against Physicians

- Actions taken against physicians are not the only story
- The number of investigations of physicians is not made public
- Erroneous prosecutions of physicians prescribing responsibly have a chilling effect on all prescribers

Most Recent Numbers:

- 2003 - 34 2010 - 25
- 2004 - 74 2011 - 66
- 2005 - 40 2012 - 44
- 2006 - 32 2013 - 31
- 2007 - 42 2014 - 21
- 2008 - 24 2015 - 31
- 2009 – 26
Government Health Agency Guidelines

- It's become all about the guidelines, quality and integrity of which are in contention
- 2009 Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain
  - Not perfect...But relatively well-balanced and highly rated in a systematic review
  - Tend to be arbitrary
  - Disingenuous in suggesting that safer and more effective treatments are readily available
  - Ex: Interagency Guideline on Prescribing Opioids for Pain 2015

CDC Guideline

The recent CDC Guideline.... practically and ethically problematic

- CDC claims the guideline is based on "scientific evidence"
  - "CDC did not formally rate the quality of evidence"
  - Are they "consensus guidelines"?
- Drafted primarily by a "Core Expert Group"
  - At least 5 Board Members of Physicians for Responsible Opioid Prescribing (PROP) provided input as Core Expert Group, Stakeholder Review Group, or Peer Review Panel members
  - Many feel that PROP is very anti-opioid, representing a conflict of interest

CDC Guideline: Recommendation or Law?

- To refer to the guideline as "voluntary" is disingenuous
- Its potential to become de facto law is very real
- States are already passing more restrictive legislation consistent with the CDC guideline
  - "Clearly the intent of CDC is that the guideline be distributed to and adopted by state public health entities and certifying organizations as if it had the legal authority of a regulation."
The greatest deception men suffer is from their own opinions.

“Leonardo da Vinci

The Media Influence on Prescribing

- The opioid crisis is “bloody” and “if it bleeds, it leads.”
- The media has been a central player in the “war on opioids” against:
  - Manufacturers
  - Prescribers
  - Patients
- PROP has become the “media darling”
  - A search of Google News indicates they’re cited almost daily

When did we last see a “feel good” story in the media about opioids helping a patient enjoy a better quality of life?

We’ve all seen it in our practices...and academic journals occasionally report benefits – including in empirical investigations

Where are the “feel-good” stories?

- May 27-28 (24-hour) Google News search for “opioid”
- 75 stories yielded
- Every story included some combination of the words “abuse”, “addiction”, “overdose” or “epidemic”
- Not a single “feel-good” story
- The closest found was entitled, “As Overdose Deaths Increase, So Do Life-Saving Organ Donations”
Freedom of Press vs Patient Respect

- Many mentioned Prince...even though toxicology reports were not yet back
- Freedom of the press is important
- But is it right to stigmatize and marginalize patients for whom there is no other option other than opioid analgesia?
- Increased media coverage of opioids and their portrayal as a social problem was empirically determined to coincide with their decreased prescription

Recent Article Seeking Balance

- "Unfortunately, the (opioid) situation has been blurred by some politicians, health professionals, and the media by their using inadequate concepts, misrepresenting and exaggerating facts, and demonizing pain patients."
- Does not sugar-coat the opioid crisis
- Yet urges balance

Saying “No”: The Easy Way Out?

- Years of indiscriminate prescribing cannot be "undone" by shifts in practice
- History should not be the cause of opiophobia, oligoanalgesia, and needless suffering
- The opioid crisis affects not only individuals, but society as a whole
- "Just saying no":
  - Not the answer, though it may seem an easy solution for many physicians and policy-makers
  - Not ethical practice; allows patients to needlessly suffer when we have medication to relieve chronic pain
  - May actually be construed as patient abandonment
Risk Management

- Abuse and addiction will always be risks
- Physicians are morally obligated to be risk managers as an expression of nonmaleficence
- Are risk mitigation strategies a panacea?
  - No, but the available data suggest that they help
- The data on the lack of use of these strategies is discouraging:
  - Screening for psychosocial and behavioral risk factors:
    - Very recent data suggest that it is uncommon, less than 6% of physicians

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Risk Management: UDT

- Hard to assess in "real world", as most studies occur in academic medical centers – likely artificially inflated prevalence
- E.g., once a program encouraging use of UDT was initiated, half of all patients receiving COT received UDT, as opposed to only 7% 2 years prior
- Recent study involving community health service patients found that only 24% on opioids received even a single UDT
- The one American systematic review on UDT efficacy – while limited leans toward efficacy for misuse prevention

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Risk Management: PDMPs

- Great heterogeneity of programs from state to state
  - Only 32% have an enrollment mandate for physicians
- Percentage of prescribers who use PDMPs nationwide is extremely difficult to determine
- Outreach efforts to register more physician users not effective
- Efficacy of PDMPs: Empirically established for reducing overdose deaths and doctor-shopping
Risk Management: Mandatory Education

- Mandatory education in opioid safety
  - A touchy topic for some physicians
  - Would such mandatory education allow physicians to make better decisions in the face of outside influences?
- Undergraduate medical education in pain management is deficient
  - Only 4 of 104 medical schools surveyed had a required pain course
  - There are no full-term pain residency programs
  - Fellowships in pain medicine are available only for a few types of specialists

Ethical Prescribing

- Calls have been made for mandatory use of:
  - UDT
  - PDMPs
  - Physician education in opioid safety
- American physicians seem reluctant to accept these risk management practices
  - Ex: Half of all PCPs said they would discontinue opioid prescribing if opioid education was required or they were compelled to provide patient education
- If physicians do not begin to universally mitigate risk associated with opioid prescribing, other stakeholders will “mitigate risk” by making opioids simply “go away”
  - Tragically, this has already begun to happen...
Summary and Conclusions

• Opioids are potentially dangerous
  ▪ As demonstrated by indiscriminate prescribing fueled by illegal marketing in the beginning of this millennium
• Our current lack of options for access to safer and more effective chronic pain management necessitates opioids remain in physicians’ pain management armamentaria
• The influence of extraneous stakeholders in American pain medicine make prescribing onerous and frightening

Summary and Conclusions

• Development of a single-payer system will go a long way toward allowing our system to catch up with those of the rest of the industrialized world
• Would any of you not feel safer prescribing if all opioids were abuse-deterrent formulations?
• Pharma isn’t perfect…but is responding to a wide range of pressures to clean up its act
• Are regulatory agencies a threat to physicians who prescribe opioids?
  ▪ Not if their risk mitigation practices are thorough, consistent, and documented
  ▪ But other stakeholders may be a threat to physician and patient autonomy

Summary and Conclusions

• “Just saying no” to prescribing probably feels safe
• Yet doing so will cause needless suffering among tens of millions of Americans for whom there is presently no better option
• Practicing aggressive risk mitigation is the only ethical answer
• Sometimes, doing the right thing is not necessarily easy but it is still the right thing.
References


15. PCSS-O Colleague Support Program and Listserv

- PCSS-O Colleague Support Program is designed to offer general information to health professionals seeking guidance in their clinical practice in prescribing opioid medications.
- PCSS-O Mentors comprise a national network of trained providers with expertise in addiction medicine/psychiatry and pain management.
- Our mentoring approach allows every mentorship to be unique and catered to the specific needs of both parties.
- The mentoring program is available at no cost to providers.

For more information on requesting or becoming a mentor visit:
www.pcss-o.org/colleague-support

- Listserv: A resource that provides an ‘Expert of the Month’ who will answer questions about educational content that has been presented through PCSS-O project. To join email: pcs-o@aaap.org.
PCSS-O is a collaborative effort led by American Academy of Addiction Psychiatry (AAAP) in partnership with: Addiction Technology Transfer Center (ATTC), American Academy of Neurology (AAN), American Academy of Pain Medicine (AAPM), American Academy of Pediatrics (AAP), American College of Physicians (ACP), American Dental Association (ADA), American Medical Association (AMA), American Osteopathic Academy of Addiction Medicine (AOAAM), American Psychiatric Association (APA), American Society for Pain Management Nursing (AsPMN), International Nurses Society on Addictions (INNSA), and Southeast Consortium for Substance Abuse Training (SECSAT).

For more information visit: www.pcss-o.org
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