SCOPE OF WORK AND DELIVERABLES

Task 1: Product Development

PRR worked with CDC subject matter experts to develop a variety of small infographics and fact sheets relating to specific injury and prevention message and subject areas.

A. Develop Fact Sheets

PRR developed two fact sheets which included:

- CDC's Opioid Prescribing Guidelines:
 Promoting Safer and More Effective Pain
 Management. This fact sheet was aimed at a general audience providing education on prescription opioids, opioids and chronic pain, improving doctor and patient communications and why the guidelines were developed.
- CDC's Opioid Prescribing Guidelines:
 Guideline for Prescribing Opioids for
 Chronic Pain. This fact sheet was targeted
 to doctors and clinicians focusing
 on how to improve practice through
 the recommendations with key areas
 including: determining when to initiate or
 continue opioids for chronic pain; opioid
 selection, dosage, duration, follow-up, and
 discontinuation; and assessing risk and
 addressing harms of opioid use.

PRR worked with a subject matter expert on the development process which included: client kickoff meetings, drafting copy, creative concepting, design, and rounds of revisions.



Fact sheet



Fact sheet

2 August 2016

B. Develop Large Infographics

PRR developed two large infographics focused on:

- Why Guidelines for Primary Care Providers?
 Myth vs. Truth, What Can Providers Do?,
 Practices and Actions
- Injury Control Research Centers Putting Research into Action to Prevent Violence and Injuries

PRR worked with subject matter experts on the development process which included: client kickoff meetings, creative concepting, design, and rounds of revisions.



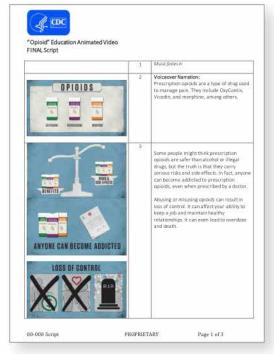
Large Infographics

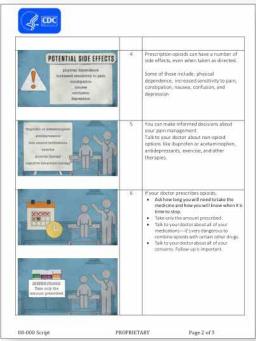
CDC - Final Report

C. Develop Brief Motion Graphic Video

CDC is preparing to launch a campaign that provides doctors with information about opioids. It includes content related to a new opioid prescribing guideline for chronic pain and current opioid research. As part of this effort, PRR developed a :90 animated video to provide educational messaging for the public. A 508-compliant version of the video was also developed. The target audience for the video is adults 25-30. The goals of the video are to:

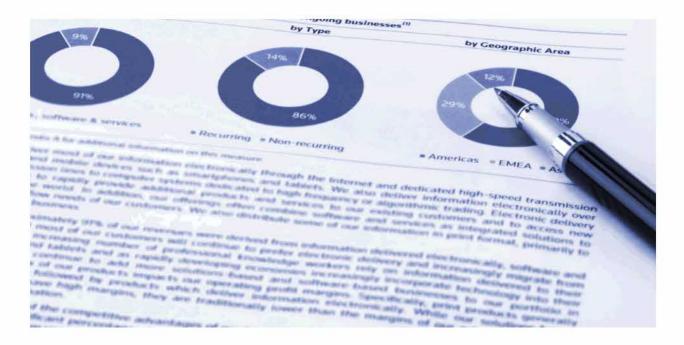
- · Educate about opioids and their risks
- Debunk myth that prescription opioids are safer than illicit opioids
- · Open communication lines with doctor





Storyboards for motion graphic video

4 August 2016



Optional Task 1: Partner Communications Assessment

A. Environmental Scan

PRR conducted interviews with five chronic pain community members. Interview questions were developed by the CDC and PRR. The overall goal of the interviews were to determine perceptions of the Prescription Drug Overdose (PDO) Guidelines within the chronic pain community and help identify potential messaging needs and outreach to this audience.

As part of this scan PRR developed a list of potential interviewees and interview questions. PRR worked with CDC to finalize and approve the interviewee list and questions.

B. Stakeholder Interviews

Five chronic pain community members were interviewed. Each telephone interview lasted between 25-40 minutes. The interviewer typed up and saved the responses in an online database. The final interviewees were representatives associated with:

- US Pain Foundation
- · Power of Pain Network
- · Pain News Network
- · Life in Motion Chiropractic
- Author, chronic pain physician

C. Research Analysis and Report

PRR conducted analysis of all survey and interview findings and prepared a topline report with key findings and recommendations.

August 2016

PROMOTING SAFER AND MORE EFFECTIVE PAIN MANAGEMENT

UNDERSTANDING PRESCRIPTION OPIOIDS

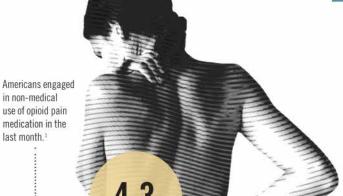
Opioids are natural or synthetic chemicals that relieve pain by binding to receptors in your brain or body to reduce the intensity of pain signals reaching the brain. Opioid pain medications are sometimes prescribed by doctors to treat pain. Common types include:

- · Hydrocodone (e.g., Vicodin)
- Oxycodone (e.g., OxyContin)
- · Oxymorphone (e.g., Opana), and
- Morphine

Opioids can have serious risks including addiction and death from overdose.



As many as 1 in 4 people receiving prescription opioids long term in a primary care setting struggles with addiction.



OPIOIDS AND CHRONIC PAIN

Many Americans suffer from chronic pain, a major public health concern in the United States. Patients with chronic pain deserve safe and effective pain management. At the same time, our country is in the midst of a prescription opioid overdose epidemic.

- The amount of opioids prescribed and sold in the US quadrupled since 1999, but the overall amount of pain reported hasn't changed.
- There is insufficient evidence that prescription opioids control chronic pain effectively over the long term, and there is evidence that other treatments can be effective with less harm.

PRESCRIPTION OPIOID OVERDOSE IS AN EPIDEMIC IN THE US



LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html

IMPROVE DOCTOR AND PATIENT COMMUNICATION

The Centers for Disease Control and Prevention's (CDC) *Guideline for Prescribing Opioids for Chronic Pain* provides recommendations to primary care doctors about the appropriate prescribing of opioid pain medications to improve pain management and patient safety:

- It helps primary care doctors determine when to start or continue opioids for chronic pain
- It gives guidance about medication dose and duration, and on following up with patients and discontinuing medication if needed
- It helps doctors assess the risks and benefits of using opioids

Doctors and patients should talk about:

- How opioids can reduce pain during short-term use, yet there is not enough evidence that opioids control chronic pain effectively long term
- Nonopioid treatments (such as exercise, nonopioid medications, and cognitive behavioral therapy) that can be effective with less harm
- · Importance of regular follow-up
- Precautions that can be taken to decrease risks including checking drug monitoring databases, conducting urine drug testing, and prescribing naloxone if needed to prevent fatal overdose
- Protecting your family and friends by storing opioids in a secure, locked location and safely disposing unused opioids





GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

CDC developed the *Guideline for Prescribing Opioids for Chronic Pain* to:

- · Help reduce misuse, abuse, and overdose from opioids
- Improve communication between primary care doctors and patients about the risks and benefits of opioid therapy for chronic pain

LEARN MORE I www.cdc.gov/drugoverdose/prescribing/guideline.html

GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

IMPROVING PRACTICE THROUGH RECOMMENDATIONS

CDC's *Guideline for Prescribing Opioids for Chronic Pain* is intended to improve communication between providers and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder and overdose. The Guideline is not intended for patients who are in active cancer treatment, palliative care, or end-of-life care.

DETERMINING WHEN TO INITIATE OR CONTINUE OPIOIDS FOR CHRONIC PAIN

- Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.
- Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
- Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

····· CLINICAL REMINDERS

- Opioids are not first-line or routine therapy for chronic pain
- Establish and measure goals for pain and function
- Discuss benefits and risks and availability of nonopioid therapies with patient





LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html

OPIOID SELECTION, DOSAGE, DURATION, FOLLOW-UP, AND DISCONTINUATION

CLINICAL REMINDERS

- Use immediate-release opioids when starting
- Start low and go slow
- When opioids are needed for acute pain, prescribe no more than needed
- Do not prescribe ER/LA opioids for acute pain
- Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if needed



When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.



When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to $\geq\!50$ morphine milligram equivalents (MME)/day, and should avoid increasing dosage to $\geq\!90$ MME/day or carefully justify a decision to titrate dosage to $\geq\!90$ MME/day.



Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.



Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.



ASSESSING RISK AND ADDRESSING HARMS OF OPIOID USE

- Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.
- Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.
- When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
- Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.
- Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

... CLINICAL REMINDERS

- Evaluate risk factors for opioid-related harms
- Check PDMP for high dosages and prescriptions from other providers
- Use urine drug testing to identify prescribed substances and undisclosed use
- Avoid concurrent benzodiazepine and opioid prescribing
- Arrange treatment for opioid use disorder if needed

LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html

WHY GUIDELINES FOR PRIMARY CARE PROVIDERS?

Primary care providers account for approximately

50% of prescription opioids dispensed

2 million

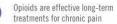
Americans, aged 12 or older, either abused or were dependent on prescription opioids in 2014

- An estimated 11% of adults experience daily pain
- Millions of Americans are treated with prescription opioids for chronic pain
- Primary care providers are concerned about patient addiction and report insufficient training in prescribing opioids

MYTH



TRUTH



There is no unsafe dose of opioids as long as opioids are titrated slowly

The risk of addiction is minimal

While evidence supports short-term effectiveness of opioids, there is insufficient evidence that opioids control chronic pain effectively over the long term, and there is evidence that other treatments can be effective with less harm.

Daily opioid dosages close to or greater than 90 MME/day are associated with significant risks, and lower dosages are safer.

Up to one quarter of patients receiving prescription opioids long term in a primary care setting struggles with addiction Certain risk factors increase susceptibility to opioid-associated harms: history of overdose, history of substance use disorder, higher opioid dosages, or concurrent benzodiazepine use.

WHAT CAN PROVIDERS DO?



First, **do no harm**. Long-term opioid use has uncertain benefits but known, serious risks. CDC's **Guideline for Prescribing Opioids for Chronic Pain** will support informed clinical decision making, improved communication between patients and providers, and appropriate prescribing.

PRACTICES AND ACTIONS



USE NONOPIOID TREATMENT

Opioids are not first-line or routine therapy for chronic pain (Recommendation #1)

In a systematic review, opioids did not differ from nonopioid medication in pain reduction, and nonopioid medications were better tolerated, with greater improvements in physical function.



START LOW AND GO SLOW

When opioids are started, prescribe them at the lowest effective dose (Recommendation #5)

Studies show that high dosages (≈ 100 MME/day) are associated with 2 to 9 times the risk of overdose compared to < 20 MME/day.



REVIEW PDMP

Check prescription drug monitoring program data for high dosages and prescriptions from other providers (Recommendation #9)

A study showed patients with one or more risk factors (4 or more prescribers, 4 or more pharmacies, or dosage >100 MME/day) accounted for 55% of all overdose deaths:



AVOID CONCURRENT PRESCRIBING

Avoid prescribing opioids and benzodiazepines concurrently whenever possible (Recommendation #11)

One study found concurrent prescribing to be associated with a near quadrupiling of risk for overdose death



OFFER TREATMENT FOR OPIOID USE DISORDER

Offer or arrange evidence-based treatment (e.g. medication-assisted treatment and behavioral therapies) for patients with opioid use disorder (Recommendation #12)

A study showed patients prescribed high dosages of opioids long-term (>90 days) had 122 times the risk of opioid use disorder compared to patients not prescribed opioids.





LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html

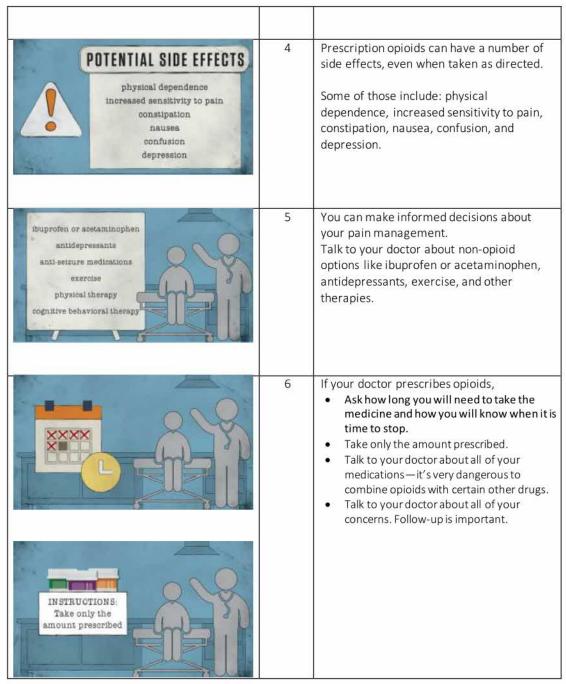


"Opioid" Education Animated Video FINAL Script

| | 1 | Music fades in |
|--|---|--|
| OPIOIDS Propried By OXYCOOONE HYBROCOONE MORPHINE | 2 | Voiceover Narration: Prescription opioids are a type of drug used to manage pain. They include OxyContin, Vicodin, and morphine, among others. |
| ANYONE CAN BECOME ADDICTED LOSS OF CONTROL RICHARD LOSS OF CONTROL RILE RILE RICHARD RILE RILE | 3 | Some people might think prescription opioids are safer than alcohol or illegal drugs, but the truth is that they carry serious risks and side effects. In fact, anyone can become addicted to prescription opioids, even when prescribed by a doctor. Abusing or misusing opioids can result in loss of control. It can affect your ability to keep a job and maintain healthy relationships. It can even lead to overdose and death. |

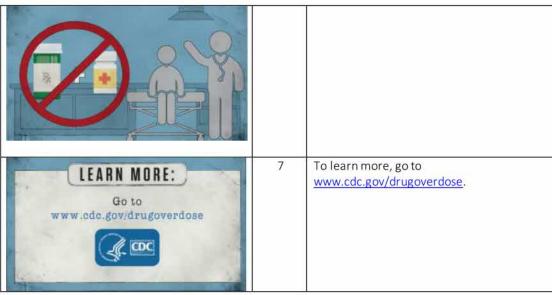
00-000 Script PROPRIETARY Page 1 of 3





00-000 Script PROPRIETARY Page 2 of 3





00-000 Script PROPRIETARY Page 3 of 3

CDC PDO Guidelines Assessment Interviews Summary

Introduction & Purpose

PRR conducted interviews with five chronic pain community members. Interview questions were developed by the CDC and PRR. The overall goal of the interviews were to determine perceptions of the Prescription Drug Overdose (PDO) Guidelines within the chronic pain community and help identify potential messaging needs and outreach to this audience. Each telephone interview lasted between 25-40 minutes. The interviewer typed up and saved the responses in an online database. The final interviewees were representatives associated with:

- US Pain Foundation
- · Power of Pain Network
- · Pain News Network
- Life in Motion Chiropractic
- · Author, chronic pain physician

Key Findings & Overarching Themes

- Many interviewees feel that the CDC's new prescription drug overdose guidelines
 were conceived with the best of intentions, but left many sufferers of chronic pain to
 question if their voices were heard.
- Interviewees unanimously agree that something must be done about opioid abuse.
- Interviewees say that the situation would improve if the guidelines were better
 informed by chronic pain experts, more specific about how they apply to different
 types of patients, and implemented by doctors on a case-by-case basis.
 - Some doctors are following these guidelines as strict law rather than recommendation, and these physicians have completely stopped prescribing opioids. This leaves few options for chronic pain patients who already depend on opioids to manage their chronic pain.
- Interviewees believe that the guidelines are beneficial for new chronic pain patients, but leave existing pain patients without options.
 - In many cases, physicians have stopped prescribing opioids altogether. Pain patients who have relied on these drugs for years are now left with little to no pain management options.
 - Chronic pain is already stigmatized. Now chronic pain patients face the stigma of addiction, even when they are using opioids responsibly for pain management.



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SEATTLE . WASHINGTON DC

 Pain News Network's independent survey distributed to chronic pain patients demonstrated that the people who these guidelines intend to help do not think they are helpful enough.

Recommendations

- Chronic pain patients are concerned that their input was not received or considered
 during the creation of these guidelines. Thus, CDC should attempt to conduct
 follow-up research to gain a better understanding of their concerns. This can be
 achieved with surveys, focus groups, or an in-depth ethnography of how pain
 medication is used by those with chronic pain.
- To improve patient-advocacy group research and outreach, partner with them to provide input on methodology and design for communications research directed at patients.
- Educate patients and providers on alternatives to opioid prescription drugs, as well
 the purpose, content, and application of CDC's PDO Guidelines.
- Continue outreach and continue the conversation on managing opioid prescription
 drug use, particularly as the PDO Guidelines are being implemented over time.
 However, reach out beyond the medical community and ensure that existing pain
 patients are included in this conversation by recruiting stakeholders of patient
 advocacy groups (see appendix).

Conclusion

While sweeping generalizations will always marginalize minority groups, consistency in execution is necessary for equity. Chronic pain patients *feel, or perceive* that the CDC has failed them because doctors are making extreme generalizations in determining appropriate care for their pain patients. In order to alleviate this perception, the CDC should continue to convey to physicians/providers that the PDO Guidelines are recommendations.

CDC should consider conducting more research to understand the fears and concerns of patients with chronic pain conditions. Understanding this group's perceptions and fears of the PDO Guidelines, will help the CDC to more successfully communicate with patient advocacy groups and will help ensure that targeted messages are being disseminated to patients. Overall, this will help CDC message and communicate to those living with chronic pain and help providers and patients understand best care options available to enhance and improve quality of life.



Appendix: Annotated Bibliography of Findings

Objective

Identify responses to the <u>CDC Guideline for Prescribing Opioids for Chronic Pain</u> beyond those individuals or agencies that were consulted during its initial development. As part of the review, PRR scanned for:

- · Concerned opinions, dissenting opinions
- Positive opinions, praise
- Neutral

Summary

Practitioners are excited to see action taken to address the prescription drug overdose (PDO) epidemic. However, the main critique we identified is that those with chronic pain and a dependence on opioid prescription drugs feel slighted and shamed. They feel as though their illnesses have now put them in a category of social outcasts. The new guideline recommending urinalysis and strict distribution potentially marginalize a group of 11 million law-abiding individuals who need opioid pain medications for intense daily pain.

From our scan of responses, PRR found that many agree this is a step in the right direction to help providers make informed decisions and stem the PDO issue. However, we also found many individuals reliant on opioids felt marginalized when they were not consulted in the development of the new CDC guideline.

In order to more fully understand the concerns of these individuals/organizations and help improve the current guideline recommendations, PRR recommends choosing nine people (or a mix) from the contact list (page 2) to interview more thoroughly. Additionally, if not contacted during the initial development of the guideline, PRR also recommends interviewing the contacts listed below from the Division of State Programs Center for Substance Abuse Prevention.

Tonia F. Gray, MPH
Division of State Programs
Center for Substance Abuse Prevention
Substance Abuse and Mental Health
Services Administration

John O'Donnell
Division of State Programs
Center for Substance Abuse Prevention
Substance Abuse and Mental Health
Services Administration



Literature Recommended List of Interview Follow-Up/Annotated Summary of Critiquing

| Author/Agency | Source | Tone | Summary |
|---------------|---|---|--|
| Anson, Pat | http://www.painnewsnetwork.org/stories/2016/1/7/cdc-holds-first-public- | Critical, wary, pessimistic, Skeptical | Addresses CDC's secrecy and failure to consult 11M Americans living with chronic |
| | hearing-on-opioid-guidelines http://www.painnewsnetwork.org/stori | | pain. These Americans are afraid that their best interests are not in the minds of those |
| | es/2015/9/16/cdc-opioids-not- | | at the CDC. While curtailing PDO is vital, we |
| | preferred-treatment-for-chronic-pain | | should not leave our already suffering |
| | | | citizens by the wayside in the process. |
| | | | Opiates have become demonized and |
| | | | people without dependencies are being |
| | | | punished. |
| Ingle, Barby | https://powerofpain.org/respond-to- | Punished for abiding the law, | A well-rounded approach is best, not one |
| | cdc-proposed-guidelines/ | seen as outsiders, pariahs | treatment is a cure-all. Patients have been |
| | | | told prescription opioids are the most |
| | | | dangerous option which is just not true. |
| | | | Ordinary, law-abiding people are being |
| | | | lumped in with individuals with chemical |
| | | | dependencies and criminal histories. |
| IPRRC NIH | https://iprcc.nih.gov/National Pain Str | Optimistic, collaborative | The guideline recommendations lead to |
| | ategy/NPS Main.htm | | safer prescribing practices and patient- |
| | https://iprcc.nih.gov/docs/HHSNational | | centered treatment decisions. |
| Konrad, Sean | http://lifeinmotionchiropsp.blogspot.co | Compromising, wary, data- | PDO has become a serious problem that is |
| | m/2016/05/new-cdc-guidelines-seen- | driven | thankfully finally being addressed, however |
| | as-boost-for.html | | the CDC is leaving many in the dust with |
| | | | these late-game decisions that seem to |
| | | | forget that not all chronic pain sufferers |



| Author/Agency | Source | Tone | Summary abuse drugs. It is good to bring |
|---|---|--|---|
| | | | abuse drugs. It is good to bring attention to this issue, though. |
| Levy, Carol | http://www.painnewsnetwork.org/stories/2016/3/29/a-pained-life-the-good-and-bad-about-cdc-guidelines | The guidelines negate themselves. | The call for urinalysis casts a black mark on every person with a chronic pain disorder and for whom opiates are prescribed. |
| Maltz, Stephanie | https://c.ymcdn.com/sites/safestates.sit e- ym.com/resource/resmgr/PolicyPDFs/Pr escription Drug Overdose .pdf | Data-driven, factual, turning point | These promising guidelines are the answer to a serious public health problem. |
| PNN Survey | http://www.painnewsnetwork.org/cdc-survey-results/ | Wronged, views guidelines as short-sighted | People in pain think that these guidelines discriminate against them, do not consider their needs, will harm them in the long term and will lead to more suffering and suicide and illegal drug overdose. |
| Terman, Gregory | http://americanpainsociety.org/about-us/press-room/message-from-the-president-about-the-cdc-guidelines | Agreement, involvement | Terman takes a holistic view that is detailed, educated and comes from a place of good faith. He is trusting that the CDC has made the right move and embarrassed that things have gone the way they have (lack of research) for so long. |
| Veasley, Christin and Cowley, Terrie | http://thehill.com/blogs/congress- blog/healthcare/270336-painful-truth- about-opioid-abuse | Lamenting, broad-scope, urgent, scientific | Policymakers' approaches are narrow, short-sighted and don't consider why opioids were used in the first place. |
| Volkow, Dr. Nora | https://www.drugabuse.gov/about- nida/noras-blog/2016/04/cdc-provides- crucial-new-guidance-opioids-pain | Addresses issue's complexity, thankful for action, dire, tempered reaction | New guidelines are desperately needed to curb this epidemic, however the research has not been completed to make effective long-term decisions on these issues. |
| Webster M.D., Lynn | http://www.painnewsnetwork.org/stories/2016/4/25/will-cdc-opioid-guidelines-help-reduce-overdoses?rq=cdc | Skeptical, fearful, long- sighted | The reduction of prescription opioids will reduce prescription opioid overdose but contribute to increased heroin and fentanyl overdoses. |



Draft of Interview Questions/Script (20-30 minute phone interview)

- 1. What is your involvement, or how are you involved with individuals that deal with chronic pain? Do you provide services? Are you an advocate? Researcher? Clinician? Other?
- 2. What kind of pain information does the community you serve need? How do you provide information on pain management? What is helpful for them?
- 3. What do you think of the new CDC Guideline for Prescribing Opioids for Chronic Pain? What is your initial response?
- 4. What about the CDC guideline recommendations are encouraging to you, what about the recommendations worry you? Explain.
- 5. Who do the guideline recommendations benefit? Who do the recommendations harm? Why? Explain why you think they are harmful.
- 6. Do you think the recommendations are too general or too specific? Why do you think this?
- 7. Are the guideline recommendations a step in the right direction or are those in charge panicking? Are the recommendations going to help solve the prescription opioid addiction problem? Why do you think this?
- 8. How would you improve the guidelines if you were writing them?
- 9. What other public health examples can the CDC look to? Do you have, or know of examples of similar recommendations you thought were well executed? Why do you feel they were well executed?
- 10. What are the next steps the CDC should take to deal with the opioid epidemic?
- 11. Is there a process the CDC should follow in updating the guideline recommendations, what does that process look like? Who should be involved? Why?



Appendix: Annotated Bibliography of Findings

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From our scan of responses, PRR found that many agree this is a step in the right direction to help providers make informed decisions and stem the PDO issue. However, we also found many individuals reliant on opioids felt marginalized when they were not consulted in the development of the new CDC guideline.

In order to more fully understand the concerns of these individuals/organizations and help improve the current guideline recommendations, PRR recommends choosing nine people (or a mix) from the contact list (page 2) to interview more thoroughly. Additionally, if not contacted during the initial development of the guideline, PRR also recommends interviewing the contacts listed below from the Division of State Programs Center for Substance Abuse Prevention.

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Division of State Programs
Center for Substance Abuse Prevention
Substance Abuse and Mental Health
Services Administration

John O'Donnell
Division of State Programs
Center for Substance Abuse Prevention
Substance Abuse and Mental Health
Services Administration



Recommended List of Interview Follow-Up/Annotated Summary of Critiquing Literature

| Author/Agency | Source | Tone | Summary |
|---------------|--|--|--|
| Anson, Pat | http://www.painnewsnetwork.org/stories/2016/1/7/cdc-holds-first-public-hearing-on-opioid-guidelineshttp://www.painnewsnetwork.org/stories/2015/9/16/cdc-opioids-not-preferred-treatment-for-chronic-pain | Critical, wary, pessimistic, Skeptical | Addresses CDC's secrecy and failure to consult 11M Americans living with chronic pain. These Americans are afraid that their best interests are not in the minds of those at the CDC. While curtailing PDO is vital, we should not leave our already suffering citizens by the wayside in the process. Opiates have become demonized and people without dependencies are being punished. |
| Ingle, Barby | https://powerofpain.org/respond-to-cdc-proposed-guidelines/ | Punished for abiding the law, seen as outsiders, pariahs | A well-rounded approach is best, not one treatment is a cure-all. Patients have been told prescription opioids are the most dangerous option which is just not true. Ordinary, law-abiding people are being lumped in with individuals with chemical dependencies and criminal histories. |
| IPRRC NIH | https://iprcc.nih.gov/National Pain Str ategy/NPS Main.htm https://iprcc.nih.gov/docs/HHSNational Pain Strategy.pdf | Optimistic, collaborative | The guideline recommendations lead to safer prescribing practices and patient-centered treatment decisions. |
| Konrad, Sean | http://lifeinmotionchiropsp.blogspot.co m/2016/05/new-cdc-guidelines-seen- as-boost-for.html | Compromising, wary, data- driven | PDO has become a serious problem that is thankfully finally being addressed, however the CDC is leaving many in the dust with these late-game decisions that seem to forget that not all chronic pain sufferers abuse drugs. It is good to bring attention to |



| Author/Agency | Source | Tone | Summary |
|---|---|--|---|
| | | | this issue, though. |
| Levy, Carol | http://www.painnewsnetwork.org/stories/2016/3/29/a-pained-life-the-goodand-bad-about-cdc-guidelines | The guidelines negate themselves. | The call for urinalysis casts a black mark on every person with a chronic pain disorder and for whom opiates are prescribed. |
| Maltz, Stephanie | https://c.ymcdn.com/sites/safestates.sit e- ym.com/resource/resmgr/PolicyPDFs/Pr escription Drug Overdose .pdf | Data-driven, factual, turning point | These promising guidelines are the answer to a serious public health problem. |
| PNN Survey | http://www.painnewsnetwork.org/cdc- survey-results/ | Wronged, views guidelines as short-sighted | People in pain think that these guidelines discriminate against them, do not consider their needs, will harm them in the long term and will lead to more suffering and suicide and illegal drug overdose. |
| Terman, Gregory | http://americanpainsociety.org/about- us/press-room/message-from-the- president-about-the-cdc-guidelines | Agreement, involvement | Terman takes a holistic view that is detailed, educated and comes from a place of good faith. He is trusting that the CDC has made the right move and embarrassed that things have gone the way they have (lack of research) for so long. |
| Veasley, Christin and Cowley, Terrie | http://thehill.com/blogs/congress- blog/healthcare/270336-painful-truth- about-opioid-abuse | Lamenting, broad-scope, urgent, scientific | Policymakers' approaches are narrow, short-sighted and don't consider why opioids were used in the first place. |
| Volkow, Dr. Nora | https://www.drugabuse.gov/about- nida/noras-blog/2016/04/cdc-provides- crucial-new-guidance-opioids-pain | Addresses issue's complexity, thankful for action, dire, tempered reaction | New guidelines are desperately needed to curb this epidemic, however the research has not been completed to make effective, long-term decisions on these issues. |
| Webster M.D., Lynn | http://www.painnewsnetwork.org/stori es/2016/4/25/will-cdc-opioid- guidelines-help-reduce- overdoses?rq=cdc | Skeptical, fearful, long- sighted | The reduction of prescription opioids will reduce prescription opioid overdose but contribute to increased heroin and fentanyl overdoses. |



Draft of Interview Questions/Script (20-30 minute phone interview)

- 1. What is your involvement, or how are you involved with individuals that deal with chronic pain? Do you provide services? Are you an advocate? Researcher? Clinician? Other?
- 2. What kind of pain information does the community you serve need? How do you provide information on pain management? What is helpful for them?
- 3. What do you think of the new CDC Guideline for Prescribing Opioids for Chronic Pain? What is your initial response?
- 4. What about the CDC guideline recommendations are encouraging to you, what about the recommendations worry you? Explain.
- 5. Who do the guideline recommendations benefit? Who do the recommendations harm? Why? Explain why you think they are harmful.
- 6. Do you think the recommendations are too general or too specific? Why do you think this?
- 7. Are the guideline recommendations a step in the right direction or are those in charge panicking? Are the recommendations going to help solve the prescription opioid addiction problem? Why do you think this?
- 8. How would you improve the guidelines if you were writing them?
- 9. What other public health examples can the CDC look to? Do you have, or know of examples of similar recommendations you thought were well executed? Why do you feel they were well executed?
- 10. What are the next steps the CDC should take to deal with the opioid epidemic?
- 11. Is there a process the CDC should follow in updating the guideline recommendations, what does that process look like? Who should be involved? Why?

CDC PDO Guidelines Assessment Interviews Summary

Introduction & Purpose

PRR conducted interviews with five chronic pain community members. Interview questions were developed by the CDC and PRR. The overall goal of the interviews were to determine perceptions of the Prescription Drug Overdose (PDO) Guidelines within the chronic pain community and help identify potential messaging needs and outreach to this audience. Each telephone interview lasted between 25-40 minutes. The interviewer typed up and saved the responses in an online database. The final interviewees were representatives associated with:

- US Pain Foundation
- Power of Pain Network
- Pain News Network
- Life in Motion Chiropractic
- Author, chronic pain physician

Key Findings & Overarching Themes

- Many interviewees feel that the CDC's new prescription drug overdose guidelines were conceived with the best of intentions, but left many sufferers of chronic pain to question if their voices were heard.
- Interviewees unanimously agree that something must be done about opioid abuse.
- Interviewees say that the situation would improve if the guidelines were better informed by chronic pain experts, more specific about how they apply to different types of patients, and implemented by doctors on a case-by-case basis.
 - Some doctors are following these guidelines as strict law rather than recommendation, and these physicians have completely stopped prescribing opioids. This leaves few options for chronic pain patients who already depend on opioids to manage their chronic pain.
- Interviewees believe that the guidelines are beneficial for new chronic pain patients, but leave existing pain patients without options.
 - In many cases, physicians have stopped prescribing opioids altogether. Pain patients who have relied on these drugs for years are now left with little to no pain management options.
 - Chronic pain is already stigmatized. Now chronic pain patients face the stigma of addiction, even when they are using opioids responsibly for pain management.



 Pain News Network's independent survey distributed to chronic pain patients demonstrated that the people who these guidelines intend to help do not think they are helpful enough.

Recommendations

- Chronic pain patients are concerned that their input was not received or considered
 during the creation of these guidelines. Thus, CDC should attempt to conduct
 follow-up research to gain a better understanding of their concerns. This can be
 achieved with surveys, focus groups, or an in-depth ethnography of how pain
 medication is used by those with chronic pain.
- To improve patient-advocacy group research and outreach, partner with them to provide input on methodology and design for communications research directed at patients.
- Educate patients and providers on alternatives to opioid prescription drugs, as well the purpose, content, and application of CDC's PDO Guidelines.
- Continue outreach and continue the conversation on managing opioid prescription drug use, particularly as the PDO Guidelines are being implemented over time. However, reach out beyond the medical community and ensure that existing pain patients are included in this conversation by recruiting stakeholders of patient advocacy groups (see appendix).

Conclusion

While sweeping generalizations will always marginalize minority groups, consistency in execution is necessary for equity. Chronic pain patients *feel, or perceive* that the CDC has failed them because doctors are making extreme generalizations in determining appropriate care for their pain patients. In order to alleviate this perception, the CDC should continue to convey to physicians/providers that the PDO Guidelines are recommendations.

CDC should consider conducting more research to understand the fears and concerns of patients with chronic pain conditions. Understanding this group's perceptions and fears of the PDO Guidelines, will help the CDC to more successfully communicate with patient advocacy groups and will help ensure that targeted messages are being disseminated to patients. Overall, this will help CDC message and communicate to those living with chronic pain and help providers and patients understand best care options available to enhance and improve quality of life.

WHY GUIDELINES FOR PRIMARY CARE PROVIDERS?

Primary care providers account for approximately

of prescription opioids dispensed

Nearly **2** million

Americans, aged 12 or older, either abused or were dependent on prescription opioids in 2014

- An estimated 11% of adults experience daily pain
- Millions of Americans are treated with prescription opioids for chronic pain
- Primary care providers are concerned about patient addiction and report insufficient training in prescribing opioids

MYTH

VS

TRUTH

Opioids are effective long-term treatments for chronic pain

There is no unsafe dose of opioids as long as opioids are titrated slowly

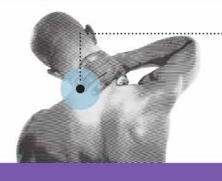
The risk of addiction is minimal

While evidence supports short-term effectiveness of opioids, there is insufficient evidence that opioids control chronic pain effectively over the long term, and there is evidence that other treatments can be effective with less harm.

Daily opioid dosages close to or greater than 90 MME/day are associated with significant risks, and lower dosages are safer.

Up to one quarter of patients receiving prescription opioids long term in a primary care setting struggles with addiction. Certain risk factors increase susceptibility to opioid-associated harms: history of overdose, history of substance use disorder, higher opioid dosages, or concurrent benzodiazepine use.

WHAT CAN PROVIDERS DO?



First, **do no harm**. Long-term opioid use has uncertain benefits but known, serious risks. CDC's *Guideline for Prescribing Opioids for Chronic Pain* will support informed clinical decision making, improved communication between patients and providers, and appropriate prescribing.

PRACTICES AND ACTIONS



USE NONOPIOID TREATMENT

Opioids are not first-line or routine therapy for chronic pain (Recommendation #1)

In a systematic review, opioids did not differ from nonopioid medication in pain reduction, and nonopioid medications were better tolerated, with greater improvements in physical function.



START LOW AND GO SLOW

When opioids are started, prescribe them at the lowest effective dose (Recommendation #5)

Studies show that high dosages (≥100 MME/day) are associated with 2 to 9 times the risk of overdose compared to < 20 MME/day.



REVIEW PDMP

Check prescription drug monitoring program data for high dosages and prescriptions from other providers (Recommendation #9)

A study showed patients with one or more risk factors (4 or more prescribers, 4 or more pharmacies, or dosage >100 MME/day) accounted for 55% of all overdose deaths.



AVOID CONCURRENT PRESCRIBING

Avoid prescribing opioids and benzodiazepines concurrently whenever possible (Recommendation #11)

One study found concurrent prescribing to be associated with a near quadrupling of risk for overdose death compared with opioid prescription alone.



OFFER TREATMENT FOR OPIOID USE DISORDER

Offer or arrange evidence-based treatment (e.g. medication-assisted treatment and behavioral therapies) for patients with opioid use disorder (Recommendation #12)

A study showed patients prescribed high dosages of opioids long-term (>90 days) had 122 times the risk of opioid use disorder compared to patients not prescribed opioids.



PROMOTING SAFER AND MORE EFFECTIVE PAIN MANAGEMENT

UNDERSTANDING PRESCRIPTION OPIOIDS

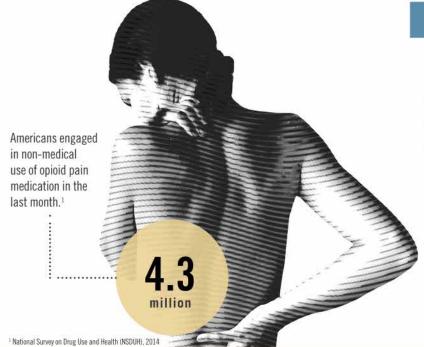
Opioids are natural or synthetic chemicals that relieve pain by binding to receptors in your brain or body to reduce the intensity of pain signals reaching the brain. Opioid pain medications are sometimes prescribed by doctors to treat pain. Common types include:

- Hydrocodone (e.g., Vicodin)
- Oxycodone (e.g., OxyContin)
- Oxymorphone (e.g., Opana), and
- Morphine

Opioids can have serious risks including addiction and death from overdose.



As many as 1 in 4 people receiving prescription opioids long term in a primary care setting struggles with addiction.



OPIOIDS AND CHRONIC PAIN

Many Americans suffer from chronic pain, a major public health concern in the United States. Patients with chronic pain deserve safe and effective pain management. At the same time, our country is in the midst of a prescription opioid overdose epidemic.

- The amount of opioids prescribed and sold in the US quadrupled since 1999, but the overall amount of pain reported hasn't changed.
- There is insufficient evidence that prescription opioids control chronic pain effectively over the long term, and there is evidence that other treatments can be effective with less harm.

PRESCRIPTION OPIOID OVERDOSE IS AN EPIDEMIC IN THE US



IMPROVE DOCTOR AND PATIENT COMMUNICATION

The Centers for Disease Control and Prevention's (CDC) *Guideline for Prescribing Opioids for Chronic Pain* provides recommendations to primary care doctors about the appropriate prescribing of opioid pain medications to improve pain management and patient safety:

- It helps primary care doctors determine when to start or continue opioids for chronic pain
- It gives guidance about medication dose and duration, and on following up with patients and discontinuing medication if needed
- It helps doctors assess the risks and benefits of using opioids

Doctors and patients should talk about:

- How opioids can reduce pain during short-term use, yet there is not enough evidence that opioids control chronic pain effectively long term
- Nonopioid treatments (such as exercise, nonopioid medications, and cognitive behavioral therapy) that can be effective with less harm
- Importance of regular follow-up
- Precautions that can be taken to decrease risks including checking drug monitoring databases, conducting urine drug testing, and prescribing naloxone if needed to prevent fatal overdose
- Protecting your family and friends by storing opioids in a secure, locked location and safely disposing unused opioids



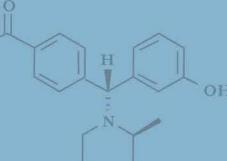


GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

CDC developed the *Guideline for Prescribing Opioids for Chronic Pain* to:

- Help reduce misuse, abuse, and overdose from opioids
- Improve communication between primary care doctors and patients about the risks and benefits of opioid therapy for chronic pain

GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN



IMPROVING PRACTICE THROUGH RECOMMENDATIONS

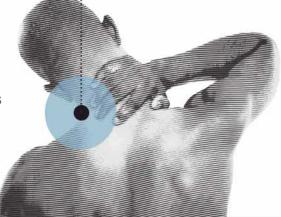
CDC's *Guideline for Prescribing Opioids for Chronic Pain* is intended to improve communication between providers and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder and overdose. The Guideline is not intended for patients who are in active cancer treatment, palliative care, or end-of-life care.

DETERMINING WHEN TO INITIATE OR CONTINUE OPIOIDS FOR CHRONIC PAIN

- Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.
- Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
- Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

CLINICAL REMINDERS

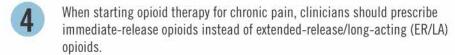
- Opioids are not first-line or routine therapy for chronic pain
- Establish and measure goals for pain and function
- Discuss benefits and risks and availability of nonopioid therapies with patient



OPIOID SELECTION, DOSAGE, DURATION, FOLLOW-UP, AND DISCONTINUATION

CLINICAL REMINDERS

- Use immediate-release opioids when starting
- Start low and go slow
- When opioids are needed for acute pain, prescribe no more than needed
- Do not prescribe ER/LA opioids for acute pain
- Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if needed



When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.

Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.

Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.



ASSESSING RISK AND ADDRESSING HARMS OF OPIOID USE

- Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.
- Glinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.
- When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
- Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.
- Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

... CLINICAL REMINDERS

- Evaluate risk factors for opioid-related harms
- Check PDMP for high dosages and prescriptions from other providers
- Use urine drug testing to identify prescribed substances and undisclosed use
- Avoid concurrent benzodiazepine and opioid prescribing
- Arrange treatment for opioid use disorder if needed

New CDC Opioid Prescribing Guidelines

Improving the Way Opioids are Prescribed for Safer Chronic Pain Treatment



The problem:

Existing guidelines vary in recommendations, and primary care providers say they receive insufficient training in prescribing opioid pain relievers. It is important that patients receive appropriate pain treatment, and that the benefits and risks of treatment options are carefully considered.



In 2012, health care providers wrote 259 million prescriptions for opioid pain relievers – enough for every American adult to have a bottle of pills ¹



300% increase

Prescription opioid sales in the United States have increased by 300% since 1999², but there has not been an overall change in the amount of pain Americans report^{3,4}.



Almost 2 million Americans, age 12 or older, either abused or were dependent on opioid pain relievers in 2013.⁵



16 thousand

In 2013, more than 16,000 people died in the United States from overdose related to opioid pain relievers, four times the number in 1999.⁶

Improving practice:

Improving the way opioids are prescribed through clinical practice guidelines can ensure patients have access to safer, more effective chronic pain treatment while reducing the number of people who misuse, abuse, or overdose from these powerful drugs.

¹Paulozzi, Mack, & Hockenberry, 2014

²CDC. Vital Signs: Overdoses of Prescription Opioid Pain Relievers – United States, 1999 – 2008. Morbidity and Mortality Weekly Report 2011: 60(43); 1487-1492. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm?s_cid=mm6043a4_w#fig2. August 17, 2015.

³Chang H, Daubresse M, Kruszewski S, et al. Prevalence and treatment of pain in emergency departments in the United States, 2000 – 2010. Amer J of Emergency Med 2014; 32(4): 421-31.

⁴Daubresse M, Chang H, Yu Y, Viswanathan S, et al. Ambulatory diagnosis and treatment of nonmalignant pain in the United States, 2000 – 2010. Medical Care 2013; 51(10): 870-878. ⁵SAMHSA, 2014

New Prescribing Guidelines

The Centers for Disease Control and Prevention (CDC) is publishing new opioid prescribing guidelines for chronic pain. The agency is working for timely release of the guidelines while ensuring that the development process:

- Meets scientific standards
- Includes expert consultation
- Allows for appropriate stakeholders to provide input
- Facilitates partnership development to enhance dissemination and uptake

Intended Purpose and Use of Guidelines

The purpose of the CDC guidelines is to provide recommendations for the prescribing of opioid pain relievers for patients 18 and older in primary care settings. Recommendations focus on the use of opioids in treating chronic pain (i.e., pain lasting longer than 3 months or past the time of normal tissue healing) outside end-of-life care.

Clinical practices addressed in the guidelines:

- Determining when to initiate or continue opioids for chronic pain outside end-of-life care
- Opioid selection, dosage, duration, follow-up, and discontinuation
- Assessing risk and addressing harms of opioid use



Guidelines Development: Methods and Processes

CDC used the Grading of Recommendations Assessment, Development, and Evaluation method to guidelines development (www.gradeworkinggroup.org). This method uses a transparent approach to grading quality of evidence and strength of recommendations. Four factors were used to determine the recommendations: 1) quality of evidence, 2) balance between benefits and harms, 3) values and preferences, and 4) costs. CDC also has developed a tiered approach to involve stakeholders in guidelines development.

Core Expert Group

The Core Expert Group includes CDC scientific staff, professional society representatives, subject matter experts, state agency representatives, and an expert in guidelines development methodology. This group reviews the evidence and consults on CDC-drafted recommendations.

Stakeholder Review Group

The Stakeholder Review Group includes a larger group of interested stakeholders that reviews the draft of CDC guidelines to improve the specificity and applicability of the recommendations. This group includes representation from professional medical organizations, community groups, and other organizations with an interest in pain management.

Peer Review and Public Comment

CDC has invited subject matter experts and the public to provide an independent review of the recommendations to ensure scientific quality and reasonableness of the recommendations.

Federal Partner Review

Interagency collaboration is critical for translation of these recommendations into practice. Federal partners were asked to review the guidelines and identify venues for dissemination and implementation.