PainWeek®

Who Will Love This Child?
Advocating for Chronic Pain Patients

Kevin L. Zacharoff, MD, FACPE, FACIP, FAAP

Disclosure

- Nothing to Disclose

Learning Objectives

- Illustrate how a shift in strategies to combat the “opioid epidemic” may have resulted in deficits in pain patient care and advocacy
- Describe the new formula for opioid analgesic risk/benefit analysis determination
- Identify commonalities in current guidelines that may have led to decreased or “deprescribing” of opioid analgesics
- Describe methods to help recognize, reflect upon, care for, and circumvent potential abandonment of the patients who need us most while striving to enhance public safety efforts to mitigate societal risk

Are Pain Patients the "Hunchback" of Today?

- Do we *still* owe pain patients the right to have their pain assessed and treated?
- How has the shift in opioid analgesic risk/benefit analysis changed the way we:
  - Believe?
  - Feel?
  - Advocate?
  - Avoid?
  - Ignore?
  - Abandon?
- Or is this all just a response to fear of regulatory scrutiny?
  - Does regulatory scrutiny protect ***patients***?

Bias, Stigma, and Pain

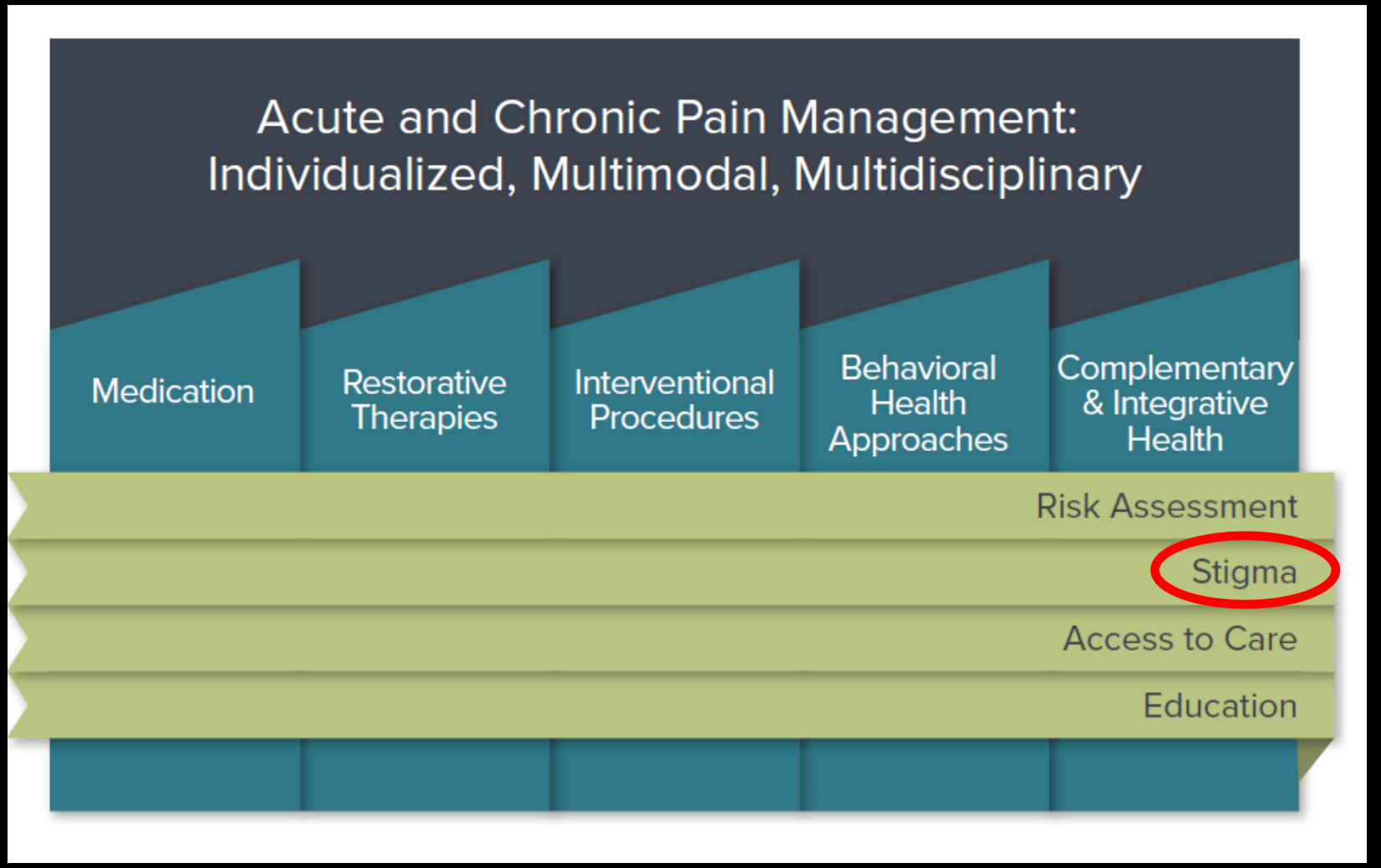
Pain Management Best Practices Inter-Agency Task Force

- "***Established to propose updates to best practices and issue recommendations that address gaps or inconsistencies for managing chronic and acute pain***"
  - The U.S. Department of Health and Human Services guided this effort along with the U.S. Department of Veterans Affairs and U.S. Department of Defense
  - The Task Force consisted of representatives from relevant HHS agencies, the Departments of Veterans Affairs and Defense and the Office of National Drug Control Policy
  - Non-federal representatives included from diverse disciplines and views, including experts in areas related to pain management, pain advocacy, addiction, recovery, substance use disorders, mental health, and minority health and more

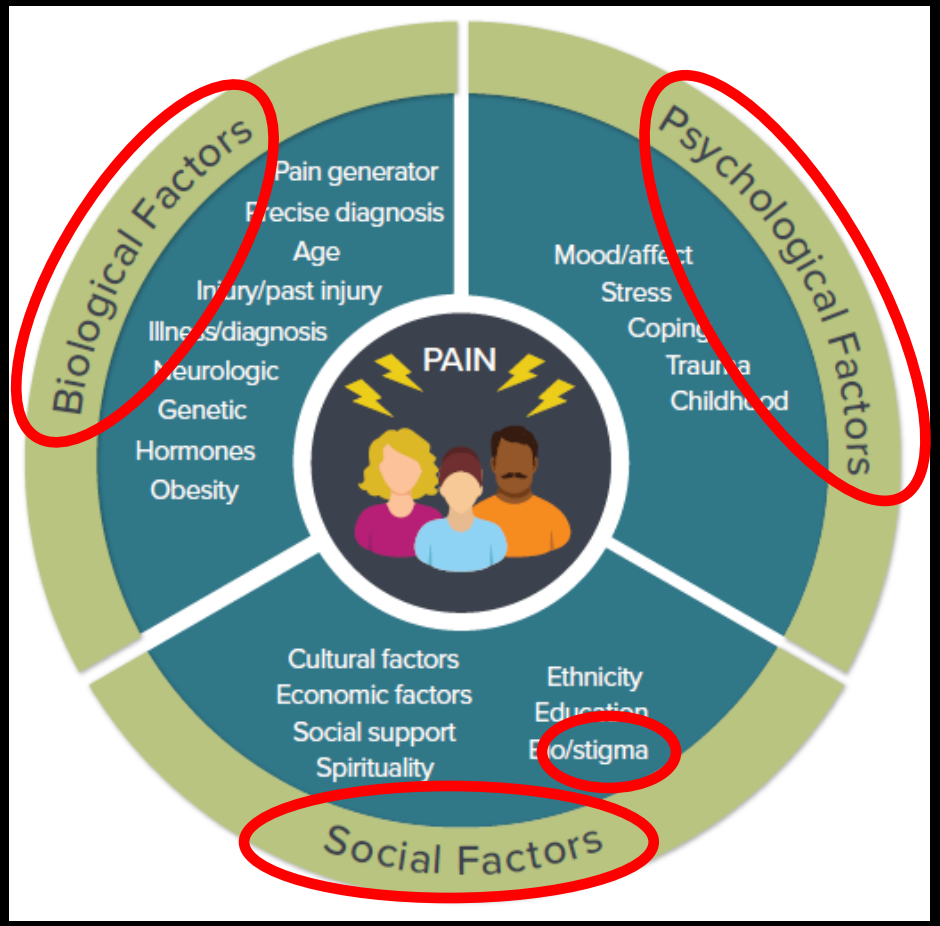
Stigma

- ***"Stigma can be a barrier to treatment of painful conditions"***
- **Often presents a barrier to care and is often cited as a challenge for:**
  - Patients
  - Families
  - Caregivers
  - Clinicians
  - Social dynamics
- **In the current environment, patients with chronic pain — particularly those being treated with opioids — can be stigmatized**
- **May be exacerbated when co-morbidities exist**
  - Anxiety
  - Depression
  - Substance Use Disorder
  - etc.

Treatment Approaches Informed by Four Critical Topics



The Biopsychosocial Model of Pain Management



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Stigma

- ***"Studies suggest that patients who are receiving or who have previously received long-term opioid therapy for nonmalignant pain face both subtle and overt stigma from:"***
  - Family
  - Friends
  - Coworkers
  - The Health Care System
  - Society
  - Insurers

Stigma

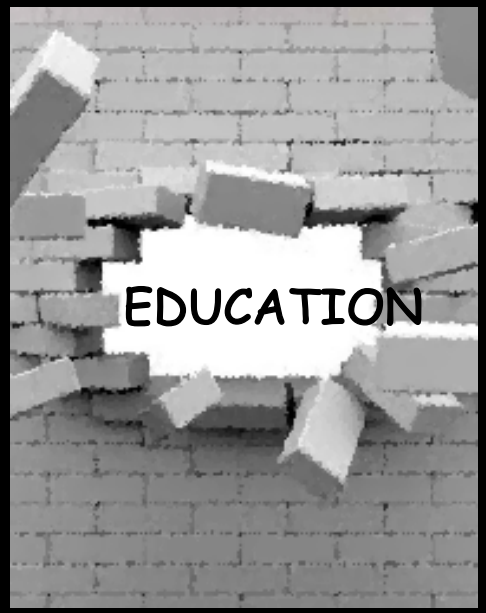
- Feelings of ***guilt***, ***shame, judgement, and embarrassment*** resulting from stigma can increase the risk for behavioral health issues, such as anxiety and depression
  - Which can further contribute to ***symptom chronicity***
- *"The sub-population of patients with painful conditions and comorbid Substance Use Disorder (SUD) face **additional barriers** to treatment because of stigmatization of both chronic pain and addiction."*
- *"Chronic pain is common among individuals with SUD, including opioid misuse, yet **stigma remains a significant barrier** to implementation of programs and treatments for such as medication-assisted treatment and naloxone"*

Recommendations

"Reducing barriers to care that exist as a consequence of stigmatization is crucial for patient engagement and treatment effectiveness"

Recommendations

"Increase patient, physician, clinician, non-clinical staff, and societal education on the underlying disease processes of acute and chronic pain to reduce stigma"



Recommendations

"Increase patient, physician, clinician, non-clinical staff, and societal education on the disease of addiction"

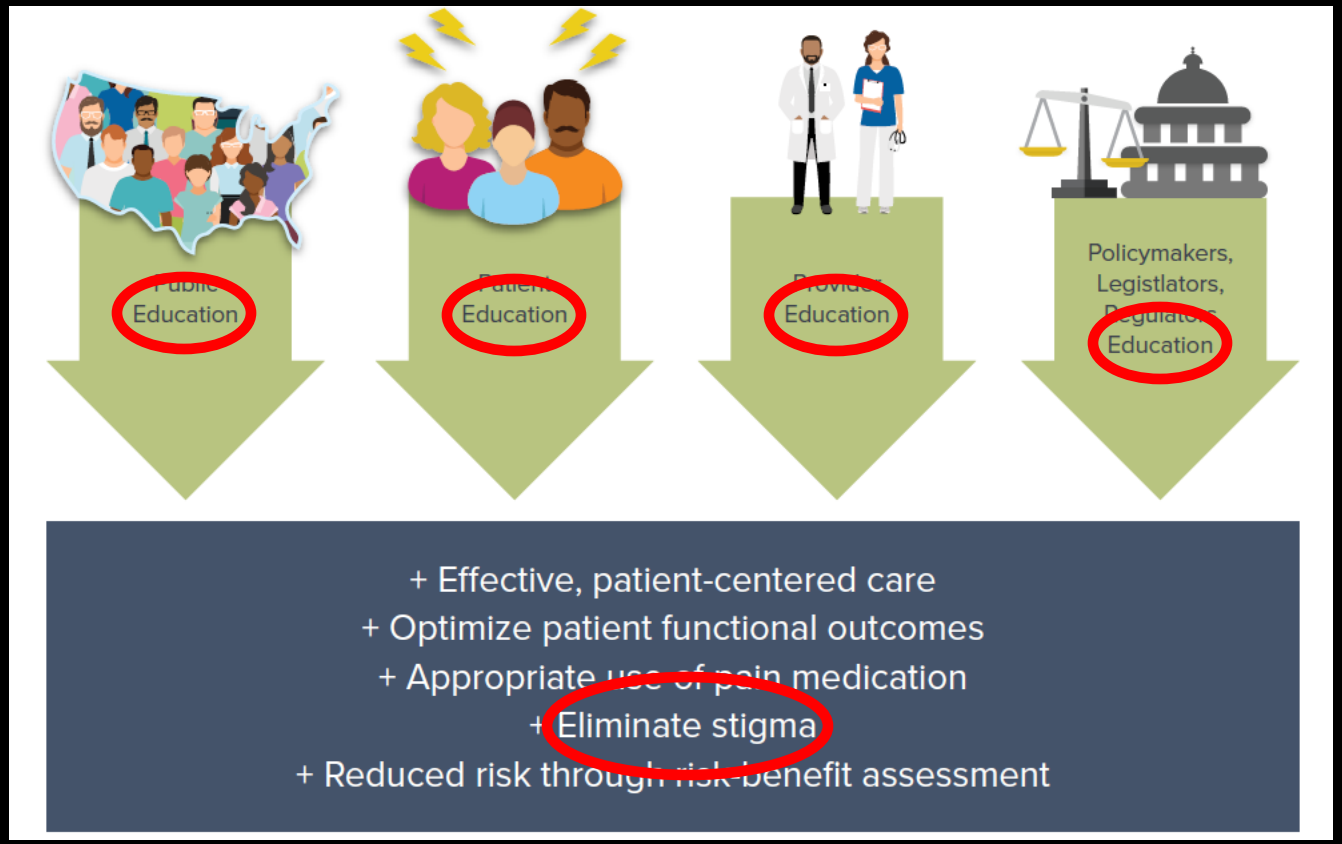
Recommendations

"Counter societal attitudes that equate pain with weakness through an awareness campaign that urges early treatment for pain that persists beyond the expected duration for that condition or injury"

Recommendations

"Identify strategies to reduce stigma in opioid use so that it is never a barrier to patients receiving appropriate treatment, with all cautions and considerations, for the management of their chronic pain conditions"

Does Education Make a Difference?



A Different Perspective on the Opioid Epidemic

- **Knee-jerk response to the Centers for Disease Control and Prevention (CDC) Guidelines**
  - "*Unfortunately, many practitioners took a broader interpretation of the recommendations and began further decreasing their prescriptions for opioids, afraid they'd be found in violation of the guidelines*"
  - "*Some reduced their patients' opioid prescriptions, while others abandoned patients who needed more than the average amount of pain management medications*"
  - "*These "corrective actions" have helped create a new opioid epidemic, one in which patients with legitimate need for pain medication may be undertreated*"

"Since the guidelines were published, some agencies viewed them as concrete rules rather than suggestions"

https://www.ashclinicalnews.org/spotlight/feature-articles/the-other-opioid-epidemic/. Accessed July 21, 2020.

A Different Perspective on the Opioid Epidemic

- *"Healthcare providers refused to write opioid prescriptions over fears of fines, or even arrests, given the heightened attention on prescribing patterns"*
- *"Pharmacists also refused to fill prescriptions"*
- *"Insurance companies used the guidelines to deny payments for prescriptions that didn't fit within them"*
- *New Terminology:*
  - ***MAXIMUM FILL***
  - ***FORCED TAPER***
  - ***DEPRESCRIBE***

https://www.ashclinicalnews.org/spotlight/feature-articles/the-other-opioid-epidemic/. Accessed July 21, 2020.

From the Patient Perspective

Published in final edited form as:

Narrat Inq Bioeth. 2018 ; 8(3): 239–245. doi:10.1353/nib.2018.0073.

On Being the "Right" Kind of Chronic Pain Patient

Caroline J. Huang[†,*]

[†]Department of Bioethics, National Institutes of Health Clinical Center

Is There a "Right" Kind of Chronic Pain Patient in the Midst of an "Opioid Epidemic"?

Living in pain is work. Real, material labor; and because the overwhelming majority of us who suffer it still endeavor also to do other work in the labor economy—have a job, raise children, or otherwise participate productively in society—opioid medication serves as an essential tool, however limited or imperfect, in getting both jobs done

Huang, C.J., On Being the "Right" Kind of Chronic Pain Patient. *Narrative Inquiry in Bioethics*. 2018 ; 8(3): 239–245. doi:10.1353/nib.2018.0073.

Is There a "Right" Kind of Chronic Pain Patient in the Midst of an "Opioid Epidemic"?

Within an hour of taking a dose of tramadol, I am able to sit down without pain, without fidgeting. No longer needing to focus on my breath or on mindfully observing the texture of pain in order to get through it, I can attend to the world around me, follow a conversation, wash the dishes, bend down to pick things up, walk my children to school or sit with them to watch a movie. I can work. I can finish this essay and still make dinner.

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Huang, C.J., On Being the "Right" Kind of Chronic Pain Patient. *Narrative Inquiry in Bioethics*. 2018 ; 8(3): 239–245. doi:10.1353/nib.2018.0073.

Is There a "Right" Kind of Chronic Pain Patient in the Midst of an "Opioid Epidemic"?

Using opioids to facilitate participation is not in itself evidence of addiction

Patients themselves often confront—and sometimes internalize—the stigma of addiction in seeking to regulate their opioid use

Huang, C.J., On Being the "Right" Kind of Chronic Pain Patient. *Narrative Inquiry in Bioethics*. 2018 ; 8(3): 239–245. doi:10.1353/nib.2018.0073.

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I permitted myself drugged reprieve, but only after I let myself sufficiently suffer, living the societal argument of blame on the drug-seeker and stigma of a potential addict

Reducing opioid use was empowering, despite the increased pain… I wasn't in school, or able to work, to contribute. Tapering off opioids was something I could do; it gave me the agency I sought in a situation where I otherwise had almost none. Standing up to severe pain became a metric of self-worth.

Huang, C.J., On Being the "Right" Kind of Chronic Pain Patient. *Narrative Inquiry in Bioethics*. 2018 ; 8(3): 239–245. doi:10.1353/nib.2018.0073.

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Chronic pain patients are not addicted—they are dependent on a medication in order to function and contribute to society. I am also dependent on 2 anti-hypertensives. I rely on aspirin for its anti-platelet properties. Would anyone ever imagine taking those treatments away because I am dependent on them? No.

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Is There a "Right" Kind of Chronic Pain Patient in the Midst of an "Opioid Epidemic"?

It was decided that my medications would be decreased, and my internal dilaudid pain pump would be turned off. As an addict, this was a terrifying thought. However, after speaking with the medical professionals I had built a trust with, I agreed to go through with their plan.

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Is There a "Right" Kind of Chronic Pain Patient in the Midst of an "Opioid Epidemic"?

I would tell others with chronic pain that opioids are almost never the appropriate long-term solution for pain. These should only be considered as a last resort when all other options have failed, for terminally ill patients, and for very short-term use after procedures. If you're on high doses of opioids and you're not getting any benefit, discuss doing a taper with your PCP or ask them to send you to a specialist who can do this.

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Is There a "Right" Kind of Chronic Pain Patient in the Midst of an "Opioid Epidemic"?

I really felt as though this [reduction] had to be a misunderstanding that would be easily corrected. During the visit I found out quickly this was not a mistake. … The last thing that he said to us was that "his patient's quality of life was not worth risking his practice."

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Huang, C.J., On Being the "Right" Kind of Chronic Pain Patient. *Narrative Inquiry in Bioethics*. 2018 ; 8(3): 239–245. doi:10.1353/nib.2018.0073.

Is There a "Right" Kind of Chronic Pain Patient in the Midst of an "Opioid Epidemic"?

Finding a physician to bring me back to the level of opioids I had been on will never happen. I had no desire to go to the streets for drugs either. I can't afford it, nor would I risk my health by getting something other than what I thought I was getting… I would probably get caught and thrown in jail. What are pain patients like myself supposed to do now?

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Is There a "Right" Kind of Chronic Pain Patient in the Midst of an "Opioid Epidemic"?

But we should worry about the voices we are not hearing: the patient who cannot take time off her minimum-wage job for hands-on therapies and by default opts for cheaper, quicker medication-based management, for example.

Huang, C.J., On Being the "Right" Kind of Chronic Pain Patient. *Narrative Inquiry in Bioethics*. 2018 ; 8(3): 239–245. doi:10.1353/nib.2018.0073.

A Different Kind of Media Attention

Pain Patients to Congress: CDC's Opioid Guideline Is Hurting Us

— Has stoked "climate of fear" leading to inadequate treatment of chronic pain

by Shannon Firth, Washington Correspondent, MedPage Today February 13, 2019

Opioid crisis fallout: Physicians increasingly avoid treating chronic pain patients, survey finds

November 6, 2019
Keith A. Reynolds

HP3 Health Professionals for Patients in Pain

Professionals Call on the CDC to Address Misapplication of its Guideline on Opioids for Chronic Pain through Public Clarification and Impact Evaluation

PUBLIC HEALTH

Pain Patients Get Relief from War on Opioids

U.S. agencies warn doctors not to abruptly cut off the medications for long-time users

By Claudia Wallis on April 19, 2019

Good News/Bad News

- Is a decrease in opioid prescribing a good thing or a bad thing?
- For whom?

The New York Times

Good News: Opioid Prescribing Fell. The Bad? Pain Patients Suffer, Doctors Say.

Doctors and insurers are using federal guidelines as cover to turn away patients, experts tell the C.D.C. and Congress.

Dr. Robert L. Wergin, right, handing a prescription to a pain patient at the Milford Family Medical Center in Milford, Neb. Michael Kirby Smith for The New York Times

By Jan Hoffman and Abby Goodnough

March 6, 2019

A Different Kind of Media Attention

Health

Opioid crackdown forces pain patients to taper off drugs they say they need

The Washington Post

By Joel Achenbach and Lenny Bernstein

September 10, 2019 at 10:54 a.m. EDT

Hank Skinner and his wife, Carol, are no strangers to pain, having collectively experienced multiple illnesses and surgeries. Hank relies on a fentanyl patch but is now being forced to lower his dosage. (Salwan Georges/The Washington Post)

Chronic pain patients form a vast constituency in America, and millions of them take opioids for relief. Changes in medical guidance covering opioids have left many of them frustrated, confused and sometimes howling mad. They feel demonized and yanked around.

Clinicians Coming to the Rescue?

More than 300 medical experts, including three former White House drug czars, contend that the CDC guidelines are harming one group of vulnerable patients: those with severe chronic pain, who may have been taking high doses of opioids for years without becoming addicted. They say the guidelines are being used as cover by insurers to deny reimbursement and by doctors to turn patients away. As a result, they say, patients who could benefit from the medications are being thrown into withdrawal and suffering renewed pain and a diminished quality of life, even to the point of suicide.

Good News: Opioid Prescribing Fell. The Bad? Pain Patients Suffer, Doctors Say.

The New York Times

Doctors and insurers are using federal guidelines as cover to turn away patients, experts tell the C.D.C. and Congress.

By Jan Hoffman and Abby Goodnough

March 6, 2019

Money for Nothing…

- Is this really happening?
- Who is left to advocate for patients with chronic pain?
  - Have we redrawn the lines between cancer and noncancer pain?
- Why might this be happening?
- Was the intention to really make sure that patients don't have access to these medications?
- What are the alternatives proposed in lieu of opioids?
  - NSAIDS?
  - Acetaminophen?

Michigan surgeons offered more money to limit opioids for pain

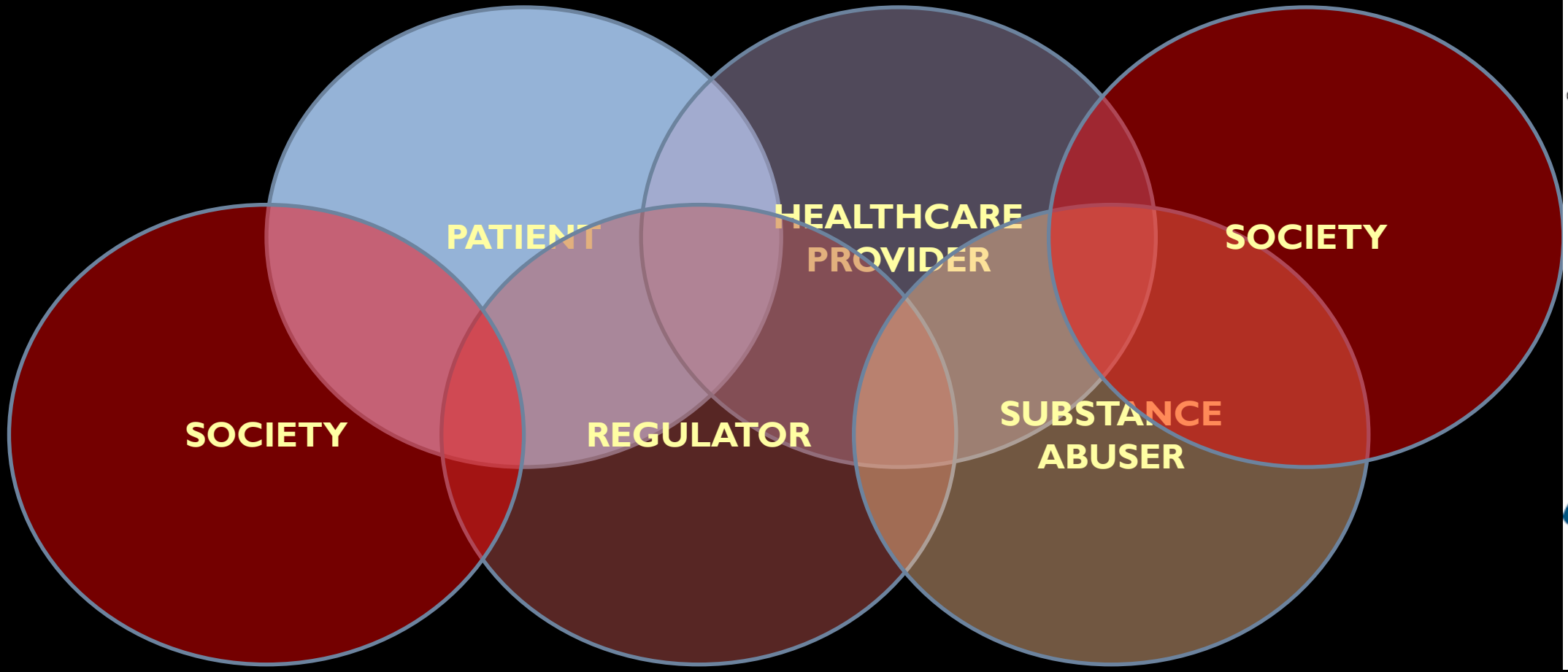
Limiting her pain pills after surgery this year left Jennie Elrod anxious and feeling like she had to "ration" her pain control. (Bridge photo by Robin Erb)

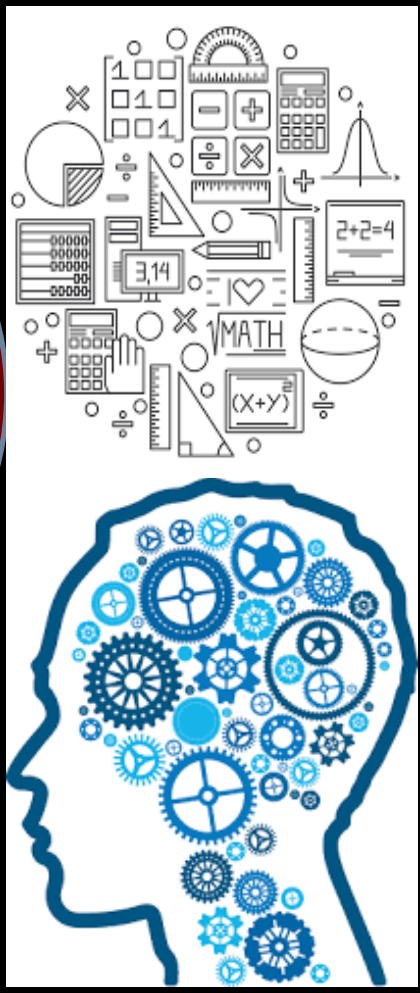
October 15, 2019 Robin Erb Michigan Health Watch

Opioids in Michigan

Clinical Considerations and Implications

The "**New Math**" for Determining Opioid Risk/Benefit Analysis





The Story of Opana ER

- *"After careful consideration, the agency is seeking removal based on its concern that the benefits of the drug may no longer outweigh its risks"*
- *"This is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse"*

https://www.fda.gov/news-events/press-announcements/fda-requests-removal-opana-er-risks-related-abuse . Accessed July 22, 2020.

The Story of Opana ER

- "*We are facing an opioid epidemic – a public health crisis, and we must take all necessary steps to reduce the scope of opioid misuse and abuse*," said FDA Commissioner Scott Gottlieb, M.D.
- "*We will continue to take regulatory steps when we see situations where an opioid product's risks outweigh its benefits, not only for its intended patient population but also in regard to its potential for misuse and abuse.*"
- "*The abuse and manipulation of reformulated Opana ER by injection has resulted in a serious disease outbreak. When we determined that the product had dangerous unintended consequences, we made a decision to request its withdrawal from the market*," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research.

https://www.fda.gov/news-events/press-announcements/fda-requests-removal-opana-er-risks-related-abuse . Accessed July 22, 2020.

Blood. 2017 Feb 16; 129(7): 896–905. PMCID: PMC5314814
Prepublished online 2016 Nov 18. doi: 10.1182/blood-2016-08-736579 PMID: 27864296

A mechanistic investigation of thrombotic microangiopathy associated with IV abuse of Opana ER

Ryan Hunt,[1,*] Ayla Yalamanoglu,[2,*] James Tumlin,[3] Tal Schiller,[1] Jin Hyen Baek,[2] Andrew Wu,[1] Agnes B. Fogo,[4] Haichun Yang,[4] Edward Wong,[5,6,7] Peter Miller,[8,9,10] Paul W. Buehler,[2] and Chava Kimchi-Sarfaty[1]

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8. Jabr FI, Yu L. Thrombotic microangiopathy associated with Opana ER intravenous abuse: a case report. J Med Liban. 2016;64(1):40-42. [PubMed] [Google Scholar]

The Patient You Lease Want to See

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The Patient You Least Want to See

JAMA April 26, 2016 Volume 315, Number 16

A PIECE OF MY MIND

Jonathan H. Chen, MD, PhD
Division of General Medical Disciplines, Department of Medicine, Stanford University, Stanford, California.

- *Signing my first orders as a medical intern was distinctly disconcerting*
- *Pharmacists corrected my orders for excessive doses of insulin or potassium, while senior physicians guided my selection of vasopressor infusions and antibiotics*
- *When it came to intravenous opioids, however, those same pharmacists never hesitated to approve my orders, and I found little structured guidance from supervising physicians*
- *With no questions asked, I included "as needed" acetaminophen, oxycodone, and IV morphine in my standard order set for every patient I admitted*
- *This often culminated in a last-minute desperate discharge plan, with many demoralizing negotiations over "just one more push of IV Dilaudid and Benadryl"*

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- *I came to appreciate a more insidious problem and, even worse, worried that I was contributing to it*
- *I soon found that the patients I least wanted to see were those fixated on negotiating for additional opioids in the hospital*
- *I was caught between challenging patients and inconsistent supervising physicians, between the power to prescribe potent medications and learning to compassionately manage pain, and between social mores steeped in prioritizing pain treatment to one recognizing the dangers of the misuse of prescription opioid drugs*

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- *With the pervasiveness of the prescription opioid problem, the inconsistent practices among even seasoned physicians, and policy calls for increased prescriber education and monitoring, we may all be "trainees" when it comes to these complex cases*
- *One resident physician summed up a collective sentiment:*
  - *"Drug seeking is almost certainly what's happening here, but I wouldn't stick that into the patient's chart since I can't be absolutely sure"*
- *Role modeling from supervising attending physicians can have a direct impact on a trainee's future career prospects and practices. I found this especially challenging in cases of drug misuse with a lack of consistency in practice patterns across (and sometimes within) different physicians, resulting in team splitting and undermined decisions.*

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- *Some residents, including me, have been overtly censured with poor attending evaluations when patients complained that we paused to discuss the risk and benefits of their requested IV medications*
- *Perhaps some find it simpler, as I did as an intern, to respond to such patients by generally avoiding them, ordering whatever they ask for, and simply keeping our head down until either we or the patient leaves the hospital*
- *One attending's explicit advice for such cases: "If you just stop ordering the opioids, these patients will eventually find their way out of the hospital"*

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- *While this was a convenient abstract philosophy, it did not offer much concrete help to the nursing staff, primary intern, and least of all the actual patient, in facing a difficult problem at the bedside*
- *With limited guidance from senior physicians in facing patients with drug-misuse problems, I believe my sense of isolation culminated in one of my last admissions as an intern. A young woman with scoliosis and chronic back pain developed prescription opioid dependency, which then turned into IV drug addiction (dissolving pills in water) and an infected heart valve*
- *"Wait! You can't just leave me like this," she exclaimed. "You have to give me something right now. Now. Now!" I covered my eyes as I wrote the order for IV morphine before I fled the room, half-terrified and half-ashamed. Once my team gathered, my attending dismissed the patient's concerns by telling her that "It was these drugs that got you into trouble in the first place, so you won't be getting anymore."*

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- *When I work with medical trainees, I hope that we can together learn a thoughtful and consistent approach to opioid prescribing in both acute inpatient and chronic outpatient settings*
- *This is just as I expect us to learn a systematic approach to prescribing insulin to patients with diabetes, recognizing that as a fundamental skill for a pervasive medical problem*
- *While many clinical topics compete for educational priority, prescription drug misuse and addiction is one that an inadequately trained medical community will routinely contribute to, if not overtly cause*

The Patient You Least Want to See

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- *Facing this is challenging, but I recall one of my medical school attending's teachings:*
- *The patient you least want to see is probably the one who needs you the most*

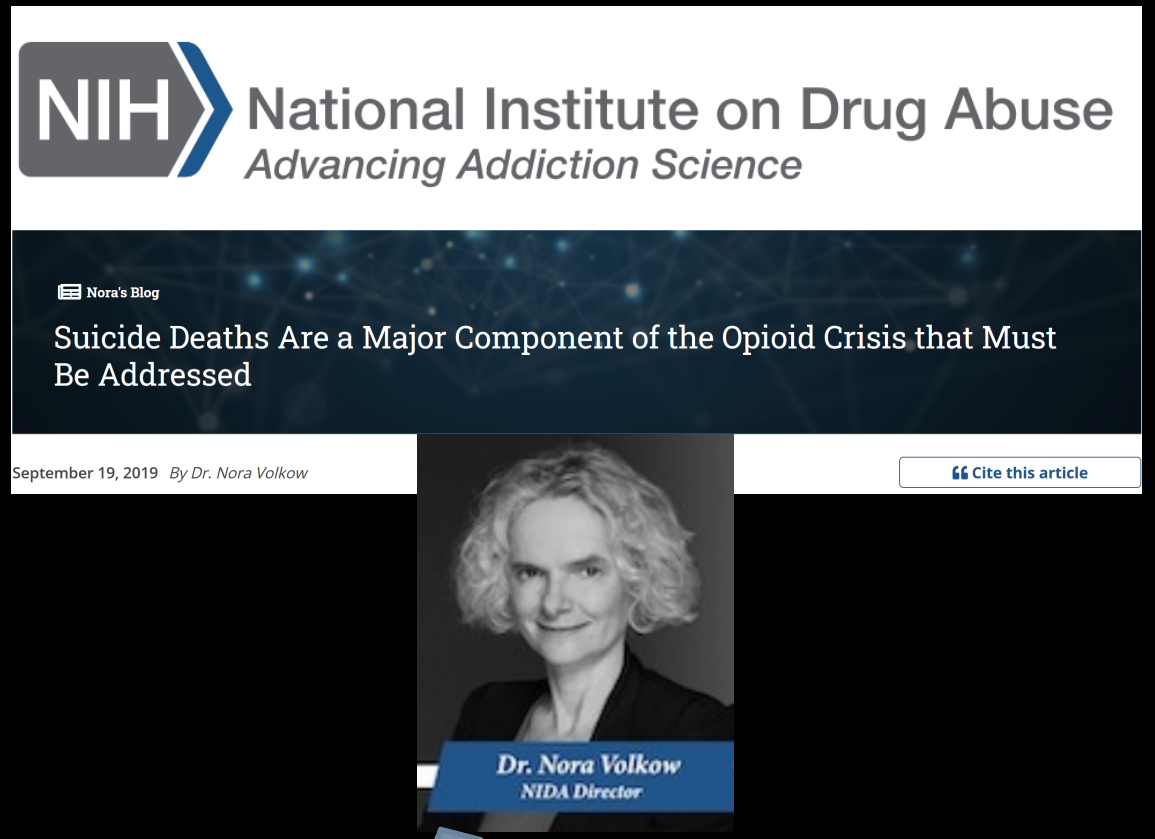
What to Do?

- Reflect and consider...
  - –Stigmatization
  - –Education
  - –Question
  - –Develop Consensus
  - –Come to terms with regulatory scrutiny in the context of delivering ethical care
    - Use the new math
    - Don’t avoid doing the calculation
  - –BE the role model
    - There is no “right” patient
    - There should not be a patient you least want to see

What *Not* to Do

- Don’t look the other way…

- *With current initiatives to reduce opioid prescribing, many pain patients find themselves either unable to get treatment they need or stigmatized as “addicts” by the healthcare system, compounding their difficulties.*



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“Cure sometimes, treat often, comfort always.”
— Hippocrates

QUESTIONS?