

NDARC

National Drug &
Alcohol Research Centre

The Difference is Research

CESPHN Webinar

Using opioid agonist treatment for pharmaceutical opioid dependence



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University

Acknowledgements

This webinar was produced for Central and Eastern Sydney Primary Health Network



Drug and Alcohol support for service providers

Central and Eastern Sydney PHN is funded to ensure an integrated regional approach to drug and alcohol services by developing evidence-based plans and service mapping that identify needs and gaps, increase efficiencies and encourage easier access to and increased referral pathways to drug and alcohol services and supports.

This website provides tools and resources to help you navigate the drug and alcohol treatment service sector and find assistance that supports your needs.



Learning objectives



1. Understand the prevalence of dependence to pharmaceutical opioids (PO)
2. Be familiar with the evidence for the use of opioid agonist treatments for PO dependence
3. Understand dose requirements for opioid agonists
4. Be familiar with safety considerations with the use of opioid agonist treatments

Introducing Olga

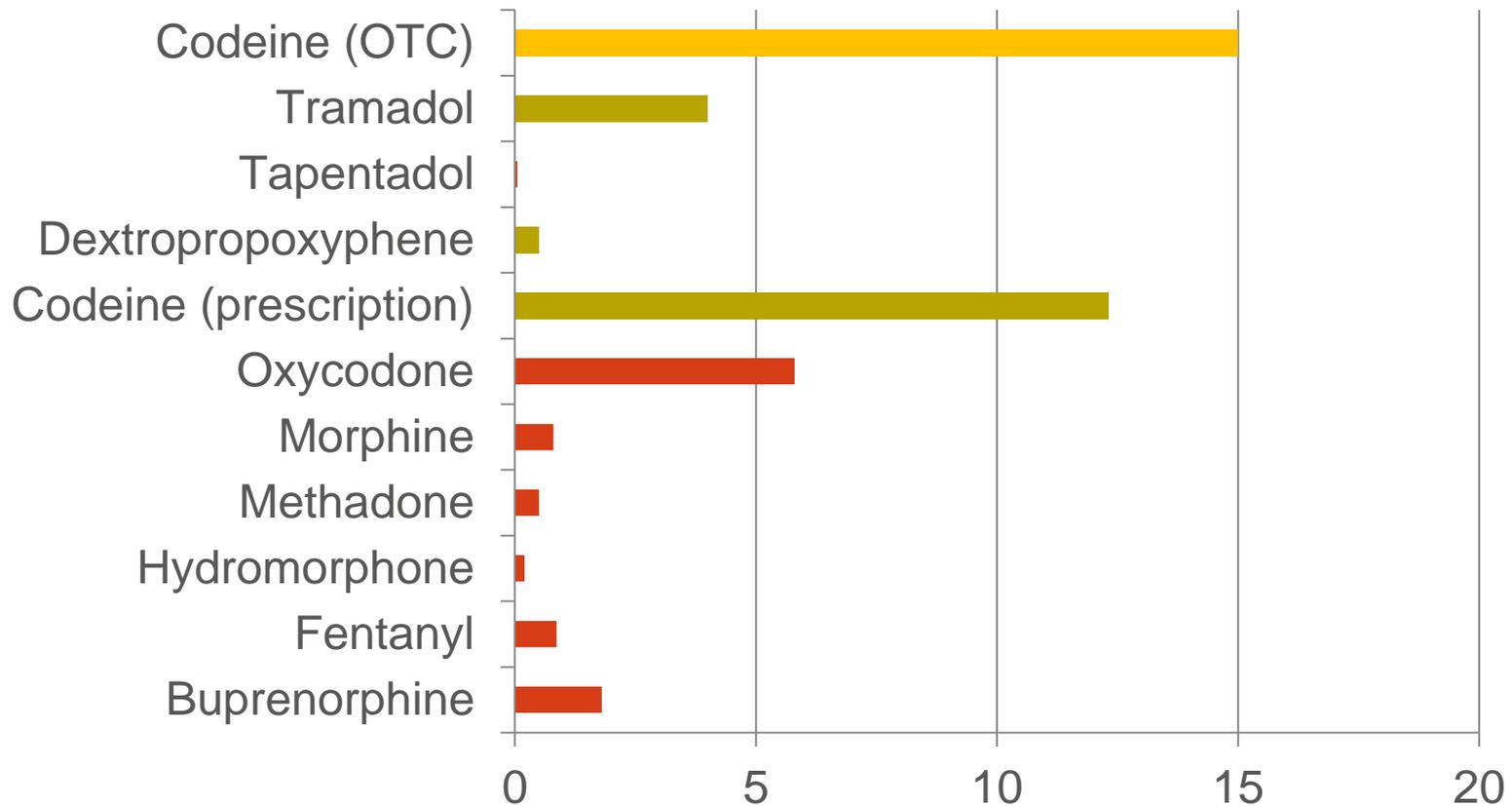


- Olga is a 49yo women with a 15 year history of codeine use (OTC and prescribed)
- Started using for headaches, increased to daily use within a few years
- Escalated during separation from partner
- Taking 45-60 tablets daily (mainly ibuprofen codeine) +/- paracetamol-codeine prescribed
- Recent duodenal haemorrhage and anaemia
- More difficulty accessing codeine (prescribed and OTC), has come to you asking for help

Prevalence of Dependence to Pharmaceutical Opioids



Most commonly used opioids in Australia



Opioid pack sales (in millions) from: Degenhardt, Gisev, Cama, Nielsen, Larance and Bruno. The extent and predictors of pharmaceutical opioid utilisation in Australia. *Pharmacoepidemiology and Drug Safety*. (2016)

Chronic pain and opioid use disorders

Systematic review: Rates of 'addiction' averaged between 8% and 12% (range, 95% CI: 3%-17%)

Pain and Opioids IN Treatment (POINT) cohort – Australian community-based cohort of people prescribed opioids for chronic pain

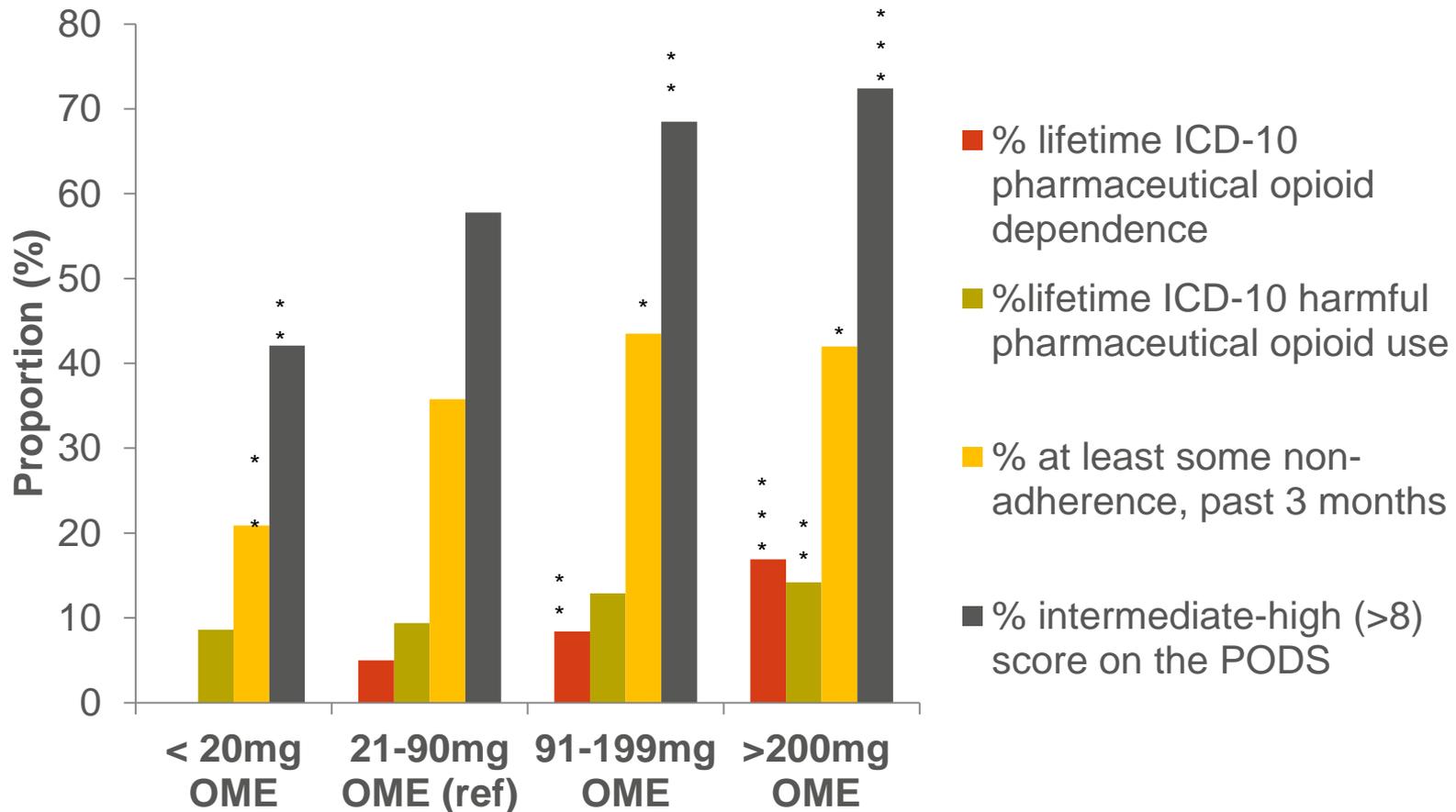
- One in four (24%) meet criteria for 'addiction' '*behaviour including one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and cravings*'
- One in five (18.6%) met lifetime criteria for ICD-10 PO use disorder
- Almost one in ten (9%) meet criteria for ICD-10 PO dependence (19% meet ICD-11 definition for dependence)

Vowles, McEntee, Julnes et al (2015). Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis. *Pain*, 156(4), 569-576.

Campbell, Nielsen, Larance et al (2015). Pharmaceutical opioid use and dependence among people living with chronic pain: Associations observed within the Pain and Opioids IN Treatment (POINT) cohort. *Pain medicine*, 16(9), 1745-1758.

Campbell, Bruno, Lintzeris, Cohen, Nielsen, Hall et al (2016). Defining problematic pharmaceutical opioid use among people prescribed opioids for chronic non-cancer pain: do different measures identify the same patients? *Pain*. (In press)

Those on the highest doses report the most problems AND report less pain relief (compared to lower doses)



Campbell et al (2015). Correlates of pharmaceutical opioid use and dependence among people living with chronic pain: Findings from the Pain and Opioids IN Treatment (POINT) study. Pain Medicine

Banta-Green et al (2010). The Prescribed Opioids Difficulties Scale: A Patient-centered Assessment of Problems and Concerns. The Clinical Journal of Pain, 26(6), 489-497.

'Adverse selection'

- Those with the most complex histories, and therefore with the most risk factors, are prescribed the highest doses
 - Participants with better socio-economic status indicators (income and education, private health insurance, employment) were **less** likely to be on longer-term opioid analgesic treatment
 - Those with poorer health (smoking, obesity and low physical activity levels) were **more** likely to receive subsequent opioid analgesic treatment.
 - Those with mental health problems and substance use disorders **more** likely to receive opioids for pain

Rogers, Kemp, McLachlan and Blyth. Adverse selection? A multi-dimensional profile of people dispensed opioid analgesics for persistent non-cancer pain. PloS one. 2013; 8:e80095.

Edlund, M. J., Martin, B. C., Devries, A., Fan, M.-Y., Braden, J. B., & Sullivan, M. D. (2010). Trends in use of opioids for chronic non-cancer pain among individuals with mental health and substance use disorders: the TROUP study. The Clinical Journal of Pain, 26(1), 1-8.

Over-the-counter codeine dependence

- Different studies (convenience samples) find approximately one in five people using OTC codeine meet dependence criteria
- No difference on demographic characteristics (age, gender, employment, education) between those that met criteria for dependence and those that do not
- Those meeting dependence criteria *more* likely to have chronic pain, psychological distress and a history of AOD problems
 - Note – most (58%) people meeting criteria of AOD problems did not have an AOD history
- Most people (75%) that met criteria for dependence had never sought any help

Nielsen, Cameron & Lee (2011) Characteristics of a non-treatment seeking sample of over-the-counter codeine users: Implications for intervention and prevention. *Journal of Opioid Management.*; 7 (5) 636-370

McCoy, Bruno and Nielsen (2017) Attitudes in Australia on the upscheduling of over-the-counter codeine to a prescription-only medication. *Drug and Alcohol Review* (In Press).

Pharmaceutical opioid dependence: Increasing treatment demand

- One in three* people in OST (*where opioid type reported) report a PO as the main drug at treatment entry



- Among people entering OST (methadone and buprenorphine+/- naloxone) increasing numbers report codeine as the main drug
 - 2014 – 2.7% of cases (1287 people)
 - 2015 – 3.5% of cases (1676 people)
 - 2016 – 4.6% of cases (1562 people*)

* missing data from Vic and ACT means actual number likely to be higher (>2000)

Australian Institute of Health and Welfare. (2016). National opioid pharmacotherapy statistics 2015. Canberra: AIHW.

Nielsen et al (2015). Changes in non-opioid substitution treatment episodes for pharmaceutical opioids and heroin from 2002 to 2011. Drug and Alcohol Dependence, 149, 212-219.

What is opioid dependence?



Different definitions: DSM IV-TR

≥ 3 occurring at any time in the same 12 month period:

1. Tolerance
2. Withdrawal
3. Opioids taken in larger amounts or longer than intended.
4. Persistent desire or unsuccessful attempts to cut down or control use.
5. A great deal of time is spent in activities necessary to obtain opioids, use opioids, or recover from their effects.
6. Important social, occupational, or recreational activities are given up or reduced because of opioid use.
7. Opioid use is continued despite knowledge of harms caused or exacerbated by opioids.

Substance use disorder (DSM-5)

Also considers craving, persistent social problems from use, use in hazardous situations

Severity depends on # of symptom criteria endorsed

Mild: 2-3 symptoms

Moderate: 4-5 symptoms

Severe: 6 or more symptoms

Definitions of opioid dependence ICD-10 (3 or more in 12 months)

Criteria include:

- developing tolerance
- experiencing withdrawal symptoms
- taking more opioids than intended
- unsuccessful attempts to cut-down use
- spending a lot of time obtaining opioids and forgoing important activities because of opioid use
- continuing to use opioids despite knowing the harmful effects

Characteristics of people who are dependent on pharmaceutical opioids

Codeine dependence (summary)

- Higher proportions of females (50-80%)
 - Increasing numbers of young makes seeking treatment
- More commonly employed
- Often commenced for an acute pain condition
- Ongoing use often driven by psychosocial stressors
- Some patients with history of alcohol / benzodiazepine use, less commonly illicit drug use
- Differing use patterns (e.g. high dose, therapeutic dependence)
- Commonly identified secondary to severe harm from taking large doses of ibuprofen and paracetamol

Dependence on prescribed opioids

Chronic Pain cohort

10-25% 'addicted'/dependent

Rarely report non-medical sources

Virtually no heroin use or history of injection

One in three report BZD

One in three report alcohol use disorders

Half meet criteria for moderate to severe depression

One in five have attempted suicide

PO Treatment Cohort (NSW)

~40% report chronic pain

Two thirds report commencing pharmaceutical opioids for pain

4 in 10 report medical source for use when problems began

Around 6 in 10 report lifetime heroin use or history of injection

Most (80%) report trauma

Half meet criteria for moderate to severe depression

4 in 10 report moderate to severe anxiety

60% report suicidal thoughts

Treatment options



Opioid agonist treatment

OST will not be appropriate for all patients that experience problems with pharmaceutical opioids ..so which patients?



OST may be appropriate where:

- Confirmed opioid dependence (ICD-10)
- Attempts to manage opioids with other strategies failed (+/- taper unsuccessful)
- Risk of overdose / relapse
- Patient willing to consider OST

Why examine the evidence for pharmaceutical opioid dependence?

- Reasons to explore:
 - Most research using opioid agonist treatments examined people who use heroin
 - Important differences in co-morbidities (e.g. more severe pain and mental health) may impact on treatment outcomes
- Treatment needs and outcomes may not be assumed from research on people who are dependent on heroin

Methadone and buprenorphine

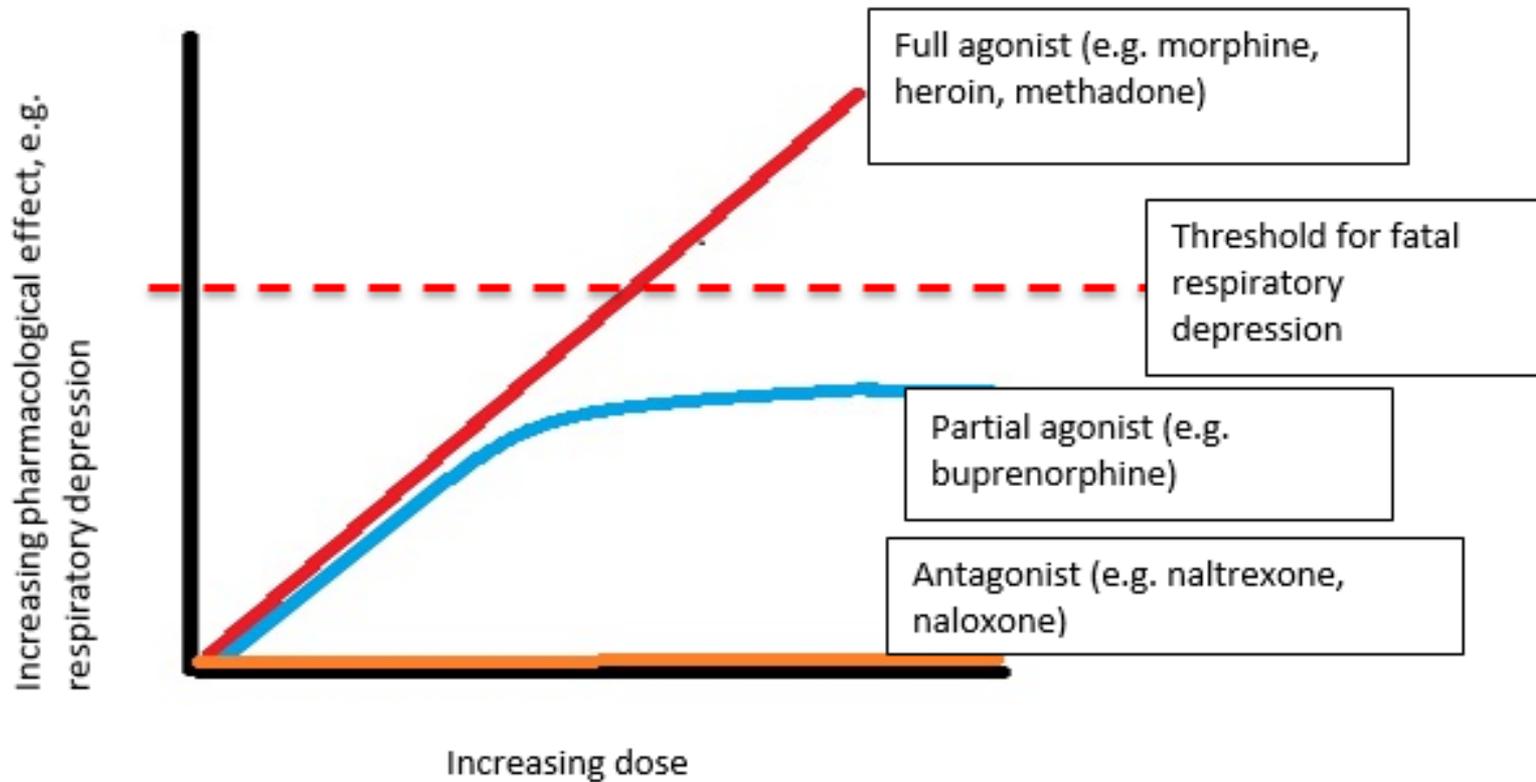
Methadone: oral liquid, full opioid agonist



Buprenorphine: usually combined with naloxone (to reduce injection), sublingual film or tablets, partial opioid agonist



Full and partial agonists



Evidence for taper (detox) v maintenance

Advantages of detoxification

- Entry point for treatment for those unwilling to enter long term treatment
- Shorter-term commitment (more flexible)

Disadvantages

- Typically low success rates e.g. PO dependence: 91-93% has 'unsuccessful outcome' with 2 or 12 weeks of treatment
- Not appropriate as standalone treatment
- Increased overdose risk

Gowing L, Ali R, Dunlop A, Farrell M, Lintzeris N. National Guidelines for Medication-Assisted Treatment of Opioid Dependence 2014.

Weiss R, et al. (2011) A Two-Phase Randomized Controlled Trial of Adjunctive Counseling during Brief and Extended Buprenorphine-Naloxone Treatment for Prescription Opioid Dependence. Arch Gen Psychiatry

Cochrane review: Taper versus maintenance

Retention and substance use outcomes are better with longer-term (i.e. maintenance treatments) compared to short-term taper or psychological interventions only

- Includes when substance use outcomes are measured with urine drug screens or self-report
- Based on three RCTs with 206 people

“Low quality evidence (small studies) suggests that most patients will have better outcomes with longer-term treatment”

Cochrane review: Methadone versus buprenorphine

Three RCTs, 360 patients

- No difference in retention outcomes
- No difference in substance use outcomes
- Other factors such as patient preference, safety and unsupervised dosing options may inform decision



Opioid agonist treatment for pharmaceutical opioid dependent people (Review)

Nielsen S, Larance B, Degenhardt L, Gowing L, Kehler C, Lintzeris N

Other aspects of treatment:

Induction

Dose

Predictors of treatment outcomes

Psychosocial treatment



Induction onto pharmacotherapy

Methadone

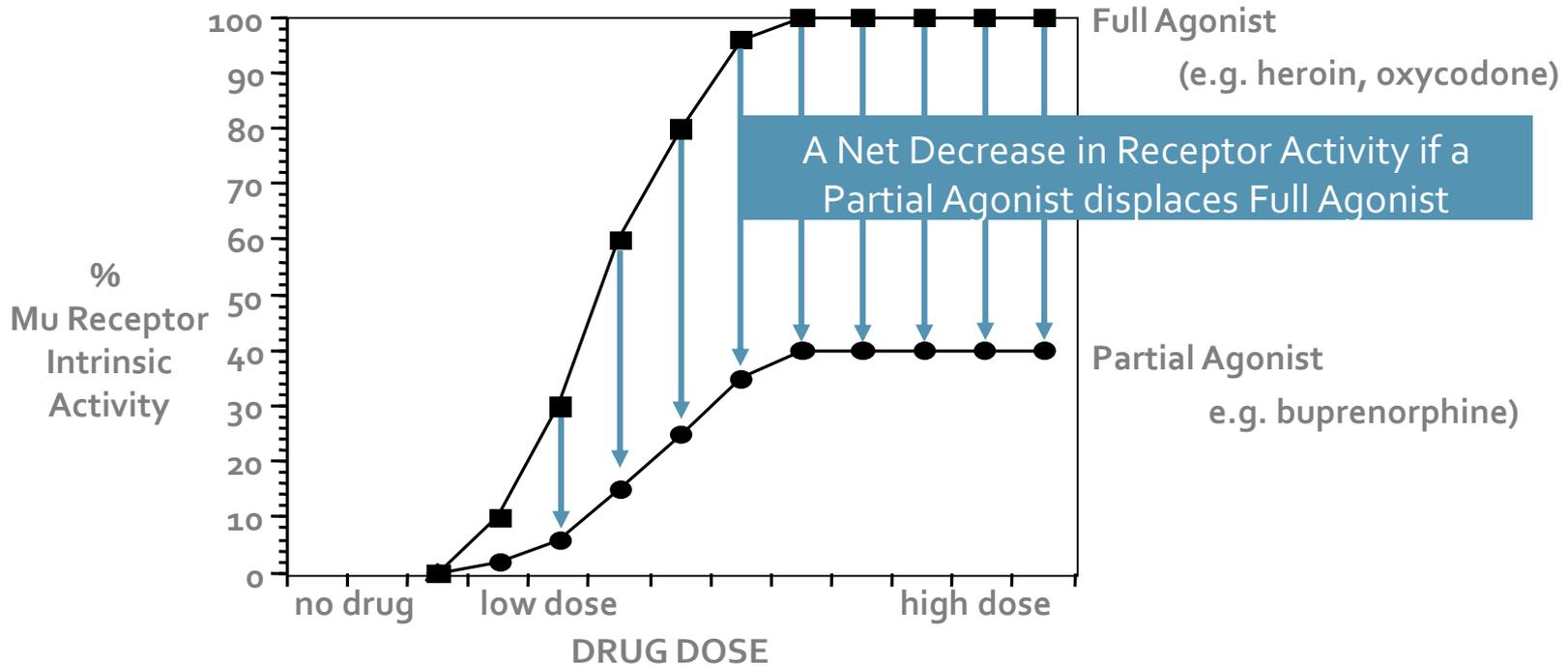
- 'Start low, go slow' – risk of toxicity, accumulation or misjudging level of neuroadaptation can lead to overdose
- Usually 20-30mg starting doses, never more than 40mg, lower doses with polydrug use or unclear level of dependence
- Monitor for sedation

Buprenorphine

- Less respiratory depression than with methadone
- Don't start until observable opioid withdrawal symptoms (sweating, dilated pupils, stomach cramps, muscle pain etc) – risk is with precipitated withdrawal
- Test dose of 2-4mg, additional dose if required after 1-2 hours

Precipitating Acute Withdrawal

- If buprenorphine is administered while opioids still active it may precipitate withdrawal when it displaces the full agonist off the mu receptors



Buprenorphine induction

Buprenorphine: Getting to the right dose and avoiding precipitated withdrawal

Studies examining occurrence of precipitated withdrawal found no difference between:

- pharmaceutical opioids and heroin
- different pharmaceutical opioids

Nb. These studies used standard protocols (i.e. start buprenorphine when in mild withdrawal, defined duration from last opioid dose until first buprenorphine dose)

→ Lower ratings of opioid withdrawal prior to buprenorphine was associated with greater risk of precipitated withdrawal

Nielsen S, et al. (2014) The relationship between primary prescription opioid and buprenorphine-naloxone induction outcomes in a prescription opioid dependent sample. The American Journal on Addictions.

Nielsen S, et al (2012) Comparing buprenorphine induction experience with heroin and prescription opioid users.

Buprenorphine treatment for codeine dependence

- Codeine is considered a 'weak' opioid
Standard induction procedures
- Dose requirements consistent with 'strong opioids' (12-16mg daily) (BPN patch insufficient)
- Considerable variation between patients

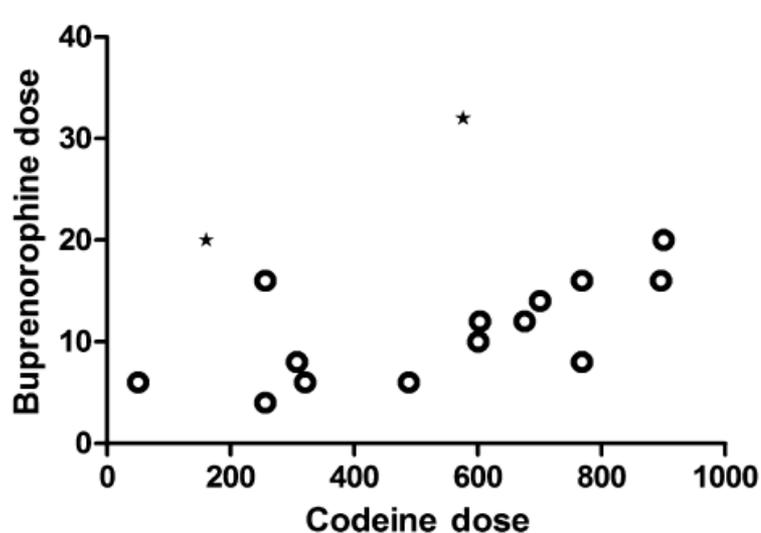
Treating codeine dependence with buprenorphine: Dose requirements and induction outcomes from a retrospective case series in New South Wales, Australia

SUZANNE NIELSEN^{1,2,3}, RAIMONDO BRUNO^{1,4}, BRIDIN MURNION², ADRIAN DUNLOP^{5,6},
LOUISA DEGENHARDT^{1,7,8,9}, APO DEMIRKOL^{3,10}, PETER MUHLEISEN² &
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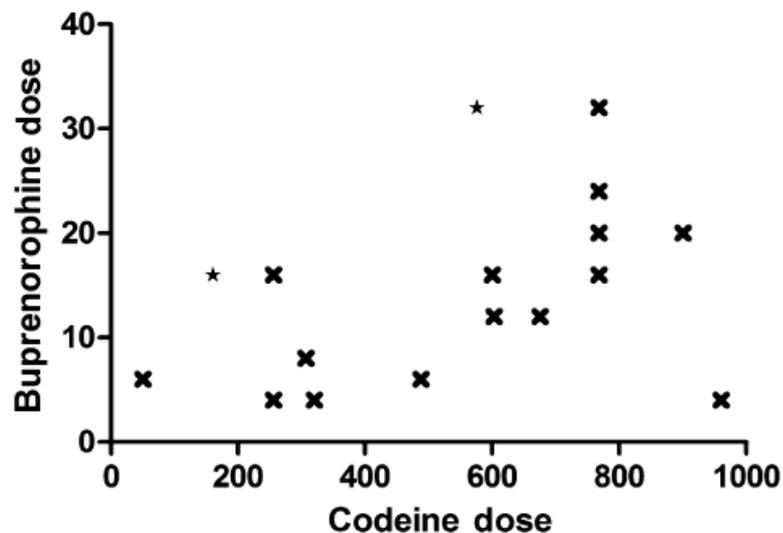


Buprenorphine dose: codeine dependence

Lots of individual variation = dose titration



a Buprenorphine dose day 7



b Buprenorphine dose day 28 of treatment



Drug and Alcohol Review (2015)
DOI: 10.1111/dar.12315

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Predictors of treatment outcomes: heroin use

In buprenorphine taper and long-term treatment studies

→ *Any heroin use* associated with poorer outcomes (more opioid use, poorer retention)

Weiss, et al. (2011) A Two-Phase Randomized Controlled Trial of Adjunctive Counseling during Brief and Extended Buprenorphine-Naloxone Treatment for Prescription Opioid Dependence. Arch Gen Psychiatry.

Nielsen, et al (2013) A comparison of buprenorphine taper outcomes between prescription opioid and heroin users. Journal of Addiction Medicine.

Nielsen et al (2015). Buprenorphine Pharmacotherapy and Behavioral Treatment: Comparison of Outcomes among Prescription Opioid Users, Heroin Users and Combination users. JSAT.

Predictors of treatment outcomes: pain

Mixed findings:

A study of 2 and 12 week buprenorphine treatment found no difference in outcome by pain status at baseline

A separate examined effect of pain on taper outcomes;

- Those with moderate to severe pain did better DURING treatment
- Those with pain had more self-reported use at follow-up (no difference in UDS)

*Note that these studies specifically excluded patients with significant pain that needed opioids for management

Buprenorphine for opioid dependence in patients with chronic pain

One small RCT showed both methadone and buprenorphine resulted in meaningful reductions in pain (patients with chronic pain and opioid dependence)

Open label, retrospective reports of patients transferring from full opioid agonists (e.g. oxycodone) to buprenorphine

- Reduced self-reported pain report after transfer to buprenorphine
- mean doses of 8–28 mg per day (dose frequency not reported)
- patients on high opioid doses (> 200 mg OME a day) show comparable or greater improvements in pain and quality of life after transfer

Psychosocial adjunct treatment with OAT

- Fewer studies overall have examined this, mixed findings → important area for more work (esp. for those with pain and dependence)
 - No difference between ‘extended counselling’ (45-60 minutes twice a week) to ‘standard medical management’ (15-20min weekly) in improving abstinence in PO dependent people prescribed buprenorphine
 - Later (smaller) study found PO dependent people may have better outcomes with psychosocial adjunct treatments (e.g. CBT), compared with those primarily using heroin in the same study
- In chronic pain treatment the role of CBT and other behavioural therapies well established

Weiss et al. (2011) A Two-Phase Randomized Controlled Trial of Adjunctive Counseling during Brief and Extended Buprenorphine-Naloxone Treatment for Prescription Opioid Dependence. Arch Gen Psychiatry.

Nielsen et al (2015). Buprenorphine Pharmacotherapy and Behavioral Treatment: Comparison of Outcomes among Prescription Opioid Users, Heroin Users and Combination users. Journal of Substance Abuse Treatment.

McCracken and Turk. Behavioural and cognitive-behavioural treatment for chronic pain: outcome, predictors of outcome and treatment process. Spine 2002.



Safety consideration with opioid agonist treatments

High-risk periods with opioid use

Induction onto treatment (first two weeks, especially with methadone)

Cessation of treatment

Change in tolerance (e.g. after a period of abstinence)

Change in health status

Periods of concomitant use of other sedatives (e.g. alcohol, benzodiazepines)

Identifying patients that may need additional support from specialist services

- Polysubstance use, unstable opioid use (i.e. presenting intoxicated)
- Unmanaged psychiatric comorbidity
- Diversion
- Chronic pain (significant pain despite stable opioid use)



Naloxone

Naloxone for chronic pain patients

Among chronic pain patients prescribed opioids:

- Most people prescribed opioids for chronic pain would expect, or appreciate being offered naloxone
- Most people prescribed opioids for chronic pain think take-home naloxone is a 'good' or 'very good' idea
- Most people prescribed opioids for chronic pain can not identify signs of opioid toxicity

Good opportunity to discuss risks with opioids and educate on safer use

Nielsen, S., et al. (2017). "Knowledge of Opioid Overdose and Attitudes to Supply of Take-Home Naloxone Among People with Chronic Noncancer Pain Prescribed Opioids." Pain medicine **In Press**.

Supplying naloxone

Check existing knowledge about recognising and responding to overdose:

- Opioid overdose can occur with heroin or prescription pain medication.
- Signs include lack of consciousness, blue/grey lips, no breathing or slow and laboured breathing/snoring, no response to sternum rub)

In case of suspected opioid overdose:

- Call an ambulance
- Administer naloxone immediately into the upper arm or thigh
- If person not breathing or laboured, slow breathing → place person on their back and start rescue breathing
- If person breathing: place them in recovery position and monitor the breathing
- Repeat naloxone dose after 2-5 minutes if not improved, or earlier if concerned (safer to give more)

Prenoxad



Overdose action plan



OPIOID OVERDOSE ACTION PLAN

How to respond to someone who has overdosed on heroin or other opioids

SIGNS OF OVERDOSE
Not responding
Shallow or no breathing
Blue lips or fingernails
Snoring or gurgling

YES →

to any of the signs above
proceed to the Action Plan

OVERDOSE ACTION PLAN

CHECK FOR DANGER

Uncapped needles, sharp objects, bystanders etc.
Make sure the environment is safe

CHECK FOR RESPONSE

Call the person's name. Shake their shoulders vigorously or rub their chest with your knuckles



If there is no response, or poor response,
SEND FOR HELP

Dial 000 and ask for an ambulance



CLEAR THE PERSON'S AIRWAY

Check their breathing

Watch for their chest rising
Look, listen and feel for 2 breaths in 10 seconds.



IF THEY ARE NOT BREATHING

or their breathing is slow or abnormal

Put them on their back, clear and open their airway, pinch their nose and give two rescue breaths

IF THEY ARE BREATHING NORMALLY

Put them in the recovery position and monitor them until help arrives



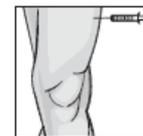
IF THEY ARE STILL NOT BREATHING

GIVE NALOXONE

Remove Naloxone mini-jet from package, unscrew the cap and screw on needle.



Inject the entire contents into muscle of the upper arm or thigh and even through clothing in an emergency.



L Note the time given,

Continue rescue breathing—
1 breath every 5 seconds

NALOXONE WON'T HARM A PERSON, AND IT MAY SAVE THEIR LIFE

IF THERE IS NO RESPONSE

Inject another dose of Naloxone in 2–5 minutes.

L Note the time given, continue rescue breathing

If you are worried give another dose at any time.

If the person is breathing normally, then put them in the recovery position and monitor them. Ensure that their airway is clear and open.

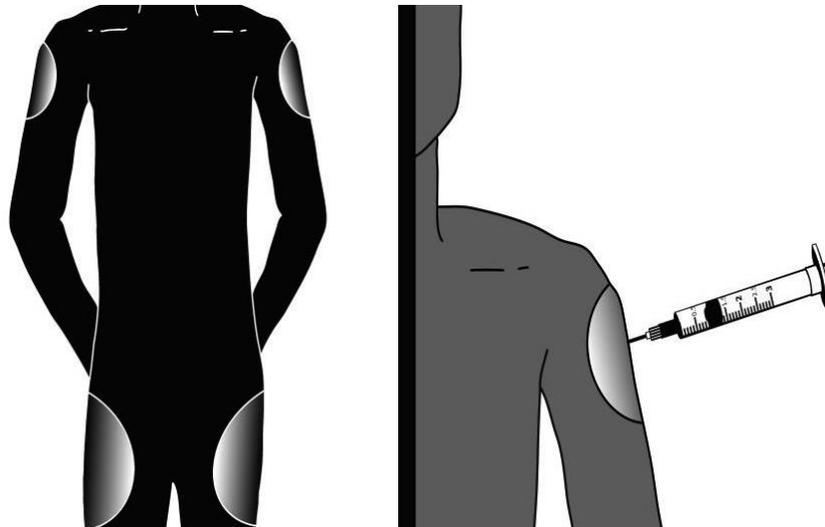
If still no response, commence CPR 30 compressions, then 2 breaths; repeat

Naloxone administration

Administer in the upper arm or outer thigh

OK to administer through clothes in an emergency

Naloxone has a shorter half-life than many opioids (e.g. heroin, methadone) → stay with the person, call the ambulance – a second dose may be required



Summary of information

- Pharmaceutical opioid dependence is common among those using opioids for pain
- Emerging evidence supports that use of opioid agonist treatment (large evidence base supports opioid agonist treatment in general)
- Dose titration is important, but ‘usual’ doses are common
- Treatment outcomes are comparable/favorable in contrast to treating heroin dependence
 - Existing treatment protocols based on earlier research appear appropriate

More information about opioid agonist treatment

In New South Wales GPs can prescribe buprenorphine for a up to five patients without accreditation

- Ideal where a patient already has a good relationship with their GP
- Secondary consultation may support less experienced prescribers, especially around induction

Information about the Opioid Treatment Program:

<http://www.health.nsw.gov.au/pharmaceutical/doctors/Pages/otp-medical-practitioners.aspx>

Opioid Treatment Accreditation Course: <https://www.otac.org.au/>

National Guidelines:

<http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/Publishing.nsf/content/ng-mat-op-dep>

How to become an OTP registered pharmacy

<http://www.health.nsw.gov.au/pharmaceutical/pharmacists/Pages/otp-pharmacists.aspx>

- Need to register with the NSW Ministry of Health
- May be eligible for the Pharmacy Incentive Scheme



A brief summary of the evidence:

Frequently asked questions on opioid agonist treatment for pharmaceutical opioid dependence: An evidence summary

Author: Dr Suzanne Nielsen
Resource Type: AOD Worker Resources, Fact Sheets, General
 [FAQ Pharmaceutical Opioid Dependence Treatment.pdf](#)



<https://ndarc.med.unsw.edu.au/resource/frequently-asked-questions-opioid-agonist-treatment-pharmaceutical-opioid-dependence>

Drug and Alcohol Specialist Advisory Service



For health professionals only:

- advise on clinical diagnosis and management of patients with alcohol and other drug related problems
- available 24 hours a day, 7 days a week.
- FREE

Sydney Metropolitan: (02) 9361 8006

Regional and rural NSW: 1800 023 687

If you are worried about complexities in the patient or person presenting to you, get advice and guidance immediately.

GLAD:



Welcome

Glad you're here!

Gp Liaison in Alcohol and other Drugs

To improve collaboration between AOD services and GPs in the CESP HN area

Public alcohol and other drug services

- SLHD
- SESLHD
- St Vincent's Network
- CESP HN

Our contact michelle.schulz@health.nsw.gov.au

GLAD To seek advice and information

Sydney Local Health District [RPAH, Concord, Canterbury]	Call RPAH 02 9515 6111	Ask for On Call Drug and Alcohol Doctor
South East Sydney Local Health District [Sydney, Prince of Wales, St George and Sutherland Hospital's]	Call Sydney Hospital 02 9382 7111	Ask for On Call Drug and Alcohol Doctor
St Vincent's Hospital Network	Call St Vincent's Hospital 02 8382 1111	Ask for On Call Drug and Alcohol Doctor

24 hour telephone advice and support for patients:

- **ADIS** (Alcohol and Drug Information Service) on **02 9361 8000** for patients to call (website also available).

GLAD: To arrange Referral

**If your patient needs specialist drug and alcohol assessment and treatment either as an inpatient or outpatient;
Call your local AOD intake team**

Sydney Local Health District [RPAH, Concord, Canterbury]	Call the Centralised Intake Line Intake: 1800 793 466 or 02 9767 8653 Email: SLHD.DHSIntake@sswahs.nsw.gov.au Fax (Camperdown): 95158970 Fax (Concord): 02 9767 8327	Ask for Drug and Alcohol Intake
South East Sydney Local Health District [Sydney, Prince of Wales, St George and Sutherland Hospital's]	Call Sydney Hospital 02 9382 7111 Fax (Surry Hills-Botany): 02 9332 8700 Fax (St George Area): 02 9113 3977 Fax (Sutherland Area): 02 9540 7097	Ask for Drug and Alcohol Intake
St Vincent's Hospital Network	Call St Vincent's Centralised Intake Line Intake: 02 9361 8080 Email: svhs.adsintake@svha.org.au Fax: 02 8382 3111	Ask for Drug and Alcohol Intake
	or Call St Vincent's Hospital 02 8382 1111	Ask for Drug and Alcohol Intake

What happened to Olga?

- Referred to GP, who referred to local Drug Treatment Clinic
- Attended assessment, no interested in opioid agonist treatment
- Tapering trialled, headaches return
- Returns to using ibuprofen-codeine
- Decided to trial buprenorphine-naloxone taper (not ready for longer treatment)
- Stabilised on 12mg daily (twice weekly pick-up),
- Mental Health Care Plan, GP is thinking about taking over prescribing buprenorphine-naloxone

Thank you for being part of this CESPHE-NDARC Webinar

To complete CPD assessment:

<https://www.surveys.unsw.edu.au/f/163149/111c/>

Open until December 12, 2017

Webinar will be available online at

<https://ndarc.med.unsw.edu.au/resource/using-opioid-agonist-treatment-pharmaceutical-opioid-dependence>

Questions?

