Optimizing Opioids Reducing Risk in Pain Management

Roman D. Jovey, MD

Learning Objectives

1. Assess and risk stratify patients with chronic pain for opioid therapy
2. Manage common opioid related side effects
3. Prescribe and monitor opioid therapy using Universal Precautions / Canadian Opioid Guidelines
4. Document key outcome measures to demonstrate benefit

Conflict of Interest Disclosure Dr. Roman D. Jovey

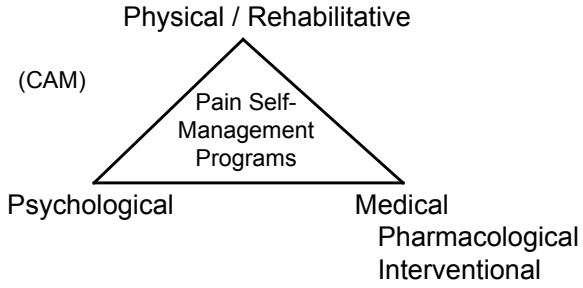
Program Title: Optimizing Opioids Reducing Risk

- Grants/Research Support: none
- Speakers Bureau/Honoraria/ Consulting Fees:
- Astra-Zeneca, Bayer, Biovail, Boehringer-Ingelheim, GlaxoSmithKline, Janssen, King, Lilly, Medical Futures Inc, Merck-Frost, Mundipharma, Nycomed, Palladin, Pfizer, Purdue-Pharma, Sanofi-Aventis, Tribute Pharma, Valeant, Wyeth

Ralph: Back in your office

- complaining of insomnia / depressed mood
- severe low back pain that radiates up his back as well as part way down his right leg
- his wife is getting on his case - unable to do his household chores
- trouble meeting their monthly expenses (stress!)
- requesting something stronger for the pain and an MRI of his back
- a buddy had surgery for a “slipped disc” and is better
  - he also wants a referral to his buddy’s surgeon

Best Practice Treatment for Chronic Pain



Opioids can be effective pain relievers at least for some types of chronic pain in some people for some period of time…

Unanswered Questions: Opioids

In which patients will opioids work?

…..for how long?

- Tolerance vs. hyperalgesia

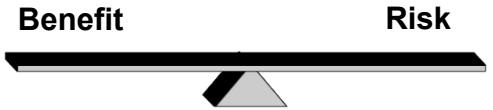
…..with what long-term side effects?

- Hormonal
- Sleep apnea

…..with what risks?

- Misuse / addiction
- Overdose deaths

The Pain Management Challenge



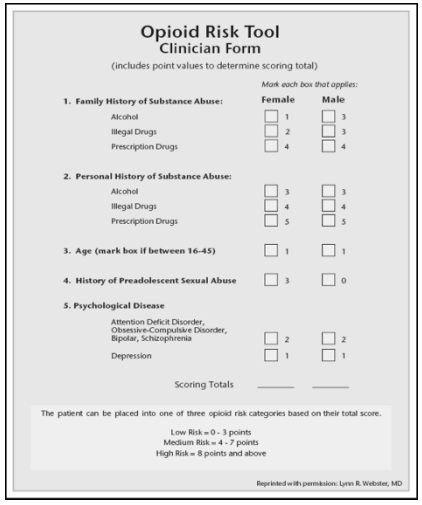
Patient-Centred Care

1. Screening and Risk Stratification

Know your patient

Screening for Opioid Misuse Risk

- Initial Screening Questions:
  - **Ask** in a routine, straightforward manner
  - Ask about number of drinks per day and per week and sedative use
  - CAGE, SOAPP-R, **Opioid Risk Tool**



Opioid Risk Tool
Clinician Form

(includes point values to determine scoring total)

	Mark each box that applies: Female	Male
1. Family History of Substance Abuse:		
Alcohol	1	3
Illegal Drugs	2	3
Prescription Drugs	4	4
2. Personal History of Substance Abuse:		
Alcohol	3	3
Illegal Drugs	4	4
Prescription Drugs	5	5
3. Age (mark box if between 16-45)	1	1
4. History of Preadolescent Sexual Abuse	3	0
5. Psychological Disease		
Attention Deficit Disorder, Obsessive-Compulsive Disorder, Bipolar, Schizophrenia	2	2
Depression	1	1
Scoring Totals	_____	_____

The patient can be placed into one of three opioid risk categories based on their total score.

Low Risk = 0 - 3 points
Medium Risk = 4 - 7 points
High Risk = 8 points and above

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Ralph– Risk Screening

- He admits he had a “wild” youth with drinking and heavy use of marijuana but settled down when he met his wife. Now occasional use of cannabis only on weekends (helps the pain) No other street drug use.
- His father and 2 paternal uncles had alcohol problems.
- Drinks alcohol (max 6-8 beers over a weekend). No interference with life
- Smokes 1 PPD. 1st cigarette within 1⁄2 hour of waking up. He quit for 2 weeks once.

Ralph

Opioid Risk Tool
Clinician Form

(includes point values to determine scoring total)

	Female	Male
Mark each box that applies:		
1. Family History of Substance Abuse:		
Alcohol	☐ 1	☒ 3
Illegal Drugs	☐ 2	☐ 3
Prescription Drugs	☐ 4	☐ 4
2. Personal History of Substance Abuse:		
Alcohol	☐ 3	☐ 3
Illegal Drugs	☐ 4	☒ 4
Prescription Drugs	☐ 5	☐ 5
3. Age (mark box if between 16-45)	☐ 1	☒ 1
4. History of Preadolescent Sexual Abuse	☐ 3	☐ 0
5. Psychological Disease		
Attention Deficit Disorder, Obsessive-Compulsive Disorder, Bipolar, Schizophrenia	☐ 2	☐ 2
Depression	☐ 1	☐ 1
Scoring Totals	____	7

The patient can be placed into one of three opioid risk categories based on their total score.

Low Risk = 0 - 3 points
Medium Risk = 4 - 7 points
High Risk = 8 points or above

Reprinted with permission: Lynn R. Webster, MD

Screening for MH Disorders

- Screening for Anxiety
  1. Generalized Anxiety Disorder Score (GAD-7)
     Arch Intern Med. 2006;166:1092-1097
- Screening for Depression
  2. The Patient Health Questionnaire PHQ – 9
     http://www.depression-primarycare.org/
- Screening for Both
  3. Hospital Anxiety & Depression Scale HADs ⇦
     Acta Psychiatr Scand. 1983 Jun;67(6):361-70
     J Psychosom Res. 2002 Feb;52(2):69-77.

HADS

Please read each statement below and circle the number which best describes how true the feeling is for you.

	Yes definitely	Yes sometimes	No, not much	No, not at all
1. I wake early and then sleep badly for the rest of the night.	(0)	2	1	0
2. I get very frightened or have panic feelings for apparently no reason at all.	3	2	1	(0)
3. I feel miserable and sad.	3	(2)	1	0
4. I feel anxious when I go out of the house on my own.	3	2	1	(0)
5. I have lost interest in things.	(0)	2	1	0
6. I get palpitations, or sensations of 'butterflies' in my stomach or chest.	3	2	1	(0)
7. I have a good appetite.	(0)	1	2	3
8. I feel scared or frightened.	3	2	(1)	0
9. I feel life is not worth living.	3	2	1	(0)
10. I still enjoy the things I used to.	0	1	2	(3)
11. I am restless and can't keep still.	(3)	2	1	0
12. I am more irritable than usual.	(3)	2	1	0
13. I feel as if I have slowed down.	3	(2)	1	0
14. Worrying thoughts constantly go through my mind.	3	(2)	1	0

Anxiety: 2,4,6,8,11,12,14 total= ____ Depression: 1,3,5,7,9,10,13 total= ____
Scoring: 0-7 = non-case; 8-10 = borderline case; >11= definite case
Zigmond AS, Snaith RP. Acta Psychiatr Scand. 1983;67(6):361-70.

A= 9
D= 13

Primary Care Triage of Patients With Chronic Pain

- **Group III Tx by specialist or Primary Care (with a lot of help)**
  - Active addictive disorder, Hx of opioid addiction
  - Major untreated psychiatric disorder
- **Group II Tx by Primary Care (with some help)**
  - Increased risk patient, in recovery, positive family Hx
  - No active addictive disorder; No major untreated psychiatric disorder
- **Group I Tx by Primary Care (without help)**
  - Lack major psychiatric comorbidity
  - No history of substance related problems

Adapted from Gourlay D. & Heit H. Pain Med 2005

2. Manage Side Effects

Optimize Outcome

Chronic Opioid Side Effects

- Constipation
- Sedation during titration (driving, work)
- Pruritis/sweats
- Dry mouth
- GE reflux symptoms

Stable dose, scheduled, titrated, long-term opioid therapy should not cause clinically significant cognitive impairment

- Hendler N. et al. Amer J Psychiatr 1980
- Zacny JP. Exp Clin Psychopharmacol 1995
- Vainio A. et al. Lancet 1996
- Zacny JP. Addiction 1996
- Lorenz J. et. al. Pain 1997
- Haythornthwaite JA, et al. JPSM 1998
- Sjogren P,et al. Pain; 2000
- Galski T, et al. JPSM 2000
- Chapman S. Clin J Pain 2002
- Sabatowski R. et al. JPSM 2003
- Tassain V. et al. Pain; 2003
- Fishbain DA. et al. JPSM 2003
- Menefee, Pain Med 2004

REVIEW ARTICLE

Systematic Review of the Quality and Generalizability of Studies on the Effects of Opioids on Driving and Cognitive/Psychomotor Performance

Angela Mailis-Gagnon, MD, MSc, FRCPC (PhysMed),†‡ Shehnaz Fatima Lakha, MSc,*† Andrea Furlan, MD, PhD,†§| Keith Nicholson, PhD,*† Balaji Yegneswaran, MD,* and Rainer Sabatowski, MD¶*

Interpretation: The commonly held concept that "chronic pain patients on stable opioids are safe to drive" cannot be generalized to all such patients in everyday practice, but may be applicable only to a subset who meet certain criteria.

Mailis-Gagnon, et al. Clin J Pain 2012; 28(6): 542-555

Systematic Review of Studies on Opioids and Driving

Probably safe to drive:

1. No other meds / substance use
2. Do not have high levels of pain
3. Lack a substantial sleep disorder
4. Do not have sig. depression or anxiety

Mailis-Gagnon A. et al. Clin J Pain 2012; 28(6):542-555

Driver Assessment-Medical Conditions

- DriveABLE: www.driveable.com
- DriveLab Inc: www.wrigroup.ca

Chronic Opioid Side Effects – "New"

- Hormonal effects
- Sleep apnea → ?CVS disease?
- Opioid induced hyperalgesia
- Immune dysfunction ??

When the side effects are greater than the benefit → switch opioids

Every patient responds uniquely to each opioid molecule.

Switching Opioids – Abrupt Switch*

1. Use opioid tables to calculate a total daily equianalgesic dose of the new opioid
2. Switch to 50-60% of the predicted dose of the new opioid and titrate to effect again
3. Provide adequate IR opioid to manage withdrawal or pain flare

*Opioid switching worksheet available on the Canadian Opioid Guideline website and in the Opioid Manager App

Equianalgesic Doses for Chronic Dosing*

MEDICATION	P.O. DOSE
Morphine	30 mg
Codeine	200-300 mg
Tapentadol	100 mg
Oxycodone	20 mg
Hydromorphone	6 mg
Fentanyl 12 mcg/hr	~30mg oral morphine/24hr
Buprenorphine 15ug/hr	~30mg oral morphine/ 24hr

* These are general guidelines only

* Studies done in healthy volunteers, or post-op

*Adapted from *Opioid Manager*, *Courtesy of: "Toronto Rehabilitation Institute" Tapentadol product monograph

Pain Medicine 2012; 13: 571–574
Wiley Periodicals, Inc.

Case Report

Overdose Deaths Demand a New Paradigm for Opioid Rotation

Lynn R. Webster, MD,* and Perry G. Fine, MD†

Webster and Fine. Pain Medicine 2012; 13: 571-74

"A New Paradigm for Opioid Rotation"

1. Decrease the the total dose of the old CR opioid 10-30% while starting the new CR opioid at the lowest dose for the formulation
2. Decrease the total daily dose of the old CR opioid 10-25% per week while titrating the dose of the new CR opioid weekly by 10-20% with a goal of switching over 3-4 weeks
3. Provide adequate IR opioid to manage withdrawal or increased pain

Webster and Fine. Pain Medicine April 2012

Canadian Opioid Guidelines R17 Elderly Patients

- Opioid therapy for elderly patients can be safe and effective (Grade B) with appropriate precautions, including lower starting doses, slower titration, longer dosing interval, more frequent monitoring, and tapering of benzodiazepines (Grade C)

Available at: http://nationalpaincentre.mcmaster.ca/opioid/

29


Clinical Review & Education

Care of the Aging Patient: From Evidence to Action

Management of Persistent Pain in the Older Patient
A Clinical Review

Una E. Makris, MD; Robert C. Abrams, MD; Barry Gurland, FRCPhysicians, FRCPsychiatry; M. Carrington Reid, MD, PhD

- Optimize physical and psychological treatments
- Use complementary medication combinations
- A trial of acetaminophen
- Avoid long-term NSAIDs
- Trial of SNRIs or SSRIs when depression present
- Trial of opioids when 1st line treatments fail

JAMA 2014; 312(8):825-836

Opioids for the Older / Fragile Patient

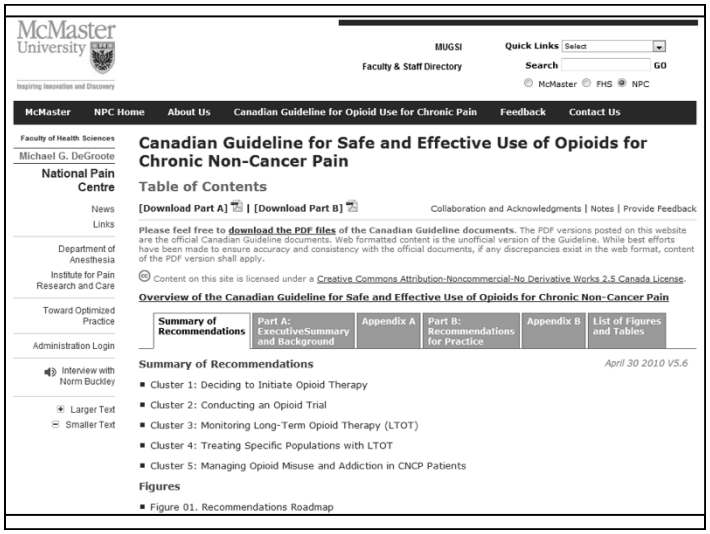
START LOW

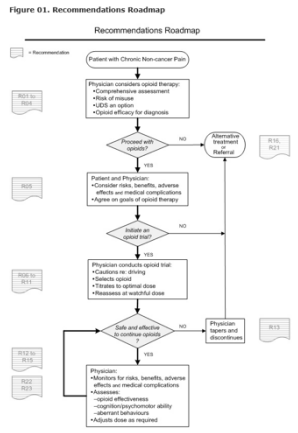
GO SLOW

MONITER CAREFULLY

3. Prescribe Safely

Reduce Risks





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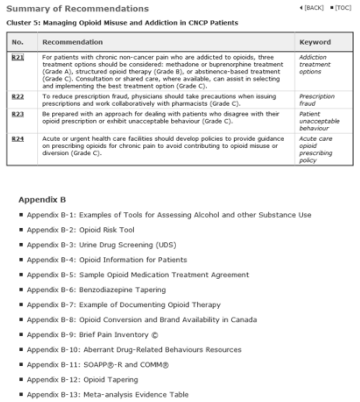
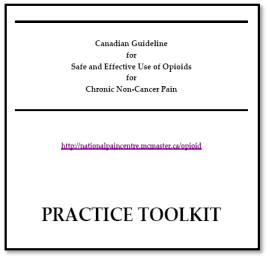


The Canadian Opioid Guidelines

- Practice Toolkit:
  - Opioid Manager*
  - Recommendations Roadmap
  - Recommendation Highlights
  - List of Recommendations
  - Tools to Use Before You Prescribe Opioids
  - Tools to Select the Right Opioid and Titrate Effectively
  - Tools to Monitor for Safety and Effectiveness
  - Opioid Tapering

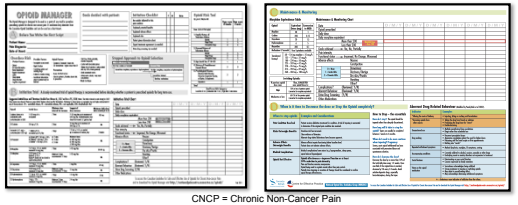


Practice Tool Kit Available at: http://nationalpaincentre.mcmaster.ca/opioid/

35

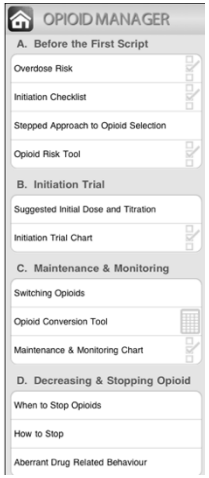
The Opioid Manager

- Is designed to be used as a point of care tool for providers prescribing opioids for CNCP
- It condenses key elements from the Canadian Opioid Guideline and can be used as a chart insert
- Revised February 2011



CNCP = Chronic Non-Cancer Pain
*Courtesy of: "Toronto Rehabilitation Institute" Available at: http://nationalpaincentre.mcmaster.ca/opioid/

36



App Availability:
- Android
- Apple iTunes

EMRs:
- Accuro (Optimed)
- Microquest
- MOIS
- OSCAR
- Practice Solutions
- Xwave
- York-Med

37

200 mg morphine equivalent = "watchful dose"

www.nationalpaincentre.mcmaster.ca/opioid/

Conducting an Opioid Trial – Watchful Dose

R10 Recommendation Statement

Chronic non-cancer pain can be managed effectively in most patients with dosages at or below 200 mg/day of morphine or equivalent (Grade A).

Consideration of higher dosage requires careful reassessment of the pain and of risk for misuse, and frequent monitoring with evidence of improved patient outcomes (Grade C).

39

Adapted from: http://nationalpaincentre.mcmaster.ca/opioid/

"Watchful Dose"

Considerations before titrating dose
>200 mg/day of morphine equivalent (ME)

- Is the pain diagnosis correct?
- Is the pain problem responsive to opioids?
- What is the patient's risk of misuse?
- Is further investigation and/or consultation required?
- Are non-opioid treatment options available?
- Is there an inadequately treated concurrent mental health disorder?

Prescribe all opioids
at all doses
with consideration and care

Written Treatment Agreements

- Low cost, low tech strategy
- Helps to demonstrate informed consent
- Effective boundary setting tool
- Must be readable, reasonable and have some flexibility

Fishman S. 1999, 2000, 2002

Wallace LS et al. Jour of Pain, 2007; 8(10):759-766

Urine Drug Testing

- Only small % of FDs in Canada include this as part of pain management
- Not funded in all provinces, technology varies
- Confusion re: interpretation of results
- Limitations using urine as a test substance
  - UDT "games" → ? Saliva drug testing

Incorporating Risk Level into Pain Management

Group III – Co-management with specialist (if available)
Written agreement, random UDTs 1-2x per month, pill counts
Exhaust all other options before considering opioids
Dispensing daily → weekly, choose opioids carefully

Group II – Tx by Primary Care with consultation (if available)
More assessment and focus on functional goals
Written agreement, UDT 3-4x per year, collateral information
Follow-up monthly, dispense q 2 wks, choose opioids carefully

Group I – Treatment by Primary Care
Utilize all Tx options, including opioids, focus on S/E
Verbal or written agreement, UDT 1-2x per year
F/U q 2-3 months, meds dispensed q 4 weeks

What to do with a +ve UDT

- FIRST – confirm the results
- Discuss with pt – ask re: addiction problem
  - Offer to refer for help
- Tighten boundaries
  - More frequent dispensing (1-2x weekly prn)
  - Decrease or D/C break through meds
  - More frequent random UDTs
  - Collateral information
- If persists, taper off of opioids

Opioids are not a panacea for all pains in all patients

There is always an individual

risk / benefit ratio

When to Stop Opioid Therapy

- No meaningful pain relief
- Persistent adverse effects

  ? Opioid hyperalgesia
- Does not achieve therapeutic goals, <u>even with effective pain relief</u>
  - ie. improved physical or social functioning

Ballantyne JC *et al*, 2003; Benyamin R *et al*, 2008; Chou R *et al*, 2009; Porreca F *et al*,2009; Slatkin NE, 2009

When to Stop Opioid Therapy

- Not cooperating with treatment plan
- Persistent out-of-bounds behaviours
  - unable to follow the treatment agreement
- Is diagnosed with an addiction disorder and refuses referral for treatment

Ballantyne JC *et al*, 2003; Benyamin R *et al*, 2008; Chou R *et al*, 2009; Porreca F *et al*,2009; Slatkin NE, 2009

Don't abandon your patient simply because of opioid-related behaviours…

…but you can abandon a treatment that is not helping

Tapering a patient off of opioids because of repeated ADRBs

- "I am sorry, I can no longer safely Rx opioids from this office for your problem."
- "I am going to taper you off of the opioids over the next __ days or weeks, but I am still willing to work with you on other treatments."
- "The only place I think that you can safely obtain opioids at this time is a methadone program. I will be happy to refer you."

Tapering Opioid Therapy

1. Discuss and document (with significant other?) :
   - Withdrawal is not dangerous
   - Typical withdrawal symptoms & time course
     hand-out
2. We may both be surprised that your pain is no worse or possibly even better
3. Discuss alternative treatment options
4. Careful with sedatives - withdrawal is more risky

Patients who are diverting or addicted may refuse to comply and leave your practice

Tapering Opioids

- Fast or slow
  - 10% per day, daily pharmacy dispensing
  - 10% q 1-2 weeks
- Use pharmacological aids
  - Clonidine, imodium, NSAID, nabilone, GPN, PGN
- Methadone (buprenorphine) taper
- Educating the patient is the most effective treatment!

Know info re: your local Methadone (Buprenorphine) Clinic

Safe Opioid Prescribing for All:

- One doctor, one pharmacist
- Tamper-evident or multiple copy pads
  - Keep Rx pads in your pocket
- Utilize Rx monitoring data where available
- Ask about the home milieu
- Limit the amount dispensed (part-fills)
- Discuss security of meds (lock them up!)

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56

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Fentanyl 'patch-for-patch' program growing in Ontario

CBC News Posted: May 12, 2015 8:05 AM ET | Last Updated: May 12, 2015 8:34 AM ET

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ONTARIO ASSOCIATION OF CHIEFS OF POLICE
OACP

PATCH4PATCH INITIATIVE

Fentanyl Abuse Prevention – A Shared Responsibility
Ontario Association of Chiefs of Police – Substance Abuse Committee 2014

THE GLOBE AND MAIL

New opioid standards to tackle widespread, serious abuse in Canada

KELLY GRANT
HEALTH REPORTER — The Globe and Mail
Published Monday, Jul. 07 2014, 2:00 AM EDT
Last updated Monday, Jul. 07 2014, 6:30 AM EDT

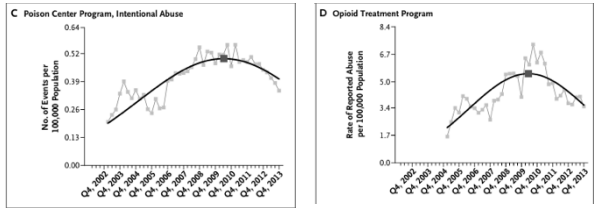
In a bid to curb Canada's widespread prescription-drug abuse problem, Ottawa is moving to force the makers of all opioids – not just the well-known painkiller oxycodone – to render their products resistant to crushing, snorting or injecting for a quick high.

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

Trends in Opioid Analgesic Abuse and Mortality in the United States

Richard C. Dart, M.D., Ph.D., Hilary L. Surratt, Ph.D., Theodore J. Cicero, Ph.D., Mark W. Parrino, M.P.A., S. Geoff Severtson, Ph.D., Becki Bucher-Bartelson, Ph.D., and Jody L. Green, Ph.D.



Dart R.C. et al. NEJM 2015;372(3):241-248

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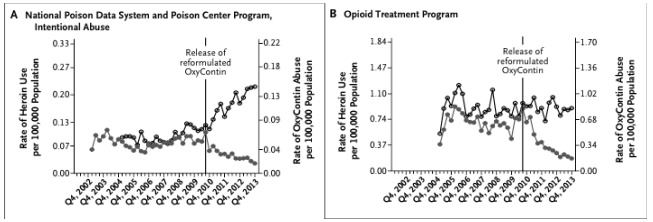


Dart R.C. et al. NEJM 2015;372(3):241-248

For every complex problem there is a simple solution…

…and it is usually wrong.

H.L. Mencken

Management of Opioid Risk Is a "Package Deal"

- Multimodal approaches
- Screening & risk stratification
  - Rx agreements
- Use of online PMP data
- Adherence monitoring
  - Urine dug screening (?oral screening)
  - Pill/patch counts
- Education re safe drug storage & no sharing of meds
- Abuse-deterrent formulations

PMP=Prescription Monitoring Programs

Adapted from Passik, 2008

4. Document Effectively

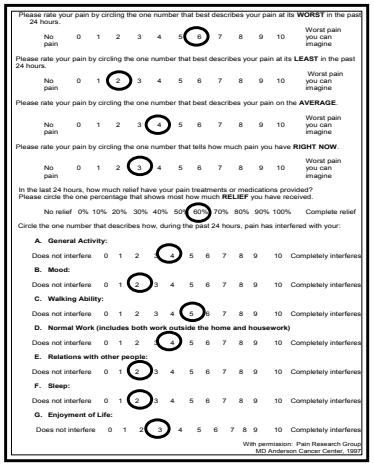
Demonstrate Positive Outcomes

Ralph– Follow-Up

- Physio for flexibility and core work
- Seen by the psychologist who used ACT to help him develop coping strategies
- TrPt injections weekly x 6
- Tried TCAs then Duloxetine – could not tolerate S/E
- Tramadol → nausea and H/As ; Acetaminophen + Codeine → too constipating
- Started Bup TD at 5ug/hr titrated weekly to 20ug/hr with adequate relief and mild constipation – managed diet
- WSIB agreed to fund a work-hardening program with a goal of gradual return to work
- Eventually agreed to reduce / taper his opioid

BPI Ralph: Follow-up Visit

Now		Initially
6/10	Please rate your pain by circling the one number that best describes your pain at its **WORST** in the past 24 hours.	8/10
2/10	Please rate your pain by circling the one number that best describes your pain at its **LEAST** in the past 24 hours.	6/10
4/10	Please rate your pain by circling the one number that best describes your pain on the **AVERAGE**.	7/10
3/10	Please rate your pain by circling the one number that tells how much pain you have **RIGHT NOW**.	7/10
60%	In the last 24 hours, how much relief have your pain treatments or medications provided? Please circle the one percentage that shows most how much **RELIEF** you have received.	10%
22/70	Circle the one number that describes how, during the past 24 hours, pain has interfered with your:	52/70



Essential Follow-up Documentation The "6A s"

1. **A**nalgesia (pain relief) ☑
2. **A**ctivities (physical and psychosocial functioning) ☑
3. **A**dverse Effects (and your advice) ☑
4. **A**mbiguous Drug Taking Behaviours (and your response) ☑
5. **A**ccurate medication record ☑
6. **A**ffect ☑

Jovey R. et al. Managing Pain. 2002 p. 121
Gourlay DL, Heit HA, Almahrezi A. Universal precautions in pain medicine: A rational approach to the treatment of chronic pain. Pain Medicine 2005;6:107-112.

Pain Management Goals

- Decrease pain
- Improve function
  - Physical
  - Psychological
  - Social
- Minimize risk
  - Patient
  - Physician
  - Society

drjovey@bell.net