Management of Controlled Medications in an Outpatient Primary Care Practice

UPMC Rural Family Medicine Residency & UPMC Williamsport Family Medicine Residency

April 12, 2024

Objectives

DISCUSS CHRONIC, NON-MALIGNANT PAIN AND MODELS OF TREATMENT.

DESCRIBE ABERRANT DRUG TAKING BEHAVIOR AND PSEUDO-ADDICTION AND THE IMPACT ON TREATING WITH CONTROLLED MEDICATIONS.

REVIEW A CONTROLLED MEDICATION RENEWAL PROGRAM FOR MANAGING PATIENTS.

BRIEFLY REVIEW OUTCOMES OF A CONTROLLED MEDICATION RENEWAL PROGRAM.

Discussion

What is your experience in the treatment of chronic, non-malignant pain (with opioids)?

ACGME FM Requirements

- IV.C.3.p).(2) This experience should include identification and treatment of substance use disorders, including alcohol use disorder and Opioid Use Disorder.

  IV.C.3.p).(2).(a) Treatment should include pharmacologic and nonpharmacologic methods and an interprofessional team.

- IV.C.3.q) There must be a structured experience in which residents address population health, including the evaluation of health problems in the community.

- V.D.3. Resident Scholarly Activity

  IV.D.3.a) Residents must participate in scholarship.

  IV.D.3.b) Residents should complete two scholarly activities, at least one of which should be a quality improvement project.

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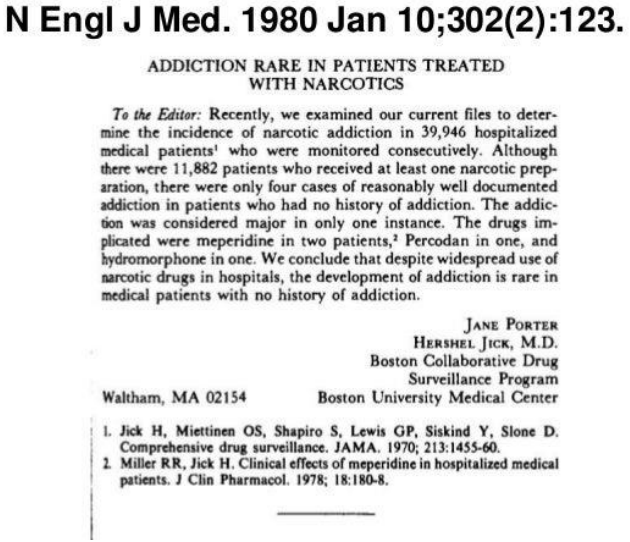
Background: Treatment Paradigm Shift

What is the problem?

- **1980 Letter** - risk of addiction to opioids while under a doctor's care was 0.5%; cited almost 1000 times
  - → 1996 Consensus Statement – titrate opioids without limit

- **2015 Article** – risk of opioid use disorder 35% among patients treated for chronic pain on opioids
  - → CDC Guidelines– for acute pain, patients should not have opioids prescribed > 3-7 days
  - No long-term (≥ 1 year) outcomes in pain/function; most placebo-controlled trials ≤ 6 weeks.
  - No differences in pain/function with dose escalation



N Engl J Med. 1980 Jan 10;302(2):123.

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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HERSHEL JICK, M.D.
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Waltham, MA 02154 Boston University Medical Center

1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

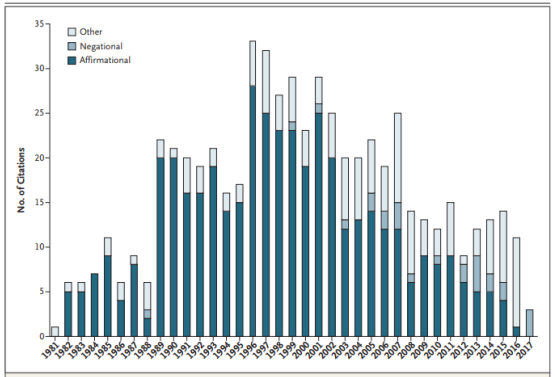
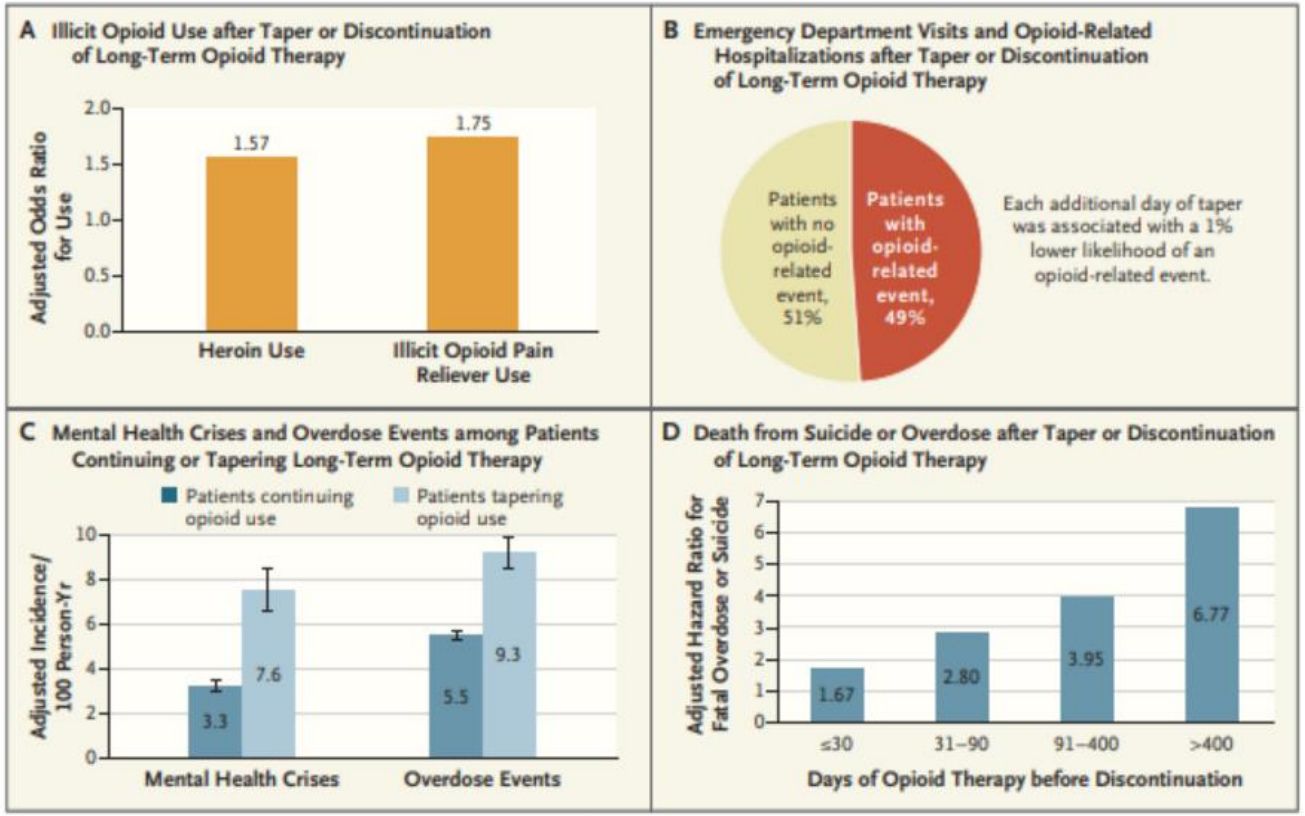


Figure 1. **Number and Type of Citations of the 1980 Letter, According to Year.**
Shown are number of citations of a 1980 letter to the *Journal* in which the correspondents claimed that opioid therapy rarely resulted in addiction. The citations are categorized according to whether the authors of the articles affirmed or negated the correspondents' conclusion about opioids. Details about "other" citation categories are provided in Section 2 in the Supplementary Appendix.

JAMA. 2017;317(11):1117-1118, Von Korff, M. *et al.* Long-Term Opioid Therapy Reconsidered. *Ann Intern Med* 2011;155:325-328, *Journal of Addictive Diseases*, 2011;30:185-194, and CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016. Accessed online at www.cdc.gov, and Leung, P. et al. A 1980 Letter on the Risk of Opioid Addiction. NEJM 376;22:2194-2195.



Risks Conferred by Tapering or Discontinuing Long-Term Opioid Therapy.

Among patients who have their long-term opioid therapy discontinued or tapered, there is an increased risk of illicit opioid use (Panel A), a high incidence of emergency department visits and opioid-related hospitalizations (Panel B), an increased incidence of mental health crises and overdose events (Panel C), and an increased risk of death from suicide or overdose (Panel D). I bars in Panel C indicate 95% confidence intervals. Data are from Coffin et al.,[2] Mark and Parish,[3] Agnoli et al.,[4] and Oliva et al.[5]

2016 CDC Guidelines

Coffin, PO & AM Barreveld. Inherited Patients Taking Opioids for Chronic Pain – Considerations for Primary Care. NEJM 386;7:611-613.

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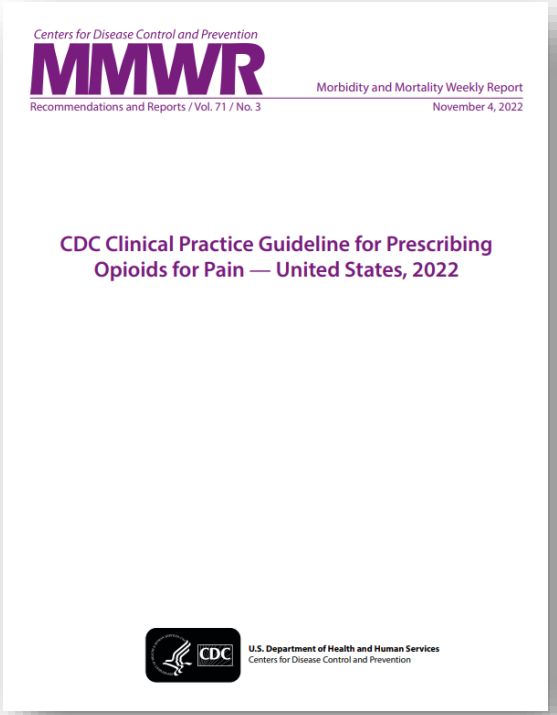
2022 CDC Guidelines

1. **Determining** whether or not to initiate opioids for pain.
2. **Selecting** opioids and determining opioid dosages.
3. **Deciding** duration of initial opioid prescription and conducting follow-up, and
4. **Assessing** risk and addressing potential harms of opioid use.



Summary of the 2022 Clinical Practice Guideline for Prescribing Opioids for Pain | Opioids | CDC

Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1

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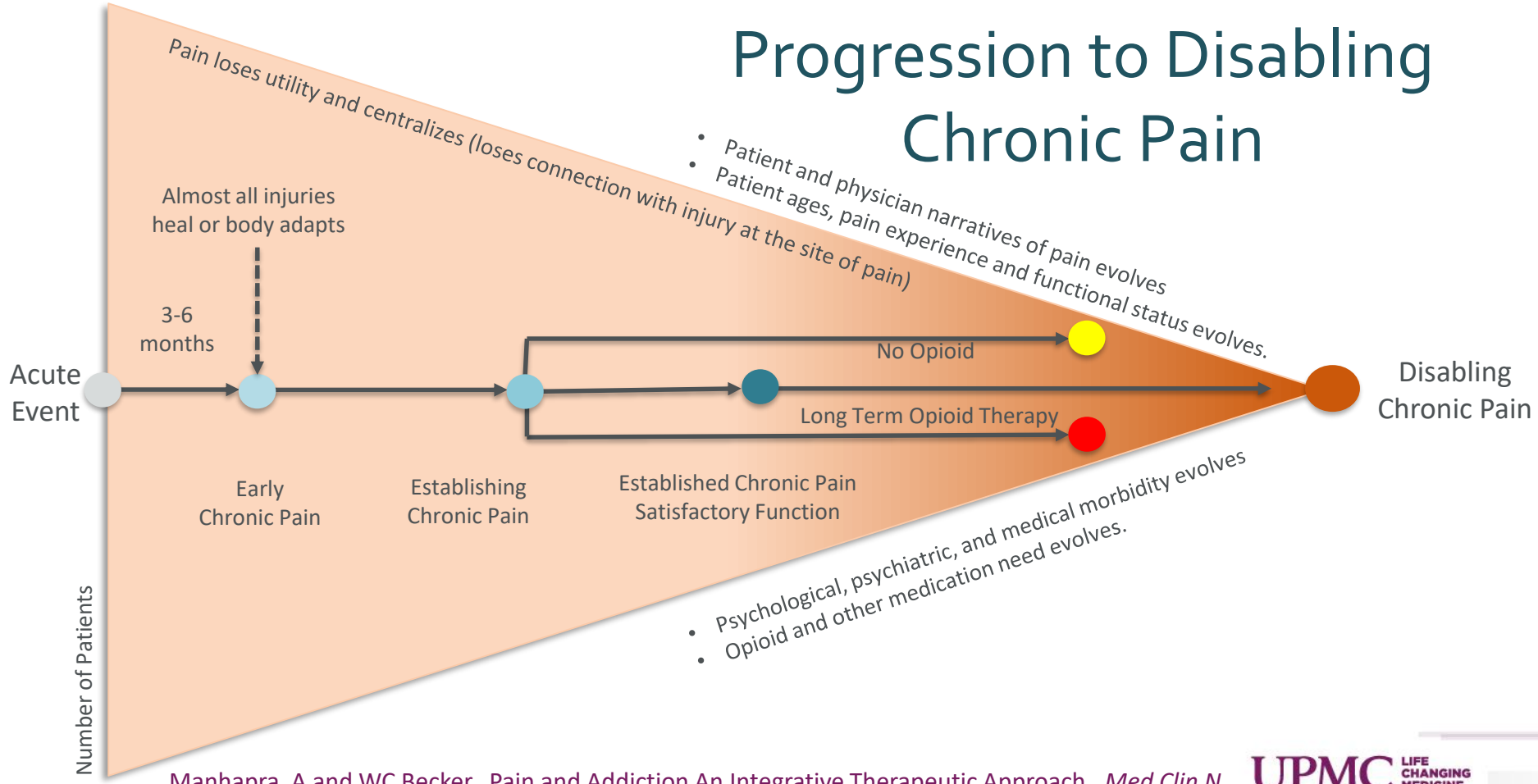
Progression to Disabling Chronic Pain



Manhapra, A and WC Becker. Pain and Addiction An Integrative Therapeutic Approach. *Med Clin N Am* 102(2018) 745-763.

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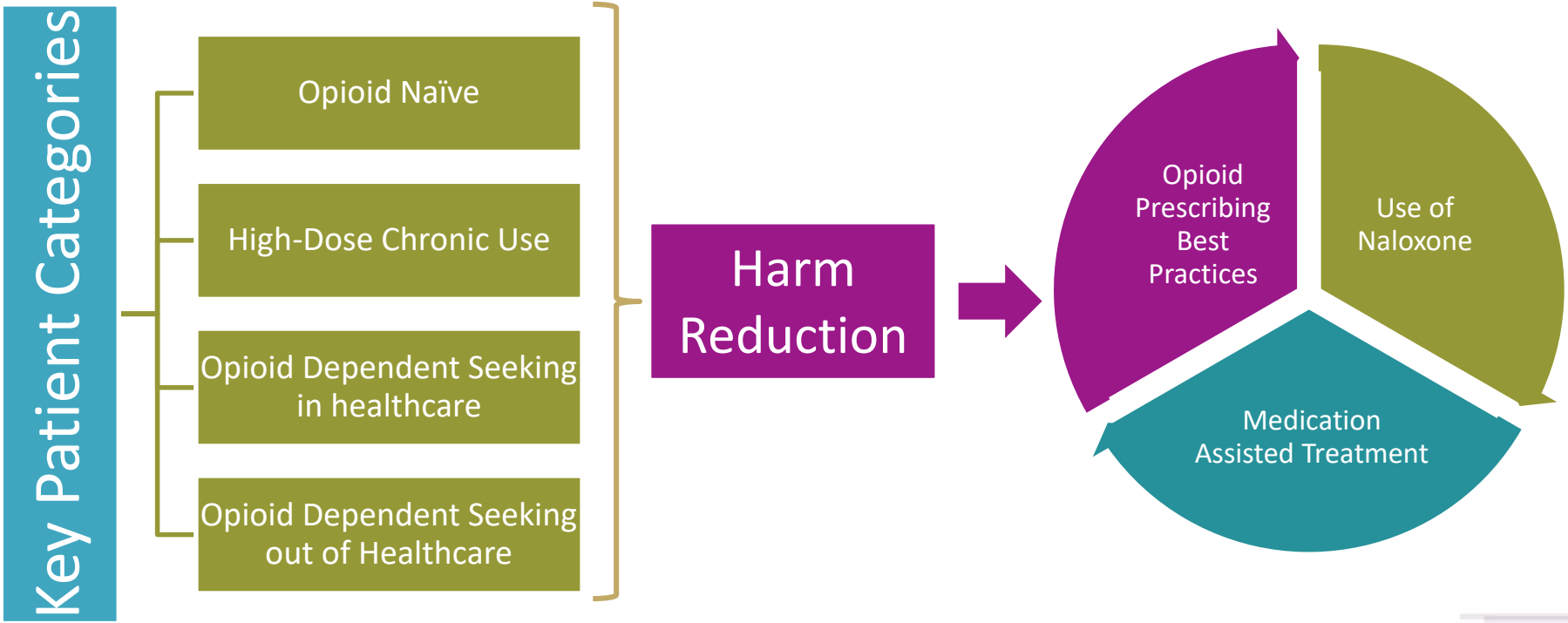
Adverse Selection in Opioid Prescribing

- **"Adverse Selection"** –
  - "Describes the process where the likelihood of a patient receiving an opioid regimen increases as the associated risks increase."
  - **Examples** –
    - History of depression or other common mental health disorders increase the likelihood of long-term opioids by 3-4 fold.
    - History of alcoholism or non-opioid drug abuse increases the likelihood by 4-5 times.
    - History of opioid abuse or dependence increases the likelihood 5-10 times.

Deyo, R.A. *et al.* Opioids for low back pain. BMJ 2015;350:g6380 and Sullivan, M.D. and C.Q. Howe. Opioid Therapy for Chronic Pain in US: promises and perils. *Pain* 2013 Dec.; 154(0 1):S94-100 .

Targeted Areas to Address Opioid-Related Overdoses and Deaths



Opioid Abuse in the US and HHS Actions to Address Opioid-Related Overdoses and Deaths. ASPE Issue Brief, 2015. Accessed online at http://aspe.hhs.gov. and Stempniak, M. A Population Health Approach to the Opioid Epidemic: 4 Types of Patients and 4 Key Strategies. *Hospitals and Health Networks* 2016. Found online at http://www.hhnmag.com.

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Patient-Centered Care

How do we provide hope when treating pain and suffering?

Components of Patient-Centered Care:

1. Biopsychosocial (spiritual) perspective
2. “Patient as Person”
3. Sharing Power and Responsibility
4. Therapeutic Alliance
5. “Doctor as Person”

Accessed online at www.ahrq.gov on 9/17/21 and Haes, H. Dilemmas in patient centeredness and shared decision making: A care for vulnerability. *Patient Education and Counseling*. 62(2006) 291-298.

Common Frameworks for the Use of Opioids in the Management of Chronic Pain

- **Law Enforcement Framework**
  - Question – Is the pain real? Is the patient telling the truth? Is there proof that the patient has or has not done something wrong?
- **Bargaining Framework**
  - Question – How low of a dose of opioids will the patient accept? Is the patient keeping up his or her end of the bargain?
- **Benefit-to-Harm Framework**
  - Question – Do the benefits of opioids outweigh the risks for this patient at this time?

Nicolaidis, C. Police Officer, Deal-Maker, or Health Care Provider? Moving to a Patient-Centered Framework for Chronic Opioid Management. *Pain Medicine.* 2011:1-8.

Common Frameworks for the Use of Opioids

	Law Enforcement Framework	Bargaining Framework	Benefit-to-Harm Framework
Goal of care	Catch "Addicts"	Negotiation	Assess Risk
Goal of Functional Assessment	Assess if pain severe enough to warrant tx	Assess "worth" of treatment	Measure actual or potential benefit to treatment
Mindset Framework	"I deserve pain meds"	"I have done what you ask.."	"Opioids allow me to do X"
When opioids have no benefit	Opioids continued b/c pt did not commit an "offense"	Patient asks for more opioids…if certain behaviors met	Reconsideration of other treatment options
Response to Aberrant behaviors	Based on severity of infraction and level of proof	Explain why this is a breach of contract	Consider differential

Nicolaidis, C. Police Officer, Deal-Maker, or Health Care Provider? Moving to a Patient-Centered Framework for Chronic Opioid Management. *Pain Medicine.* 2011:1-8.

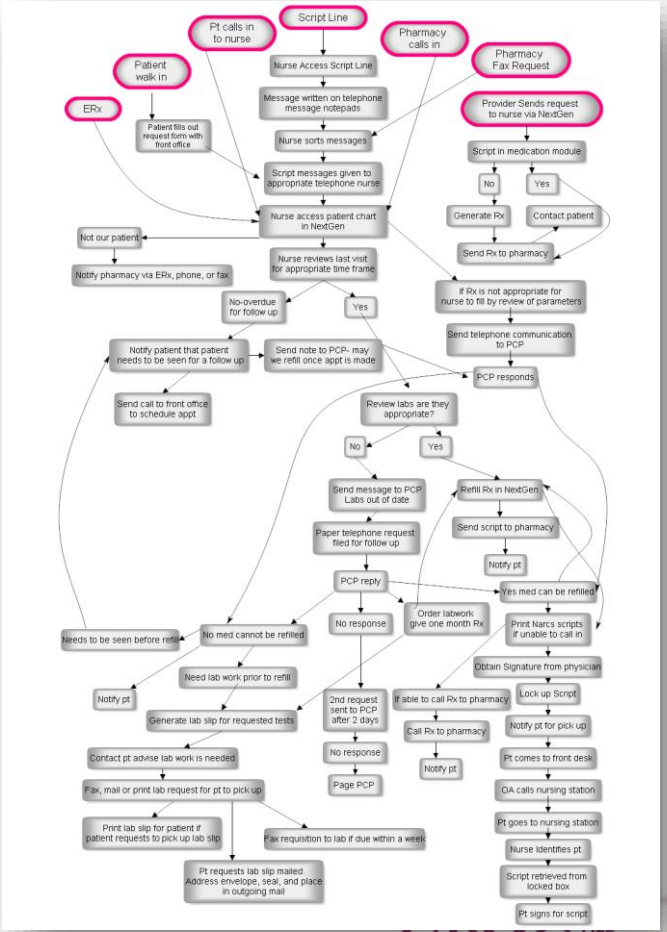
“Universal Precautions”

Category	Recommendation
Attitude	Compassion/Avoid Judgment
Education	Opioid Risks/Non-opioid Treatment/Med Take Back/Avoid Diversion/planned taper
Prevention	Acute/Chronic Pain/Opioid Abuse
Screening	Depression/SUD/OUD/Urine Screens – Refer if “+”
Harm Reduction	PDMP/Opioid Rx limits/Avoid Sedative & Opioid Combo/Naloxone
Comprehensive Assessments	Opioid Exposure History & Monitor for Withdrawal/Overdose/Response to Treatment
Develop Differential Diagnosis	Diagnosis/Aberrant Behavior/Mental Status changes
Team Approach	Discuss concerns/consultants/Who writes Rx?

Pre-Intervention

- Patient frustration/anger
- Staff/Physician interruptions/frustration
- Inability to monitor opioid use/parameters
- Frequent phone calls to the office for controlled medications

BEDLAM



Residency Subcommittees to Address Opioids/Chronic Pain

Screening

- **GOAL:** Evaluate present screening processes in our office in regard to chronic pain management and to develop standardized evidence-based screening practices to improve the care of our patients.

Protocols

- **GOAL:** Evaluate present protocols in our office for chronic pain management and to develop a standardized protocol for the management of patients with chronic non-malignant pain.

Controlled Medication Renewal

- **GOAL:** Evaluate present refill processes in our office regarding chronic pain management and to develop a standardized refill protocol to improve the care of our patients.

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CNMP Protocol

CNMP - Initial Visit Checklist		
Action	Yes	No
Previous Opioid Exposure?		
Old Records?		
Diagnostic Evaluation Complete? Clear Diagnosis?		
Pain/Function Evaluation? – PEG-3; (alternative - Brief Pain Inventory (BPI))		
Non-opioid Treatments Tried?		
Screening? – ex. PHQ-9, GAD-7, Opioid Risk Tool (ORT) (or SOAPP-R), PTSD, SUD Screen, Urine Drug Screen (UDS), Prescription Drug Monitoring Program (PDMP)		
Risk Mitigation Addressed? – Education, Controlled Substance Agreement (CSA), Naloxone (if risk factors)		
Comprehensive Treatment Plan? – discuss goals, opioid prescribing recommendations (none on 1st visit, not first-line, use lowest amount, no long-acting when starting, avoid benzo & opioid combo)		
Follow up 1 to 4 weeks and < 3 months thereafter?		

CNMP - Follow Up Visit Checklist		
Action	Yes	No
Diagnosis requiring opioids?		
Pain/Function Evaluation? – PEG-3		
Screening Completed? – ex. PHQ-9, ORT, SUD, UDS, PDMP		
○ **Every Prescription -** PDMP		
○ **Every Visit –** Aberrant Drug Taking Behavior, Risk factor for overdose?		
○ **Annual or Periodic –** PHQ-9, SUD Screen, UDS, PTSD		
Risk Mitigation Addressed? – education, naloxone (if risk factors); CSA updated annually; UDS at least annually		
Appropriate for Controlled Medication Renewal Program? Stable dose, no ADR's or Aberrant Drug Taking Behavior, etc.		
Comprehensive Treatment Plan? – discuss goals, non-opioid options maximized, opioid prescribing recommendations (offer taper, use lowest amount, use caution at any dose, careful with dose ≥ 50 MME/day and avoid increasing dosage to ≥ 90 MME/day, avoid benzo & opioid combo		
Follow Up < 3 months		
Documentation Appropriate?		

Controlled Medication Renewal Program

Case -

55 yo patient on chronic opioid therapy for chronic, debilitating pain…each month they call for a renewal of their medication. They are petrified of running out because their pain will get out of control causing them to miss work. The staff is frustrated that they always calls so early for the renewal before it is even time for a new prescription. They have taken the same medication for several years.

In stable patients, controlled medication renewals are completely predictable.

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Aberrant Drug Taking Behavior

Definition - “Describes dysfunctional activities suggesting misuse”

Continuum of behaviors from mild to severe.

The most predictive are:

- Selling Rx drugs, forgery, stealing drugs
- Injecting oral drugs, use of illicit drugs,
- Rx losses, multiple unsanctioned escalations
- Requesting specific drugs, use of drugs for other symptoms
- Hoarding of medication and frequent calls to the prescribing provider’s office

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Controlled Medicaton Renewal Program

Aberrant Drug Taking Behavior – Diff. Dx.

- Addiction
- Pseudo-addiction
- Other Psychiatric Disorders.
  - Axis I – anxiety/depression
  - Axis II – Personality Disorders
- Encephalopathy associated with medication toxicity
- Psychosocial or emotional issues – Family discord, financial worries, “rebellion”
- Recreational Use – pleasure, escape peer pressure
- Criminal Intent

Webster, L. and B. Dove. Avoiding Opioid Abuse While Managing Pain. Sunrise Silver Press, 2007.

Controlled Medication Renewal Program

Pseudo-Addiction = Uncontrolled Pain

- Mimics addictive behavior
- Clock watching, hoarding, drug seeking behavior
- Occurs when pain is undertreated
- Disappears with proper treatment

Controlled Medication Renewal Program

Case Options -

- Prescribe no controlled medications
- Schedule Monthly Appointments
- ~~3 – One Month Pre-dated Rx~~
- Proactive Prescription Management

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Renewal Program - Steps to Development

1. Research – staff ownership, patients who qualify
2. Development – database, parameters to be monitored, office flow, & pick-up dates
3. Initiation – education of staff/patients, go-live date, & short prescription until go-live

January 16, 2013

Dear Valued Patient,

In an effort to improve the medical care we provide to you, we are changing the way we refill medicines which are called "controlled" by the federal government. These are medications which need to be monitored more closely due to their potential addictive qualities. Examples of these medications include oxycodone, fentanyl, and methadone.

For patients who receive a controlled medication on a regular basis, we will provide you with the dates when these prescriptions can be picked up in our office. This will allow you to know when your refills are ready, and you will no longer have to call the Residency Center each month to get a refill.

Given that controlled medications have some risks for your health, we will ask you to sign a controlled substance agreement with your doctor if you are on a controlled substance for an extended period of time. Such an agreement is helpful to you and your physician to clarify what the expectations are in regards to these medications.

Finally, we wish you the best in regards to your health and hope that we are able to continue to meet your healthcare needs. Please let us know what questions you have.

Sincerely,

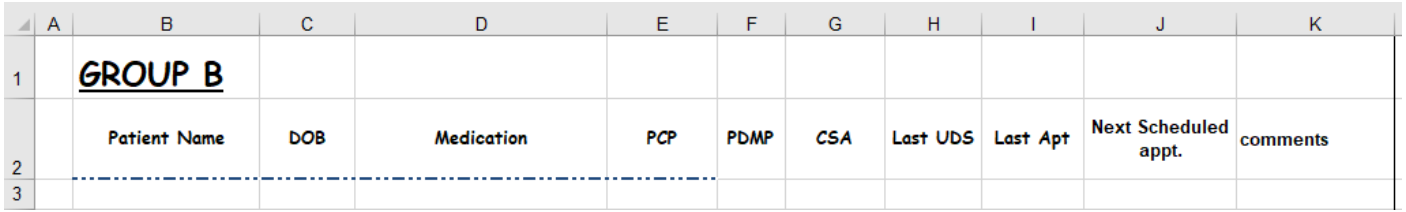
Your Physician

Controlled Med Renewal Program

Scheduled Renewal Dates :

- Designed to occur on the same weekday of every month – ex. First Wednesday
- Accommodates holidays and provider vacations
- Allows monitoring in the background of specified patient parameters – CSA, office visits, UDS, PDMP…

Monthly Renewal Dates
1/10/24
2/7/24
3/6/24
4/3/24
5/1/24
5/29/24
6/26/24
7/24/24
8/21/24
9/18/24
10/16/24
11/13/24
12/11/24



	A	B	C	D	E	F	G	H	I	J	K
1		GROUP B									
2		Patient Name	DOB	Medication	PCP	PDMP	CSA	Last UDS	Last Apt	Next Scheduled appt.	comments
3											

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Controlled Medication Renewal Program

Patient Outcomes in Our Practice:

- ✓ Patient opinion of the new process: 79% thought the process is much better than the old or the best way to renew controlled medications.
- ✓ Patient functioning: 88% thought they functioned the same or better at one and four months after initiation.
- ✓ Patient satisfaction with their provider: Patients' satisfaction increased but was not statistically significant from pre- to post-implementation.

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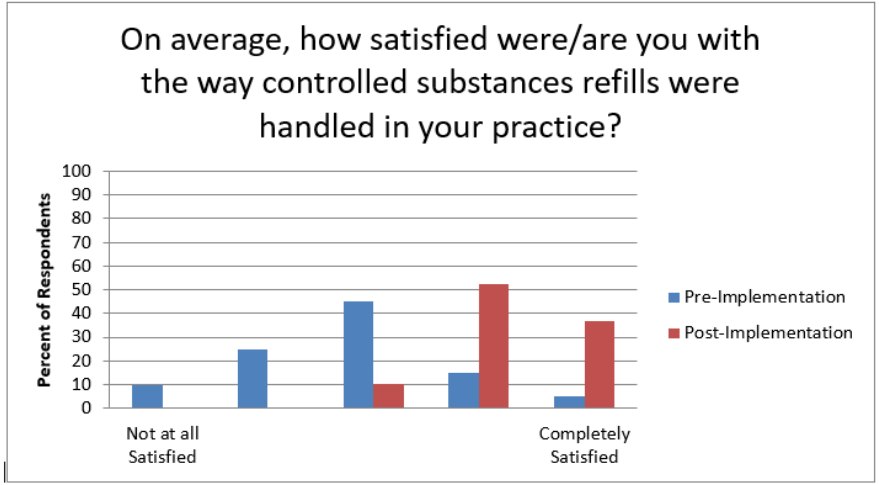
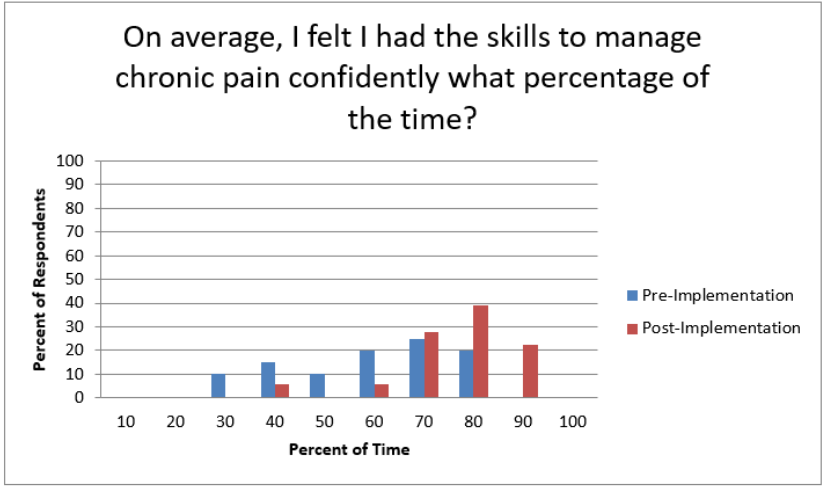
Controlled Medication Renewal Program

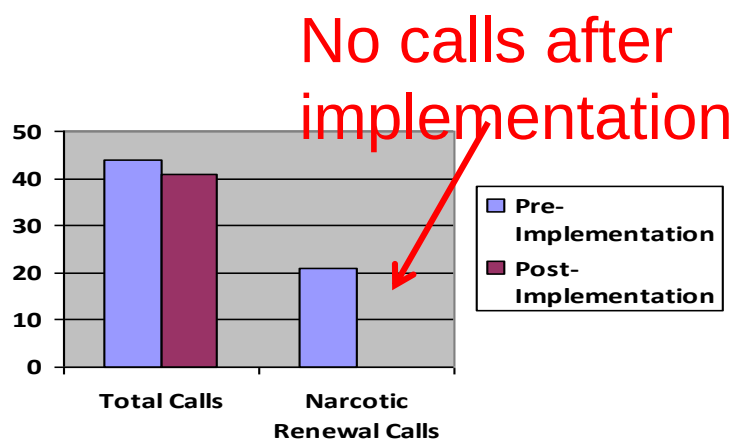
Resident Perception of the Renewal Program in Our Office:



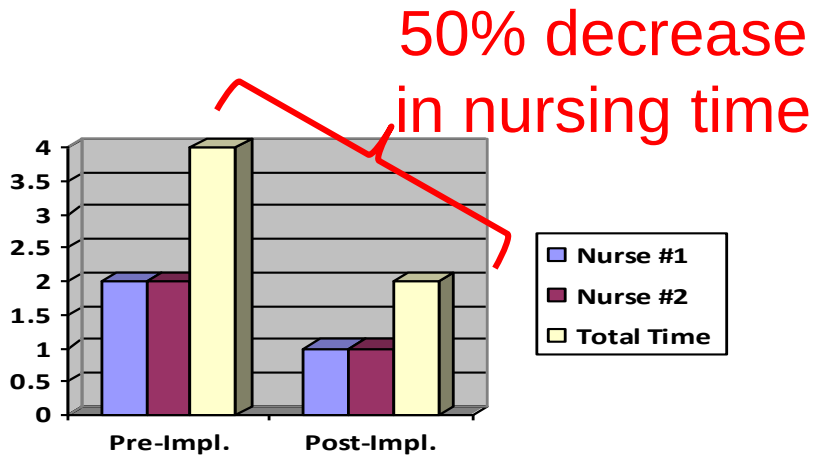


Controlled Drug Renewal Program

How many calls did patients make to the office?



How much time did renewing controlled meds take staff/wk?



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Goals & Data for Renewal Program

Controlled Substance Agreement - 100% of patients prescribed a controlled medication for longer than 6 weeks duration will have a controlled substance agreement signed in the medical record

- Expectations: includes all controlled medications, signed annually, minors (18 years) will have a parent or guardian sign the agreement, 12 and older will also sign the agreement.

Office Visits – for opioids, an office visit at least every 3 months, and for behavioral medications an office visit at least every 6 months

Urine Drug Screen – a urine drug screen on at least an annual basis

Year	Total Residency Patient Panel	# of Patients with Schedule 2 Prescriptions	CSA (Threshold 75%)	UDS	UTD Appts (Threshold 75%)
August 2012	n/a	61 (opioids only)	13%	n/a	n/a
May 2014	4300	117 (2.7%)	61%	n/a	n/a
July 2017	n/a	164	48%	n/a	n/a
October 2019	4900	131 (2.7%)	95%	88%	61%
June 2021	n/a	n/a	92%	n/a	83%
May 2022	4528	108 (2.4%)	90%	95%	81%
June 2023	4669	113 (2.4%)	100%	81%	94%

Quality Care for Pain is Similar to Caring for a Garden…

"Garden care involves observing your garden regularly and addressing issues as they arise. There is no magic "green thumb" that you develop. You will avoid most problems by checking your plants regularly for the basics like roots having enough air/water and leaves getting enough sun. Your plants will likely need some specialized pest control or organic fertilizer at some point…."

Accessed online at Gardening 101 for green thumbs in the making 🌱📗 Kickstart your horticultural journey (homefortheharvest.com) on 3/17/2024.

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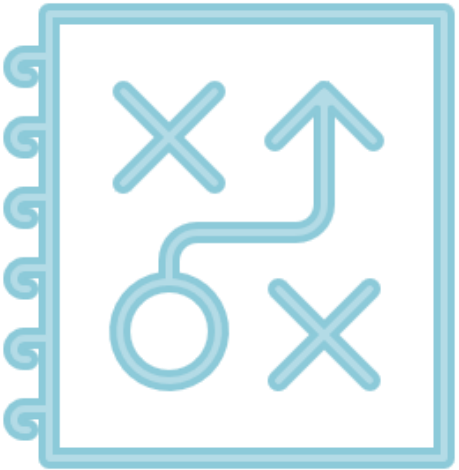
Discussion



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