The Opioid Epidemic: Guidance for Healthcare Providers

A presentation addressing the evolving standard of care for prescribing opioids for chronic pain.

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Governor's Institute on Substance Abuse
Raleigh, NC

Changes By Choice
Durham, NC

Why talk about opioid prescribing?

Chronic pain is a *common* but often complex clinical problem

Clinicians have been *criticized* for inadequate treatment of pain

Partly as a result…the use of all *prescription opioids has increased dramatically* in the past 15 years.

And…

Partly as a result**…** *problems* from their use have *also* increased dramatically.

Who is Dying from Opioid Overdose?

Majority of deaths are people in pain: *Patients or non-medical users*

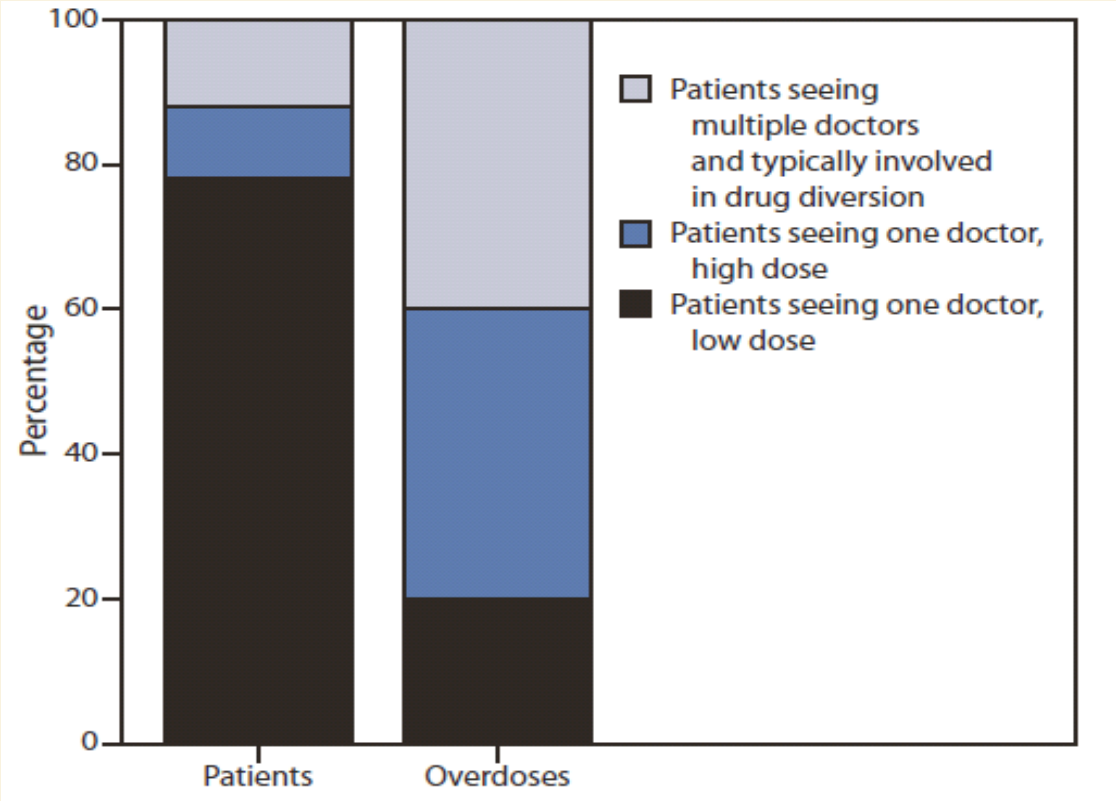
Non-medical (non-prescribed) users: 25-65% of opioid deaths

- over 70% get meds from friend or family
- estimates indicate half are people in pain

Medical (prescribed) users: 35-75% of opioid deaths

- white, rural, chronic pain, low SES, mood disorders poor treated,
- financially burdened, single/divorced, previous misuse of meds
- 80% of deaths are patients at >100 MME (MEQ) per day

Risk Related to Dose and Number of Prescribers



- Low dose is defined as <100 morphine equivalent dose per day.
- Most patients (80%) are on low dose, prescribed by one doctor.
- **80% of overdoses are patients on high dose:** half one doctor, half multiple doctors.

CDC: Morbidity and Mortality Weekly Report: Jan. 13, 2012

Clinical Challenge: *Balancing Access and Safety*

CHALLENGE: Balancing relief of pain but minimizing untoward outcomes:

-Adequate treatment is needed and expected for chronic pain, a common, at times disabling condition…

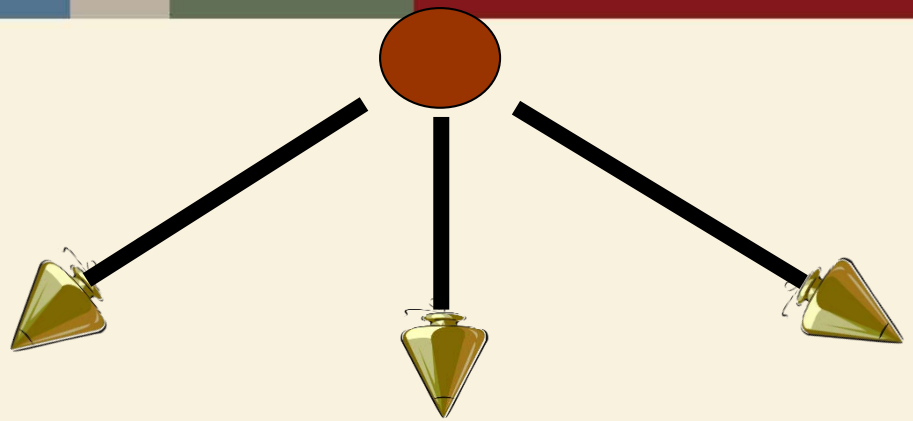
-Knowledge base related to chronic pain management is evolving and often inadequate…

-Outcome data as it relates to using opioids is at this time is woefully inadequate…

Clinicians face increased regulatory oversight and legal attention for BOTH under-treatment and over-treatment of chronic pain

In the setting of a changing expected standard of care.

Pushing Back the Pendulum



Avoidance

Will not prescribe opioids:

- Exaggerated perception of risk
- Fear of regulatory action
- Inadequate knowledge of addiction

Balance

Rational pharmacology:

Application of basic principles of medicine:

- Therapy tailored to risk stratification
- Tx adapted based on monitoring and outcome

Overuse or Misuse

Prescribing without attention to dangers:

- Inadequate monitoring
- Excessive dosing
- Failure to respond to abuse

Adapted from S.Passik

The Nature of Chronic Pain and the Role of Opioids in its Management

Pain Can Be Acute or Chronic

< 3 Months

- Usually obvious tissue damage
- Pain resolves upon healing
- Protective function

≥ 3-6 Months

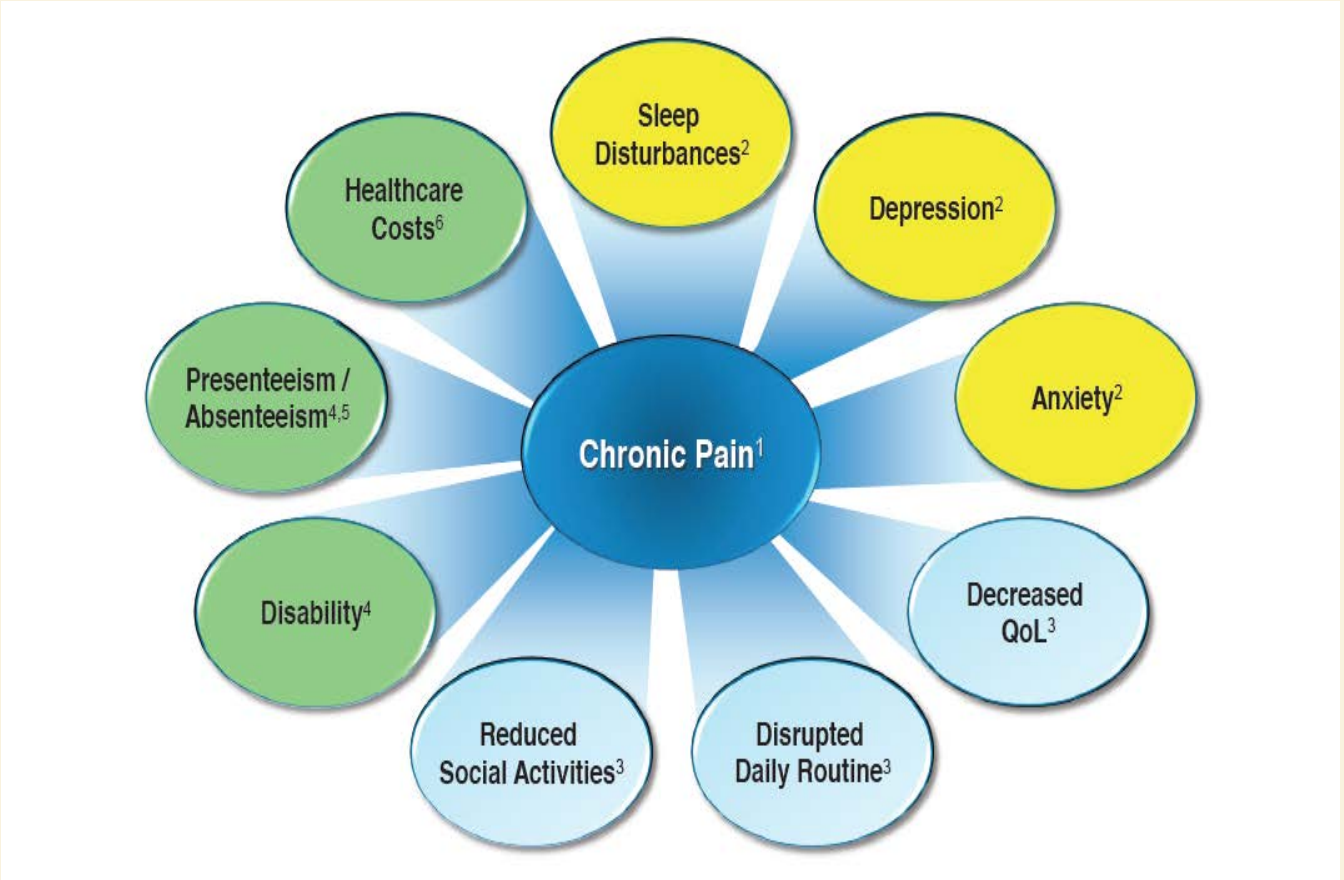
- Pain lasts for 3 months or more
- Pain beyond expected period of healing
- No protective function

"Chronic pain can be a disease in its own right"

IOM Report on Pain, 2011

1. Cole. Hosp Physician. 2002;38:23-30.
2. Turk, DC, Okifuji A. J Consult Clin Psychol 2002;70(3):678-690.
3. Chapman CR, Stillman M: Pathological Pain, Handbook of Perception: Pain and Touch. Edited by Krueger L. New York, Academic Press, 1996, pp 315-342.
4. Kehlet et al. Lancet 2006; 367: 1618-25.

Chronic Pain Can Be Multidimensional



Note: Even appropriate treatment of chronic pain may not resolve all associated conditions.

1. Douglas C et al. *J Neurosci Nurs.* 2008;40(3):158-168.; 2. Tang NKY et al. *J Sleep Res.* 2007;16(1):85-95.; 3. Hawker GA, Stewart L, French MR, et al. *Osteoarth Cartil.* 2008.; 4. Munce SE et al. *J Occup Environ Med.* 2007;49(11):1206-1211.; 5. Stewart WF et al. *JAMA.* 2003;290(18):2443-2454. 6. Ritzwoller DP et al. *BMC Musculoskelet Disord.* 2006;7:72-81.

Optimal Management Approach
Biological + Psychological + Social

Biological

- Lesion treatment: surgical, interventional
- Symptom treatment: pharmacology, interventional
- Rehabilitative/Physical Therapies: stretching/exercise, massage, gait/ posture training,
- Complementary Alternative Medicine: yoga, acupuncture

Psychological

- Psychological Therapies: CBT, biofeedback, relaxation, problem-solving, guided imagery.
- Patient Self-Management: adaptation, pacing of activity, planned rests, etc.

Social

- Social support, environment, job change, family involvement, ancillary services

Opioids for Chronic Pain: *What do we know and not know?*

Most literature surveys & uncontrolled case series

RCTs tend to be short duration though some up to 24 months

and sample sizes tend to be <300 pts

Many pharmaceutical company sponsored

Pain relief modest but is documented:

- Some statistically significant, others trend towards benefit
- Cochrane review 2010 with 44% showing at least 50% pain relief

Functional endpoints few thus improvement not demonstrated

Not substantially different than the Cancer Pain literature

Balantyne JC, Mao J. NEJM 2003, Nobel M 2010
Martell BA et al. Ann Intern Med 2007; Eisenberg E et al. JAMA. 2005

Noble, et al Cochran Review 2010

Long-term opioid management for chronic non-cancer pain, conclusion stated:

- 23% discontinued due to adverse events, including lack of effect
- Weak evidence suggests that there is clinically significant pain relief
- Improvement in quality of life and functional status is inconclusive
- Serious adverse events, including iatrogenic opioid addiction, are *rare*.

"Evidenced Based Treatment…"

"data are mixed…reviews support efficacy for period of months…

"suggest a subpopulation can benefit long term…but no high quality evidence about long-term effectiveness"

In the absence of adequate evidence it is *wrong* to necessarily conclude that:

- Opioid drugs lack long-term effectiveness
- Risks exceed benefits overall, or in subpopulations

Alternative conclusions are equally likely:

- Some patients benefit…some are harmed
- Some subpopulations "*over-treated*"…some *"under-treated"*

Russell Portenoy presentation 2014

Expanded awareness of opioid related risk

Common, long known side effects:

-constipation, nausea, sweating, urinary retention

-sedation, cognitive and psychomotor impairment, insomnia

Increased awareness of other side effects:

-hormonal imbalance and/or sexual dysfunction

-cardiac dysrythmia and sudden death

-respiratory depression and/or sleep apnea

Increased awareness of risks of misuse, overuse, addiction

Increased awareness of risks associated with higher doses

What does this mean for a clinician treating pain?

Adequate assessment and informed consent before a *trial* of opioids:

-Pain treatment does not *equal* opioids.

-Opioids are *not equally effective* for all chronic pain.

-Opioids are *not typically the first line treatment* for chronic pain

-Opioids may be useful but are *rarely sufficient* (multimodal optimal*)*

-Opioids have *significant risk*…particularly at higher doses

Goal is *functional improvement, managing (not eliminating) pain and safe use*.

***Mitigate risk with ongoing monitoring*, continued opioid use depends on:**

-Demonstrated *efficacy* (improved function and pain management)

-Demonstrated *safety* (no aberrant medication behaviors)

Tools and strategies available to mitigate risk

Risk stratification as part of assessment:

- Screening tools and strategies

Treatment planning based on risk assessment:

- Adequate informed consent/treatment agreements
- Multi-modal emphasis
- Use of referral and co-treatment

Monitoring

- Prescription monitoring programs (PDMPs)
- Urine or other toxicology screening
- Ancillary status reports (other clinicians, family)
- **Adapting treatment in response to risky or problematic behaviors**

How effective are strategies for mitigating risk when prescribing opioids?

State of the Art: Most of these strategies are based on expert or consensus opinion: They have face validity but little outcome data to support their use.

Dept. of HHS: Agency for Healthcare Research and Quality:
The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain: 2014

http://www.ahrq.gov/research/findings/evidence-based-reports/opoidstp.html

However: Increasingly they are promoted and *expected* as part of the evolving standard of care for use of opioids for chronic pain.

Including all current consensus guidelines.

Evolving "Standards of Care" Related to Opioid Use

Various national guidelines:

Federation of State Medical Boards (FSMB) Guidelines: ***Use of Opioid Analgesics in the Treatment of Chronic Pain in the Office Setting*: 2013**

All 50 states have individual published guidelines on rational use of opioids, based upon FSMB 2013 revised guidelines.

http://library.fsmb.org/pdf/pain_policy_july2013.pdf

Center for Disease Control: *CDC Guideline for Prescribing Opioids for Chronic Pain: United States 2016*

http://www.cdc.gov/drugoverdose/prescribing/guideline.html

Strong Consistency Among Various Guidelines

All of the national and Arizona guidelines (as well as most others) are consistent with each other in most areas:

1. More attention to initial *risk assessment as well as pain assessment*
2. More attention to adequate *informed consent* and *education about risks*
3. Reinforce that opioids are *not first-line* therapy and *multi-modal* preferred
4. Discouragement of *"excessively high"* dosing

Consistency Among Guidelines Continued

5. Encouragement of *"therapeutic trial"* based on *pain, function and safe use*.
6. More attention to ongoing *monitoring of benefit and risk (aberrant behaviors)*
7. Routine use of *prescription monitoring programs* (*PDMPs*)
8. Recommended use of initial and recurrent *urine drug screening*
9. Interventions for abuse and use of *addiction treatment* when needed

Variations on These Themes

1. How much emphasis on *non-opioid vs opioid* treatment and how often use opioids long term (eg: rarely use opioids and/or rarely beyond 3 months…).
2. How strongly or specifically emphasize *monitoring all patients*.
3. Preference for not starting with *long-acting/extended release* opioids.
4. How clearly define *"excessively high dose."*
5. How strongly emphasize avoiding *opioids and benzodiazepines.*
6. Attention to prescribing opioids for *acute pain.*
7. Attention to active prescribing of *naloxone.*

CDC Guideline 2016

Twelve recommendations:

1. Opioids are not first line therapy/combine with non-opioid tx.

2. Establish goals for pain and function

3. Discuss risks and benefits

4. Use immediate release opioids when starting

5. Use lowest effective dose:

Reassess when >50 MME and avoid >90 MME

6. Prescribe short durations for acute pain:

Usually < 3 days, Rarely >7 days

CDC Guideline 2016 Continued

7. Evaluate benefits/harms frequently:
Initially within 1-4 wks of starting, then every 3 mos.

8. Use strategies to mitigate risk, including offering naloxone for higher risk (eg: history overdose or SUD, dose >50 MME, current benzo)

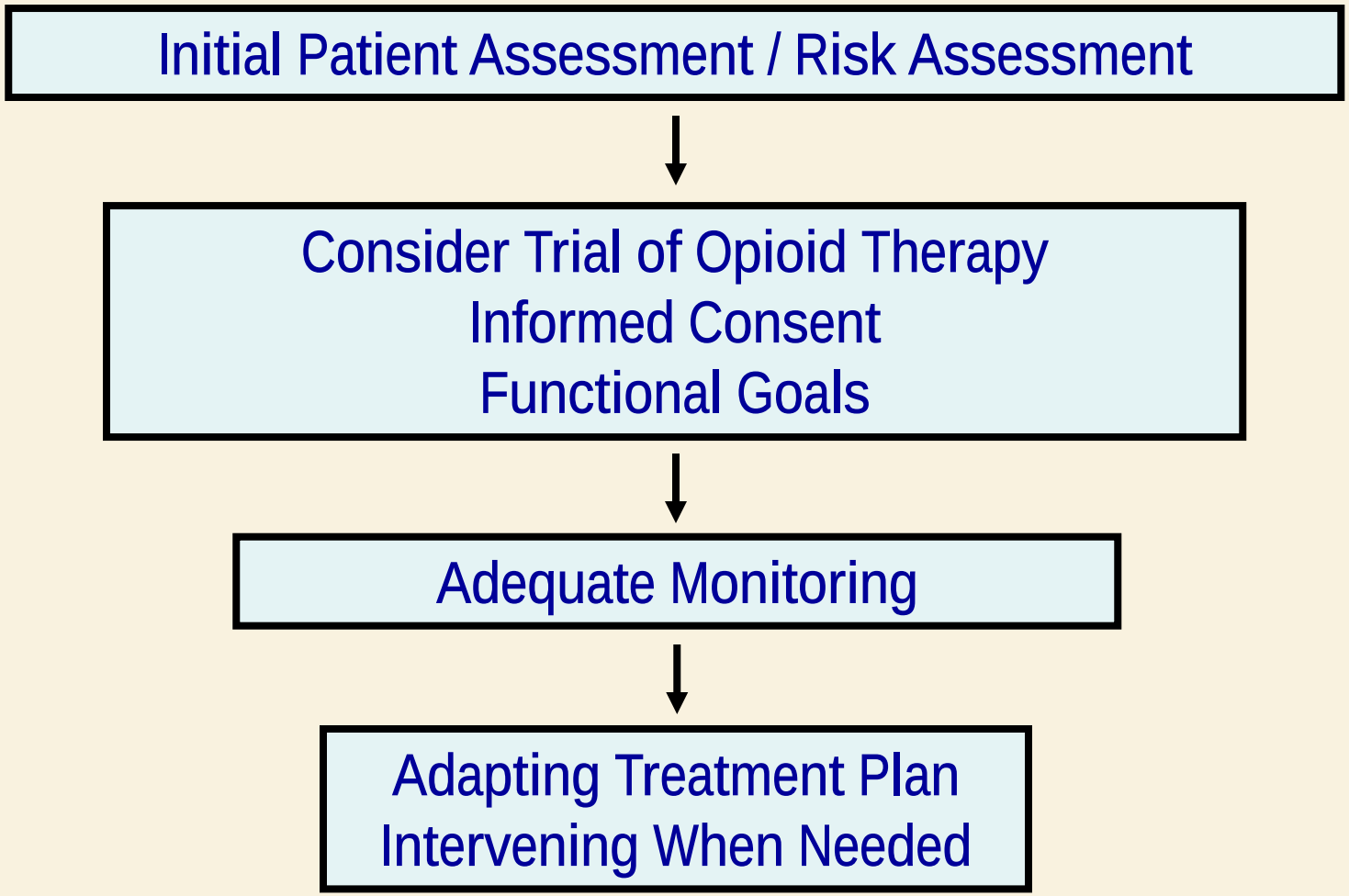
9. Review PDMP: When starting and periodically: Every Rx to every 3 mos.

10. Use urine drug screening: Before starting and at least annually

11. Avoid concurrent opioid and benzodiazepine prescribing.

12. Offer treatment for opioid use disorder, usually buprenorphine or methadone.

Rational Use of Opioids for Chronic Pain



Adapted from Katz NP. Patient Level Opioid Risk Management. PainEDU.org Manual. 2007

Perform a Risk Assessment to Stratify Level of Risk for Use of Opioids

- Adequate history and focused physical exam
- Information from prior or current providers
- Information from family or other significant others
- Standardized Instruments: Opioid Risk Tool (ORT)
- Medication prescription history through PMP
- Initial urine drug screen prior to prescribing

Possible Consequences of Risk Assessment for Initial Treatment Planning

Relative risk *directly* impacts further treatment planning:

- ➔ Whether or not to use opioids or other controlled meds
- ➔ Whether to treat in your setting or refer
- ➔ Frequency of visits
- ➔ Use of refills
- ➔ Frequency of drug screening/PDMP/ancillary contact
- ➔ Ancillary treatment expectations
  - Referral for consultation
  - Referral for co-treatment
  - Referral for buprenorphine or methadone

Adapting Treatment Based on Risk Level

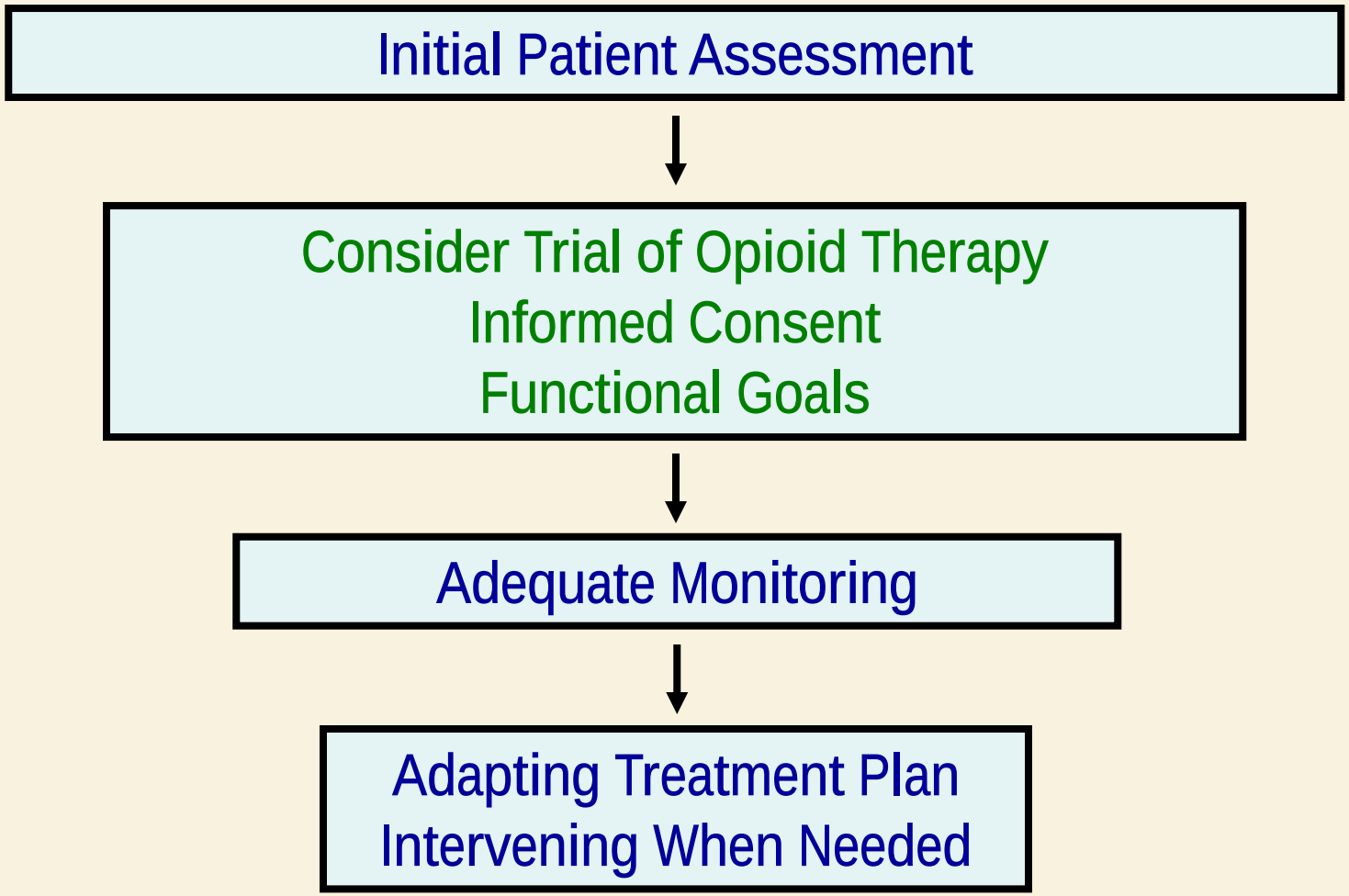
Lower risk <<< >>> Medium risk <<< >>>Higher risk

*<<<<<< **"COMFORT ZONE"** >>>>>>>*

Knowledge
Experience
Resources

Pain
Substance Abuse
Psychiatric

Treatment Algorithm: Steps in the Rational Treatment of Chronic Pain



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Goals of Opioid Therapy: Realistic and Targeted

- Pain *management*, not *elimination*
- Targeted *functional* improvement

- **SMART** goals:

specific

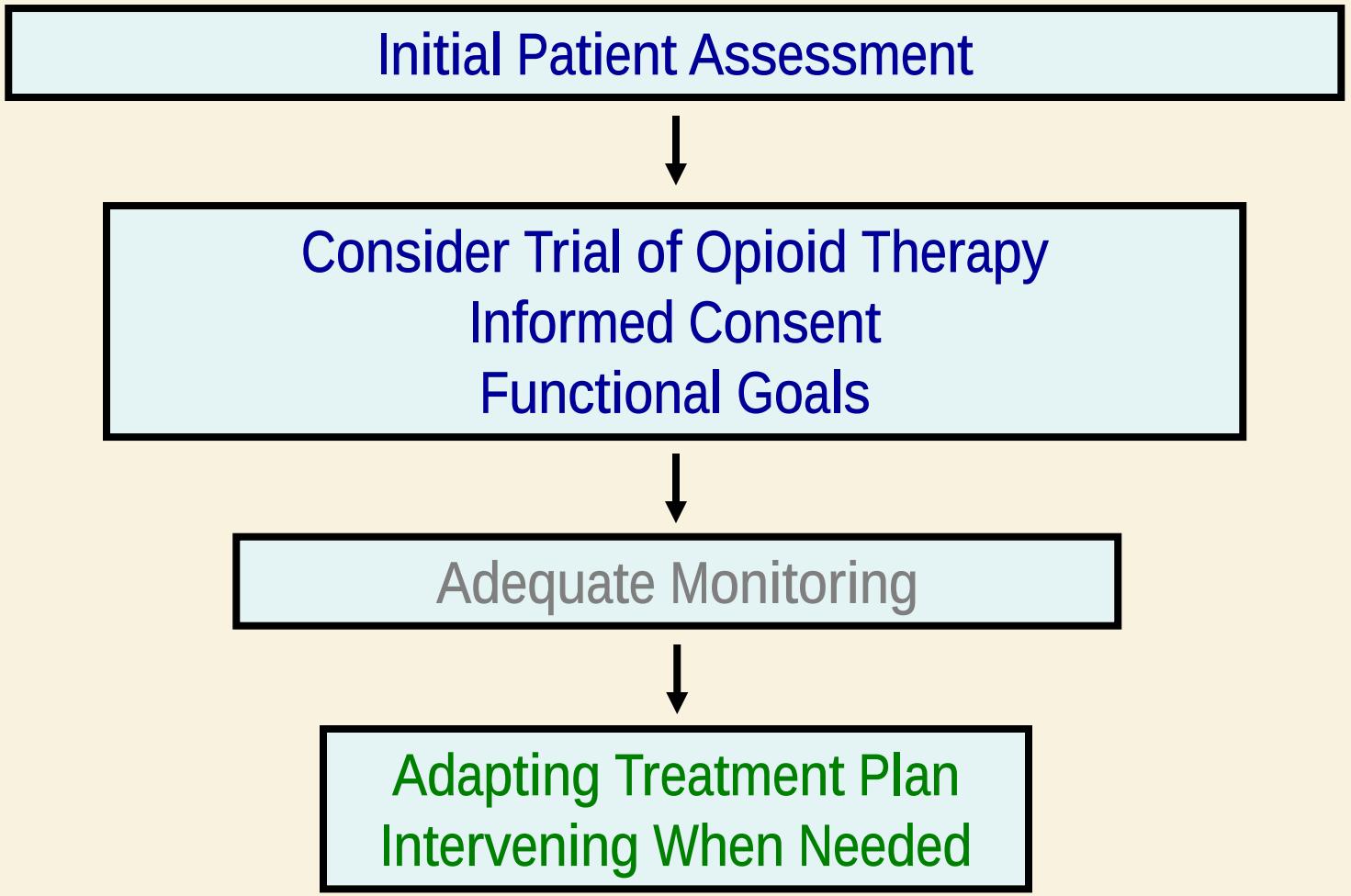
measurable

action oriented

realistic

time-sensitive

Treatment Algorithm: Steps in the Rational Treatment of Chronic Pain



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Regular Monitoring and Adapting Treatment

Recurrent assessment: **The 4 A's**

- Analgesia/Anxiety
- Activity/function
- Adverse effects
- Aberrant behaviors

Establish at *start* of treatment…"routine"…"practice standard…"

Patient report *and* ancillary as needed per risk level:

-collateral contacts, other clinicians, PDMP, drug screening, call-backs

Adapt treatment in response to outcome and monitoring.

Use standardized tools when available.

DOCUMENT!

Four As: Passik SD, Weinreb HJ. Adv Ther. 2000.

Optimize Office Systems

Saves Time and Stress

Develop and implement:

- Office controlled med policies
- Patient/Prescriber Agreements
- Management flow sheet
- Staff roles/responsibilities
- Referral and support resources *(pain, mental health, addiction)*

Courtesy of:

Boston University School of Medicine Continuing Medical Education

SCOPE of Pain
Safe and Competent Opioid Prescribing Education

Monitor and Adapt for Inadequate Pain Relief

- Adjunctive non-opioid meds
- Adjunctive non-med modalities

Continued pain does not necessarily mean more opioids…

- reinforce multi-modal orientation
- reinforce active self-management
- rely on "therapeutic trial" orientation

- **Stay in your area of expertise…*your comfort zone***
- When in doubt-get help
- Benefits of established protocols: Consultation at >90 MME

Monitor for Aberrant Medication Behaviors: Who Misuses/Abuses Opioids and Why?

Non-medical Use/Abuse

- Recreational abusers
- Diverting for profit

"Medical Use"

- Pain patients seeking more pain relief
- Patients escaping emotional pain

Patients using for non-pain conditions

Maintenance of addiction

- Self treatment
- Aware or unaware

Defining and identifying misuse, abuse and addiction

Aggravated by vague or misleading terms:

- *"drug seeking"*
- *"doctor shopping"*
- *"pseudo-addiction"*
- *"chemical coping"*
- *"dependence vs addiction"*
- Further confounded by *overlap* in presenting behaviors
- *Skewed perspective* may exaggerate sense of risk

Opinion: “everyone on chronic opioid therapy *is a little bit addicted…”*

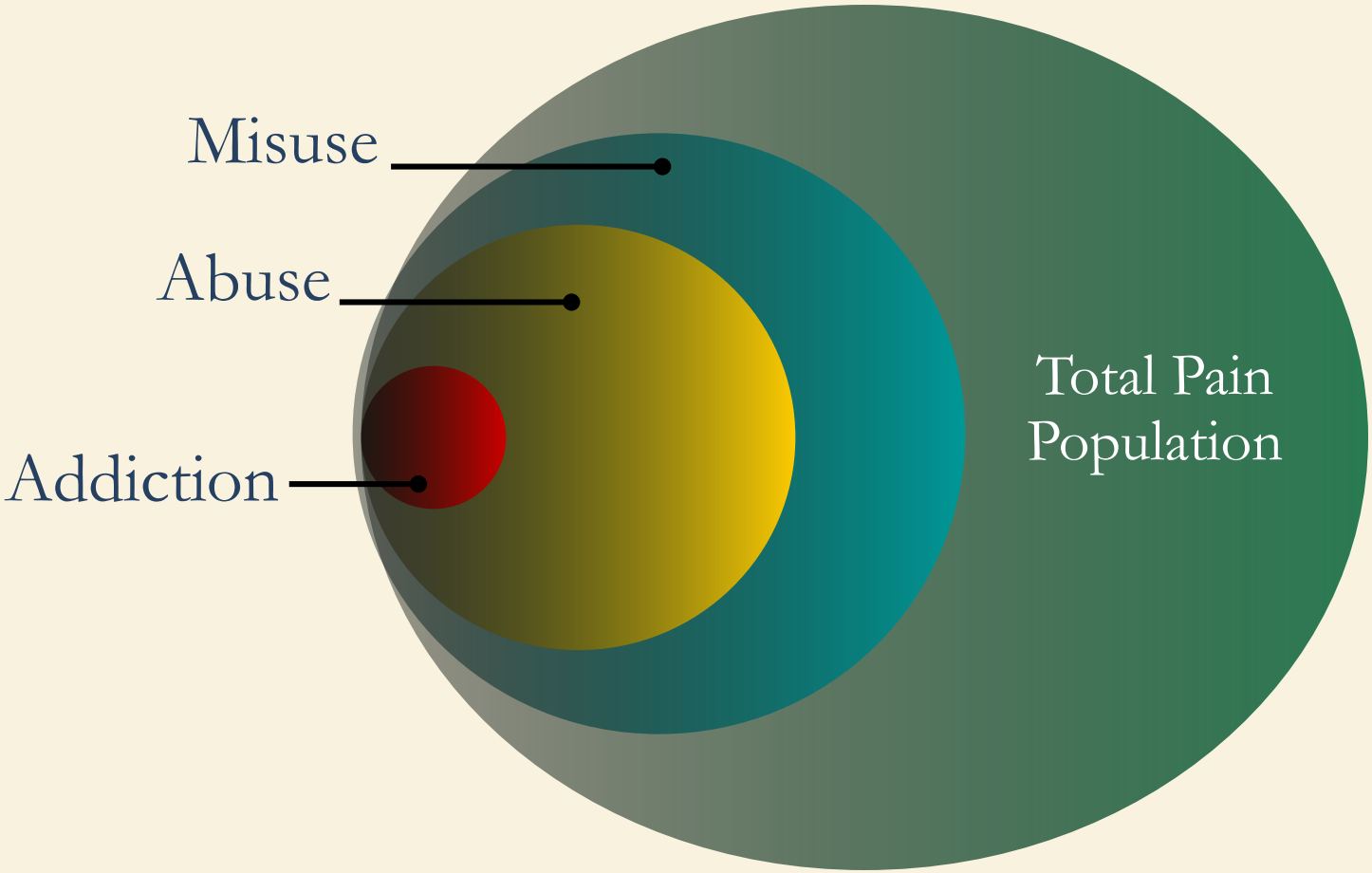
Physical dependence----

“Emotional dependence”

“Complex dependence”

----Addiction

Relative Prevalence of Misuse, Abuse, and Addiction



Webster LR, Webster RM. *Pain Med.* 2005;6(6):432-442.

Responding to aberrant medication related behaviors

Intervention appropriate to identified problem:

- *get curious, engage the patient, intervene*
- *not playing "gotcha"*

Intervention *based on level of risk* and concern for safety:

- *educating/clear limits/no surprises*
- *trust but responsibility*

Likely may involve *changing* the treatment plan:

- *increasing frequency or intensity of monitoring*
- *referring for consultation or co-treatment*
- *stopping the medication*

Document!

Opioid Dependence/Addiction: *Treatment Alternatives*

Refer for taper or detox: outpatient or inpatient

- Inpatient if needed for safety or structure
- Increased treatment and monitoring if outpatient tapering

Refer for substitution therapy with *methadone* (opioid treatment program…**not** office-based)

Refer or transfer to *buprenorphine/naloxone* (office-based)

Tools and Resources for Clinicians

- PCSS-O (www.pcss-o.org) PCSS-MAT (www.pcssmat.org)

- Boston University SCOPE of Pain (REMS trainings)

  www.scopeofpain.com

  www.opioidprescribing.com

- Web-sites with tools/protocols:

  Example: Institute for Clinical Systems Improvement (ICSI)

  https://www.icsi.org/_asset/bw798b/ChronicPain.pdf

  Example: Washington State Agency Medical Directors Group (AMDG)

  http://www.agencymeddirectors.wa.gov

Naloxone (*Narcan*) Rescue Kits: Prescribe for Patients at *Increased Risk*

Chronic pain populations:

- During induction (particularly long acting: eg: methadone)
- Those on higher doses (eg: >100 MME)
- Those on benzodiazepines
- If demonstrating other risk behaviors: alcohol or benzo abuse, illicit drug use
- If unstable co-morbidities present:
  - psychiatric, interpersonal
  - medical (e.g. COPD, sleep apnea)

Risks of naloxone rescue:

- Severe withdrawal symptoms and agitation.
- Recurrent overdose as wears off
- Always call 911!

Naloxone Resources

Education materials (communities, patients, families)

Resources for clinicians (protocols, forms, ordering kits):

- Project Lazarus

  http://www.projectlazarus.org/naloxone-od-antidote

- SAMHSA Toolkit

  http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742