An international multidisciplinary consensus statement on the prevention of opioid-related harm in adult surgical patients













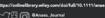














Opioid Stewardship non-medical prescribers

Dr Nicholas Levy Consultant in Anaesthesia West Suffolk Hospital

























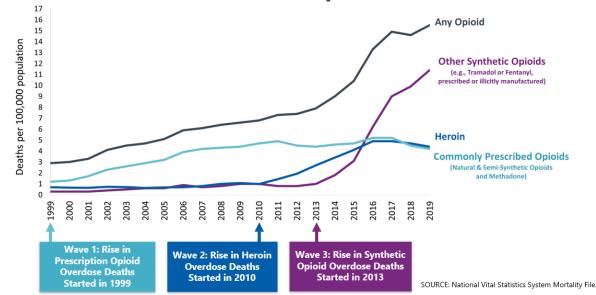




Aims

- Define NMP prescribing roles
- Define opioid stewardship
- Discuss ORADEs and the need for opioid stewardship
- Discuss drivers for opioid use and misuse
- Discuss new international, MHRA and GMC guidance
- Discuss components of opioid stewardship

Three Waves of the Rise in Opioid Overdose Deaths



























Non-medical Prescribers

- either
- Independent or
- Supplementary prescribers

Overview

A range of non-medical healthcare professionals can prescribe medicines for patients as either Independent of Supplementary Prescribers.

Independent prescribers are practitioners responsible and accountable for the assessment of patients with previously undiagnosed or diagnosed conditions and for decisions about the clinical management required,

including prescribing. They are recommended to prescribe generically, except where this would not be clinical appropriate or where there is no approved non-proprietary name.

Supplementary prescribing is a partnership between an independent prescriber (a doctor or a dentist) and a supplementary prescriber to implement an agreed Clinical Management Plan for an individual patient with the patient's agreement.

Independent and Supplementary Prescribers are identified by an annotation next to their name in the relevan professional register.

Information and guidance on non-medical prescribing is available on the Department of Health website at www.dh.gov.uk/health/2012/04/prescribing-change.

For information on the mixing of medicines by Independent and Supplementary Prescribers, see *Mixing of medicines prior to administration in clinical practice: medical and non-medical prescribing*, National Prescribing Centre, May 2010 (available at www.gov.uk/government/publications/mixing-of-medicines-prior-to-administration-in-clinical-practice-medical-and-non-medical-prescribing).

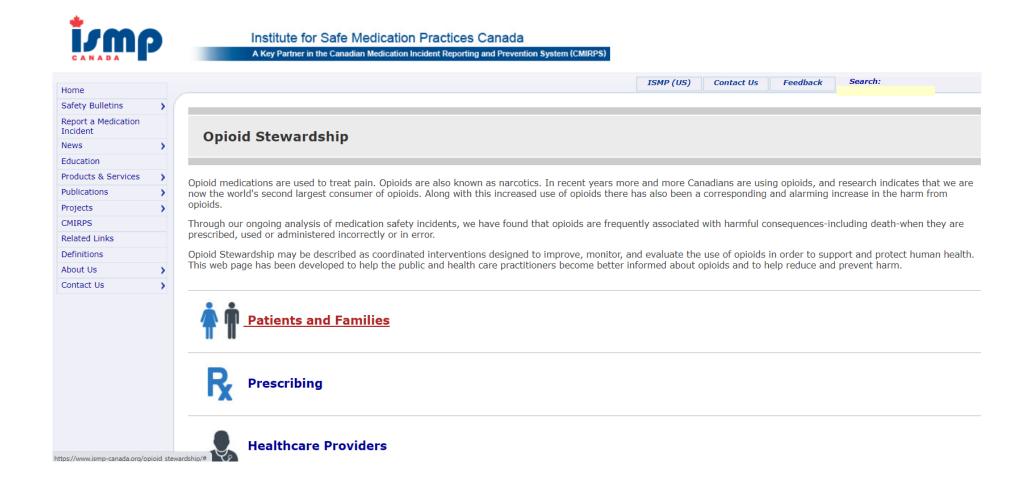
For information on the supply and administration of medicines to groups of patients using Patient Group Directions see Guidance on prescribing.

In order to protect patient safety, the initial prescribing and supply of medicines prescribed should normally remain separate functions performed by separate healthcare professionals.

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Opioid Stewardship



ISMP definition

 Opioid Stewardship may be described as coordinated interventions designed to improve, monitor, and evaluate the use of opioids in order to support and protect human health.

Co-ordinated Safe disposal

- Education of HCPs
- Education of Patients
- Leaflets
- Facilities



Opioid Stewardship are coordinated interventions designed to improve human health.

Pain relief has 4 vital functions

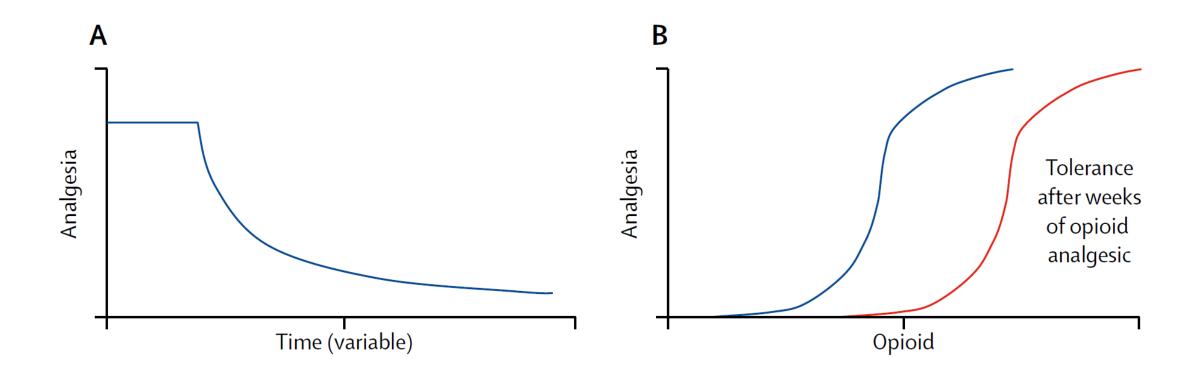
- 1. Humanitarian
- 2. Attenuate stress response
- 3. Promote function
- 4. Promote recovery and return to optimal health



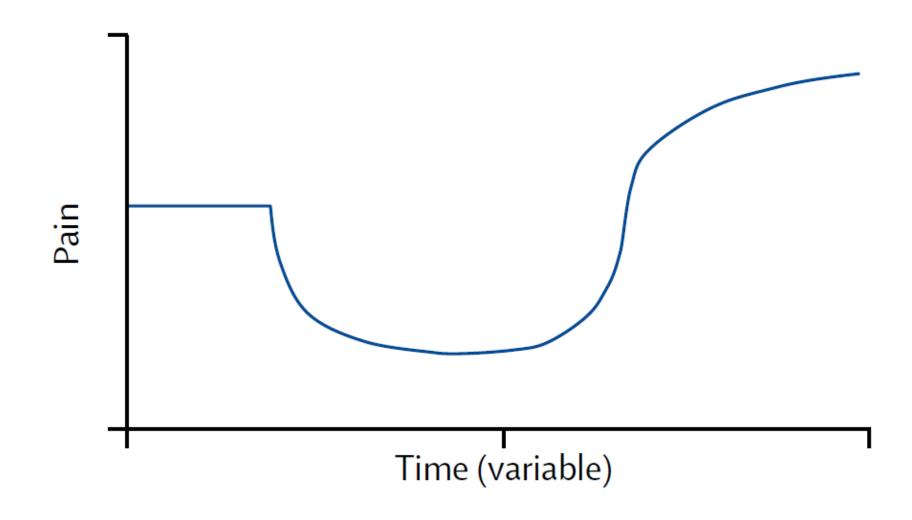
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- Has the patient got opioid resistant pain ?
- Is the patient developing tolerance?
- Is the patient developing opioid induced hyperalgesia?
- Do the opioids need deprescribing?
- Does the patients have ORADEs

Tolerance to opioid analgesia



Opioid induced hyperalgesia



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Inpatient opioid-related adverse drug events (ORADEs)

JAMA Surgery | Original Investigation

Association of Opioid-Related Adverse Drug Events With Clinical and Cost Outcomes Among Surgical Patients in a Large Integrated Health Care Delivery System

Shahid Shafi, MD, MBA, MPH; Ashley W. Collinsworth, ScD, MPH; Laurel A. Copeland, PhD; Gerald O. Ogola, PhD, MPH, MS; Taoran Qiu, MS; Maria Kouznetsova, PhD, MPH; I-Chia Liao, MPH; Natalie Mears, BA; An T. Pharm, PharmD, MBA; George J. Wan, PhD, MPH; Andrew L. Masica, MD, MSCI

ORADE Descriptions	Severity
Respiratory	
Pulmonary congestion & hypostasis	Mild
Pulmonary insufficiency following surgery and trauma Respiratory complications Other pulmonary insufficiency, not elsewhere classified	Moderate
Bradypnea	Moderate
Acute respiratory failure	Severe
Hypoxemia Hypoxia	Moderate
Mechanical ventilator	Severe
Central Nervous System	
Delirium Altered mental status Confusion – classified otherwise	Moderate
Nervousness	Mild
Dizziness/vertigo	Mild
Gastrointestinal	
Dry mouth	Mild
Paralytic ileus Postoperative ileus	Moderate
Constipation Constipation - narcotic	Mild
Nausea/vomiting following GI surgery Nausea/vomiting	Moderate
Opioid Antagonist	
Naloxone Naloxegol Methylnaltrexone Other Adverse Events	Moderate
Dermatitis/Pruritus	Mild
Bradycardia, postoperative	Moderate
Fall from bed Other accidental fall Accidental fall (not specified)	Moderate
Drugs causing adverse events in therapeutic use	Mild

Impact of inpatient opioid-related adverse drug events

Table 2. Risk-Adjusted Clinical and Cost Outcome Estimates for Patients With and Without ORADEs^a

	Value (95% CI) ^b		
Outcome	ORADE	No ORADE	Difference
Inpatient mortality, %	3.0 (2.8-3.3)	0.1 (0.1-0.2)	2.9
Discharge to another care facility, %c	20.0 (19.5-20.6)	10.4 (10.2-10.6)	9.6
LOS, d	6.8 (6.7-6.8)	5.2 (5.1-5.3)	1.6
Cost of hospitalization, \$d	25 599 (24 974-26 104)	17 374 (17 191-17 547)	8225
30-d Readmission, %	8.9 (8.5-9.4)	7.1 (7.0-7.3)	1.8

ORADEs in the Community

- Social impact
- Financial impact on the person, the family and the community
- Opioid use disorder
- Opioid diversion
- Drug driving
- Death from opioid induced ventilatory impairment
- Transition to illicit opioid use

THE OPIOID EPIDEMIC BY THE NUMBERS



130+ People died every day from opioid-related drug overdoses³



10.3 m People misused prescription opioids in 2018



47,600 People died from overdosing on opioids²



2.0 million People had an opioid use disorder in 2018



808,000 People used heroin in 2018¹



81,000 People used heroin for the first time'



2 million
People misused
prescription opioids
for the first time¹



15,349
Deaths attributed to overdosing on heroin (in 12-month period ending February 2019)²



32,656

Deaths attributed to overdosing on synthetic opioids other than methadone (in 12-month period ending February 2019)²

SOURCES

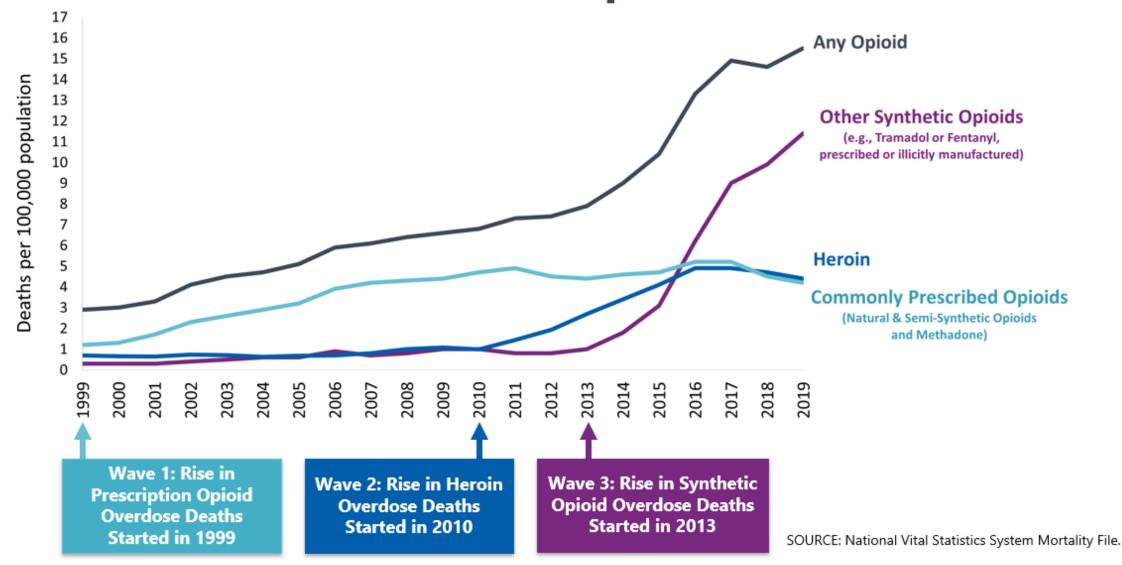
- 1. 2019 National Survey on Drug Use and Health. Mortality in the United States, 2018
- 2. NCHS Data Brief No. 329, November 2018
- NCHS, National Vital Statistics System. Estimates for 2018 and 2019 are based on provisional data.





Opioid use and misuse-the other epidemic

Three Waves of the Rise in Opioid Overdose Deaths

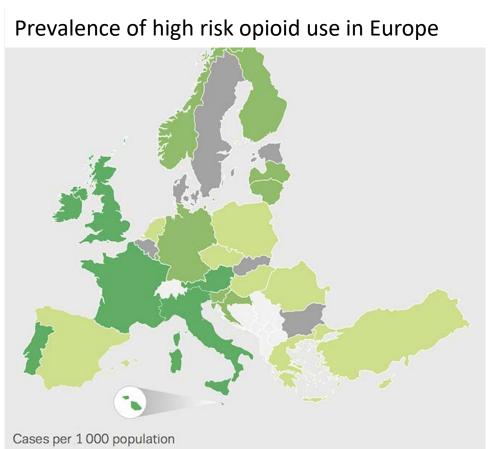


Opioid use and misuse- the other UK epidemic



UK figures

- 5% of the population prescribed opioids in 2015
- 18% in Scotland
- 5% of the population misuse prescription opioids
- 1998 and 2016, opioid prescriptions increasing+++
- Morphine equivalency consumption is now 431 mg per person per year



>5.0

No data

2.51-5.0

OPIOIDS IN BRITAIN: BY NUMBERS

In 2017 there were:

Increase from 2007



41.43m prescriptions





11, 543 overdoses





1,985 deaths

41%

3 x more deaths in the North East than London **113,000** opioid prescriptions are handed out every day

5 deaths per day on average

10% of patients are on opioids in Blackpool

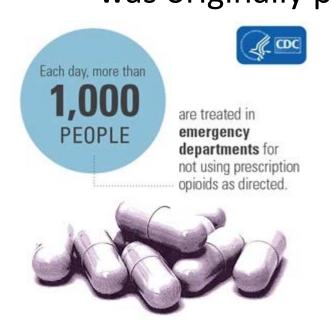


Opioid misuse and Opioid diversion

• Opioid mis-use is use without a prescription or use for reasons other than that for which the opioid was prescribed.

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was originally prescribed





Why does proper opioid disposal matter?

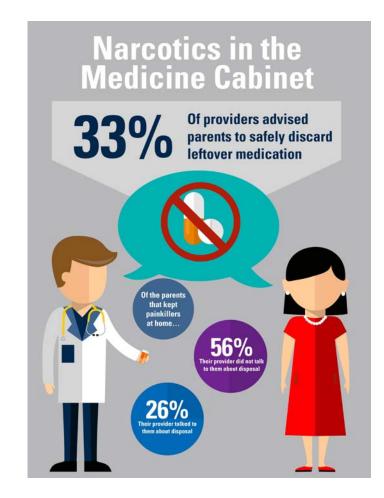
Protecting Family and Friends



2/3 of teens who report prescription abuse get the medicines from friends, family and acquaintances.

teens has misused or abused a prescription drug at least once in their lifetime.¹

children died and 116,000 were treated in the ER for drug poisoning in 2009.²



Driving under the influence of prescription opioids

Age and Ageing 2016; **45:** 628–634 doi: 10.1093/ageing/afw115 Published electronically 26 July 2016 © The Author 2016. Published by Oxford University Press on behalf of the British Geriatrics Society.

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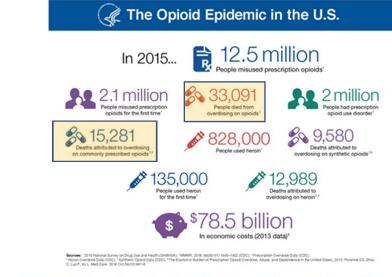
New opioid analgesic use and the risk of injurious single-vehicle crashes in drivers aged 50-80 years: A population-based matched case-control study



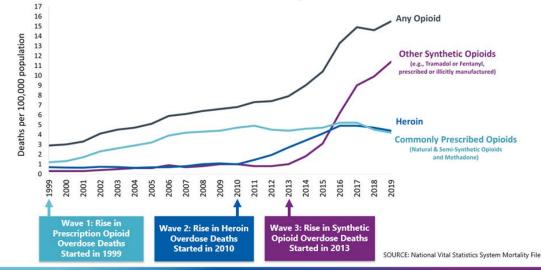
 Increased risk of fatal road traffic collisions within 30 days of commencing opioids

Opioid induced ventilatory impairment

- More than just respiratory depression
- Relaxation of upper airway
- Depression of consciousness
- Compounded by other sedatives eg gabapentinoids



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Drug Safety Update

Latest advice for medicines users

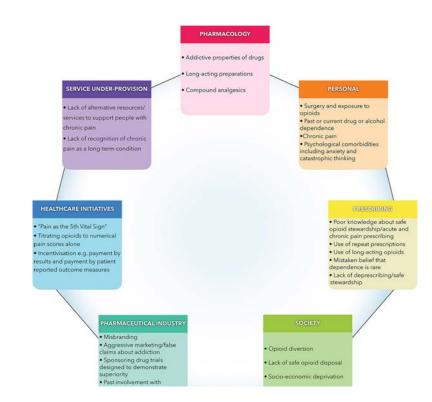
The monthly newsletter from the Medicines and Healthcare products Regulatory Agency and its independent advisor the Commission on Human Medicines

Pregabalin (Lyrica): reports of severe respiratory depression

Pregabalin has been associated with infrequent reports of severe respiratory depression, including some cases without the presence of concomitant opioid medicines. Patients with compromised respiratory function, respiratory or neurological disease, renal impairment; those using concomitant central nervous system (CNS) depressants; and people older than 65 years might be at higher risk of experiencing these events and adjustments in dose or dosing regimen may be necessary.

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Drivers for opioid use and misuse

CBS NEWS / $June~21, 2018, 7:47\,AM$

Purdue Pharma used deceptive sales tactic for OxyContin after settlement, ex-sales rep says

PHARMACOLOGY

- · Addictive properties of drugs
- Long-acting preparations
- Compound analgesics

PERSONAL

- Surgery and exposure to opioids
- Past or current drug or alcohol dependence
- •Chronic pain
- Psychological comorbidities including anxiety and catastrophic thinking

HEALTHCARE INITIATIVES

chronic pain

SERVICE UNDER-PROVISION

· Lack of alternative resources/

services to support people with

• Lack of recognition of chronic

pain as a long-term condition

- "Pain as the 5th Vital Sign"
- Titrating opioids to numerical pain scores alone
- Incentivisation e.g. payment by results and payment by patient reported outcome measures



PRESCRIBING

- Poor knowledge about safe opioid stewardship/acute and chronic pain prescribing
- Use of repeat prescriptions
- Use of long-acting opioids
- Mistaken belief that dependence is rare
- Lack of deprescribing/safe stewardship

PHARMACEUTICAL INDUSTRY

- Misbranding
- Aggressive marketing/false claims about addiction
- Sponsoring drug trials designed to demonstrate superiority
- Past involvement with

SOCIETY

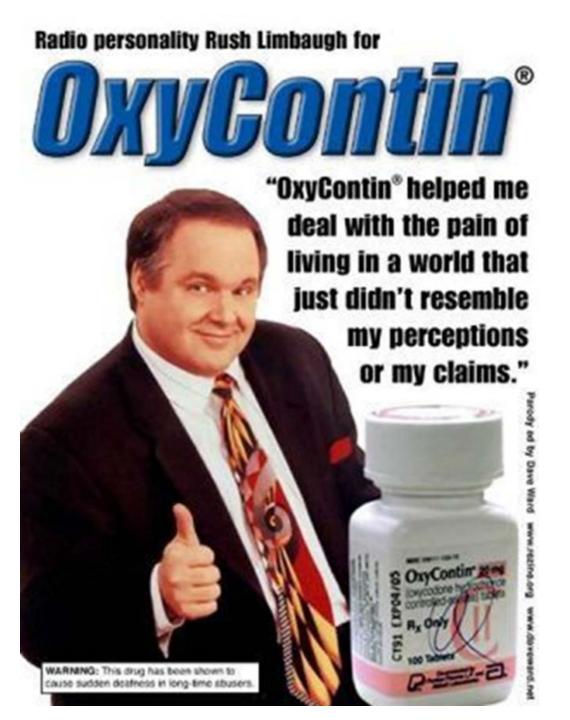
- Opioid diversion
- Lack of safe opioid disposal
- Socio-economic deprivation

Purdue will plead guilty to federal charges, reaches \$8.3 billion deal over opioid crisis

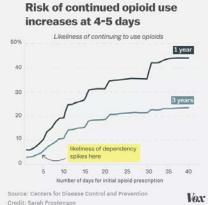
By ED SILVERMAN @Pharmalot / OCTOBER 21, 2020

CBS NEWS | June 21, 2018, 7:47 AM

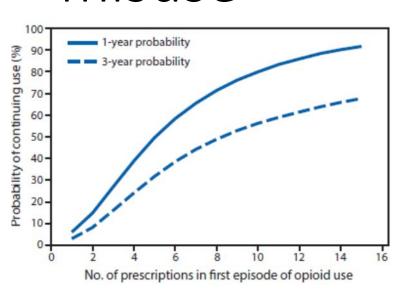
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Centers for Disease Control and Prevention

Morbidity and Mortality Weekly Report

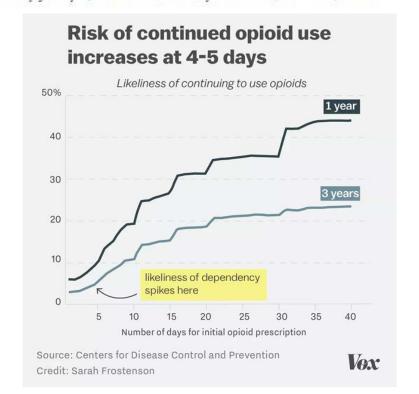
March 17, 2017

Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015

Anuj Shah¹; Corey J. Hayes, PharmD^{1,2}; Bradley C. Martin, PharmD, PhD¹



Weekly / Vol. 66 / No. 10



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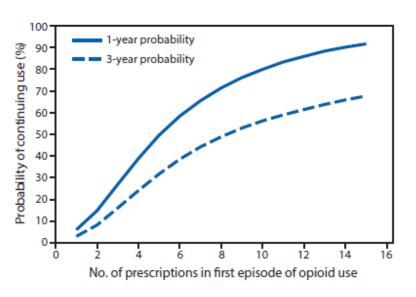
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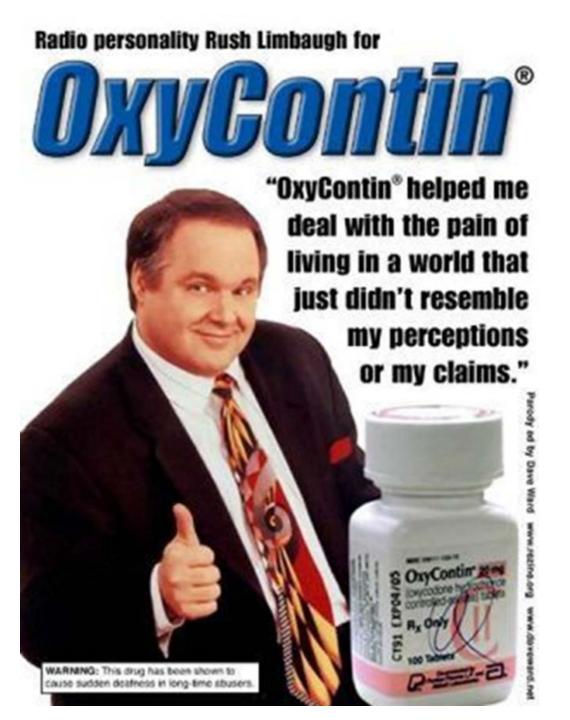


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Drivers for opioid use and misuse

The 5th Vital Sign:

How Treating Pain Contributed to the Opioid Epidemic









SERVICE UNDER-PROVISION · Lack of alternative resources/ services to support people with chronic pain • Lack of recognition of chronic pain as a long-term condition pain scores alone

HEALTHCARE INITIATIVES

- "Pain as the 5th Vital Sign"
- Titrating opioids to numerical
- Incentivisation e.g. payment by results and payment by patient reported outcome measures

Long-acting preparations

PHARMACOLOGY

· Addictive properties of drugs

Compound analgesics

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Why does proper opioid disposal matter?



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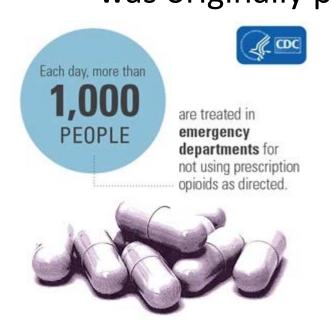
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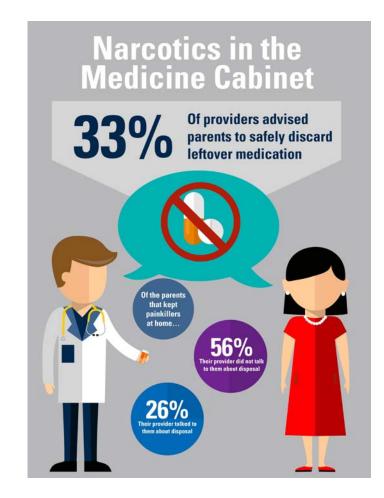
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Drivers for opioid use and misuse

Takeaways from our research on opioid prescribing after surgery









Prescription size is the strongest predictor of how much opioid a person will use

https://ihpi.umich.edu/sites/default/files/2019-02/Opioids_Surg_FINAL_2.22.19.pdf

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Unrealistic expectations

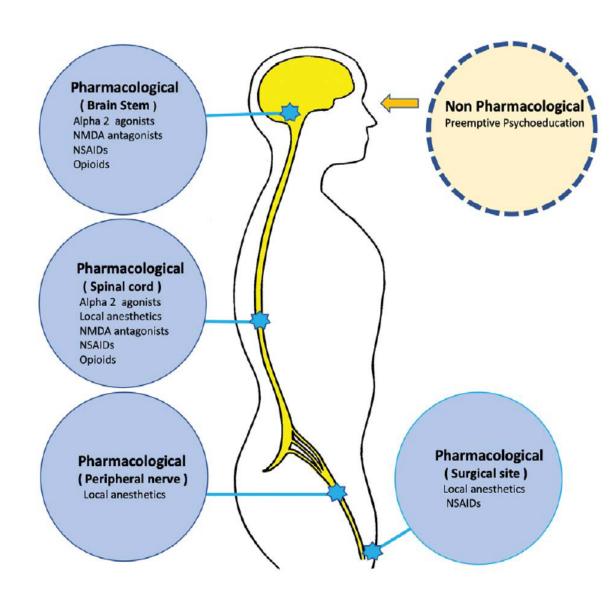


Figure. Schematic diagram of non-pharmacological preemptive pain psychoeducation as a part of multimodal perioperative pain control option. NMDA indicates *N*-methyl-p-aspartate; NSAID, nonsteroidal anti-inflammatory drugs.

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Drug Safety Update



Latest advice for medicines users

The monthly newsletter from the Medicines and Healthcare products Regulatory Agency and its independent advisor the Commission on Human Medicines

Volume 14 Issue 2 September 2020	
Contents	
Opioids: risk of dependence and addiction	page 2
Transdermal fentanyl patches for non-cancer pain: do not use in opioid-naive patients	page 5

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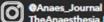
Patients should be advised on safe storage and disposal of unused opioids and directed to avoid opioid diversion to other individuals.

Levy N, Quinlan J, El-Boghdadly K et al. An international multidisciplinary consensus statement on the prevention of opioid-related harm in adult surgical patients. *Anaesthesia* 2020 Epub 7 Oct.

https://onlinelibrary.wiley.com/doi/full/10.1111/anae.15262









- Pre-operative weaning of opioids where possible
- Realistic expectations

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Function should be used to guide opioid administration

Functional Pain Score

A — no limitation the patient is able to undertake the activity without limitation due

to pain (pain intensity score is typically zero to three);

B — mild limitation the patient is able to undertake the activity but experiences

moderate to severe pain (pain intensity score is typically four to

ten); and

C — significant limitation the patient is unable to complete the activity due to pain, or pain

treatment-related adverse effects, independent of pain intensity

scores.

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Functional outcomes should guide provision of opioid analgesia, rather than unidimensional pain scores alone.



Multimodal analgesia should be optimised and patients educated about the use of non-pharmacological and nonopioid analgesia.



Long-acting opioids should not be used routinely for acute postoperative pain.



A patient-centred approach should be used to limit the number of tablets and the duration of usual discharge opioid prescriptions, typically to less than a week.



Automated post-discharge repeat prescriptions for opioids should be avoided. Perform a patient review if more opioids are requested.



Hospitals should have strategies to mitigate the occurrence of opioid-induced ventilatory impairment.

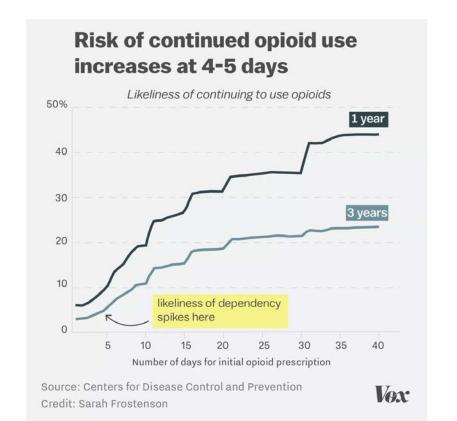


Modifiable factors that have been identified as increasing the risk of opioid-induced ventilatory impairment and persistent postoperative opioid use should be addressed.



Patients should be advised on safe storage and disposal of unused opioids and directed to avoid opioid diversion to other individuals.

 Limit the number of tablets and the duration of opioid prescriptions, typically to less than a week.





For acute pain, prescriptions should only be for the expected duration of pain severe enough to need opioids. Three days or less is often enough; more than seven days is rarely needed.

An international multidisciplinary consensus statement on the prevention of opioid-related harm in adult surgical patients





















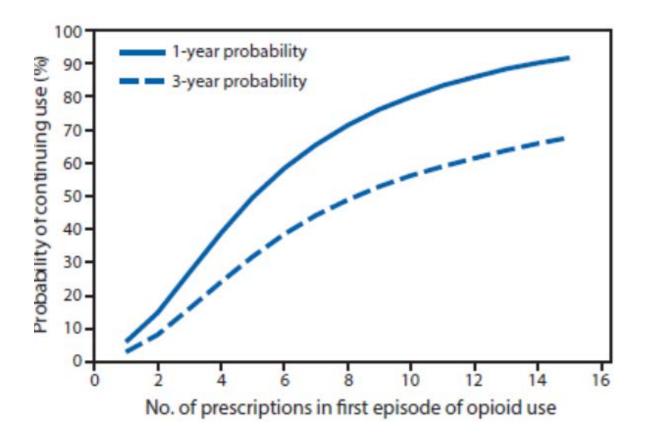


Antibiotic and Opioid stewardship

- Consider them both as courses
- With an end date of treatment



Avoid repeat prescriptions of opioids



An international multidisciplinary consensus statement on the prevention of opioid-related harm in adult surgical patients





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Drug Safety Update



Latest advice for medicines users

The monthly newsletter from the Medicines and Healthcare products Regulatory Agency and its independent advisor the Commission on Human Medicines

Volume 14 Issue 2 September 2020	
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Transdermal fentanyl patches for non-cancer pain: do not use in opioid-naive patients	page 5

Drug Safety Update



Advice for healthcare professionals:

- opioid medicines (opioids) provide relief from serious short-term pain; however longterm use in non-cancer pain (longer than 3 months) carries an increased risk of dependence and addiction
- discuss with patients that prolonged use of opioids may lead to drug dependence and addiction, even at therapeutic doses – warnings have been added to the labels (packaging) of UK opioid medicines to support patient awareness
- before starting treatment with opioids, agree with the patient a treatment strategy and plan for end of treatment

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You can find the latest version of this guidance on our website at www.gmc-uk.org/guidance

THIS GUIDANCE COMES INTO EFFECT ON 5 APRIL 2021

Good practice in prescribing and managing medicines and devices

You are responsible for the prescriptions that you sign. You must only prescribe medicine when you have adequate knowledge of your patient's health. And you must be satisfied that the medicine serves your patient's need.

This guidance comes into effect on 5 April 2021.

General

Medical

Council

Download the guidance

Value and decombered their models are the French and Walak

Controlled drugs and other medicines where additional safeguards are needed

- 59 Some categories of medicine may pose particular risks of serious harm or may be associated with overuse, misuse or addiction. When prescribing, you should follow relevant clinical guidance, such as drug safety updates on the risk of dependence and addiction associated with opioids.¹⁷
- 60 If you don't have access to relevant information from the patient's medical records you must not prescribe controlled drugs or medicines that are liable to abuse, overuse or misuse or when there is a risk of addiction and monitoring is important. Exceptions to this are when no other person with access to that information is available to prescribe without unsafe delay and it is necessary to:
 - a avoid serious deterioration in health or avoid serious harm
 - b ensure continuity of treatment where a patient is unexpectedly without access to medication for a limited period.

Prescribing at the recommendation of a colleague

76 If you prescribe based on the recommendation of another doctor, nurse or other healthcare professional, you must be satisfied that the prescription is needed, appropriate for the patient and within the limits of your competence.

· / /

17 See MHRA safety drug update on <u>opioids and risk of</u> <u>dependence and addiction</u>.

Obtaining a patient's consent

50 You should be proportionate when obtaining a patient's consent. For most prescribing decisions, you can rely on a patient's verbal consent, as long as you are satisfied that they've had the opportunity to consider any relevant information and decided to go ahead. Sometimes a patient's signature is required on a form, for example to comply with an MHRA drug safety alert about a medicine with serious side effects.



Guidance on professional standards and ethics for doctors

Decision making and consent

Working with doctors Working for patients

General Medical Council





Shared decision making

NICE guideline Published: 17 June 2021 www.nice.org.uk/guidance/ng197

The BRAN acronym





Make the most of your appointment

It can be a bit daunting having an appointment – but asking your healthcare professional the four **BRAN** questions can help you make the right choice for you.





What are the Benefits?





What are the Risks?





What are the Alternatives?



Nothing
What if I do Nothing?

Aims

- Define NMP prescribing roles
- Define opioid stewardship
- Discuss ORADEs and the need for opioid stewardship
- Discuss drivers for opioid use and misuse
- Discuss new international, MHRA and GMC guidance
- Discuss components of opioid stewardship



Avoiding the known risk factors

- Unrealistic expectations
- Aiming for reduction in unidimensional pain intensity scores
- Use of modified release opioids
- Repeat prescriptions
- Long duration

- 1. Research
- 2. Education of prescribers
- 3. Education of Patients and carers
- 4. Realistic expectations
- 5. Treat opioid prescriptions for non-cancer pain as a course
- 6. Avoid repeat prescriptions
- 7. Avoid co-prescribing with other sedatives

- 8. Avoid long duration
- 9. Avoid drug driving
- 10. Promote safe storage
- 11. Promote safe disposal
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Need to implement effective strategies





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Deprescribing Advice

- Expectation to stop opioids
- How to stop opioids



Patient information

Stopping Pain Killers



Pain Service

West Suffolk NHS Foundation Trust Hardwick Lane, Bury St Edmunds, Suffolk IP33 2QZ Tel: 01284 713000, www.wsh.nhs.uk



Putting you first

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Realistic expectations

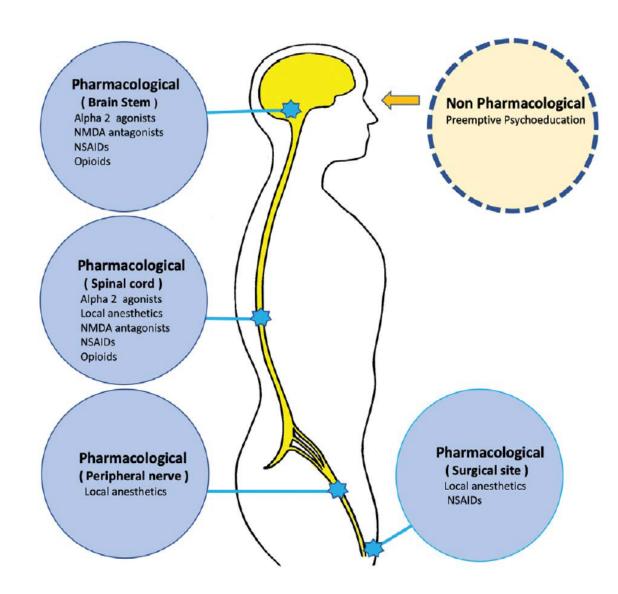


Figure. Schematic diagram of non-pharmacological preemptive pain psychoeducation as a part of multimodal perioperative pain control option. NMDA indicates *N*-methyl-p-aspartate; NSAID, nonsteroidal anti-inflammatory drugs.

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Opioids must be considered a course of treatment

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Opioid induced ventilatory impairment

- More than just respiratory depression
- Relaxation of upper airway
- Depression of consciousness
- Compounded by other sedatives eg gabapentinoids



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Pregabalin (Lyrica): reports of severe respiratory depression

Pregabalin has been associated with infrequent reports of severe respiratory depression, including some cases without the presence of concomitant opioid medicines. Patients with compromised respiratory function, respiratory or neurological disease, renal impairment; those using concomitant central nervous system (CNS) depressants; and people older than 65 years might be at higher risk of experiencing these events and adjustments in dose or dosing regimen may be necessary.

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Driving under the influence of prescription opioids



Driving and skilled tasks

Drowsiness may affect performance of skilled tasks (e.g. driving); effects of alcohol enhanced. Driving at the start of therapy with opioid analgesics, and following dose changes, should be avoided.

For information on 2015 legislation regarding driving whilst taking certain controlled drugs, including opioids, see *Drugs and driving* under Guidance on prescribing.



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Preventing harm from opioid diversion

How to Safely Store Prescription Opioids Store in original Safeguard medicines Keep 1 in a locked cabinet or lockbox to know if there is any missing young children



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Safe Disposal

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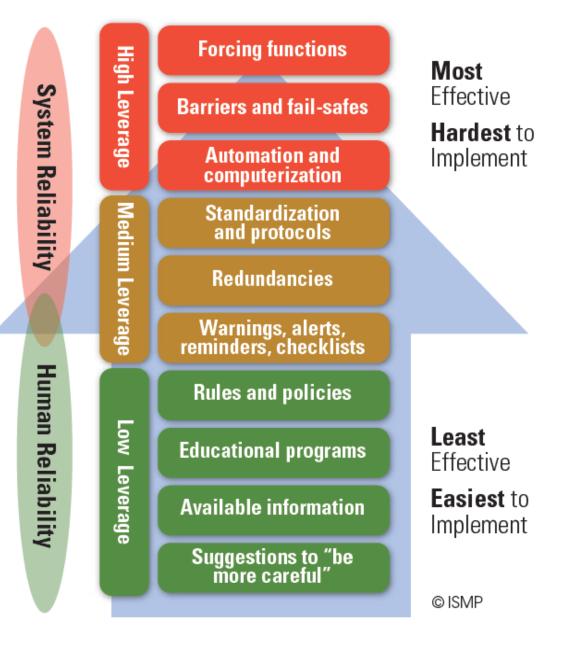
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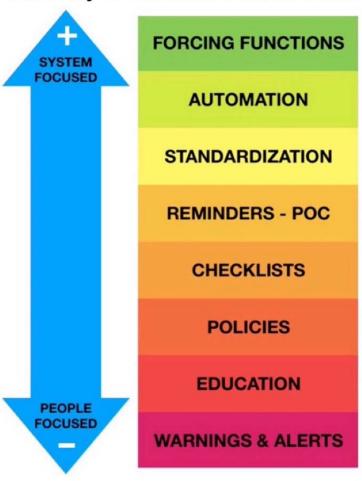
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Implementing opioid stewardship



Human factors and forcing functions

Hierarchy of Intervention Effectiveness



forcing function

mechanisms built into the workflow to prevent specific errors or reduce their impact

Examples of Human factor engineering in healthcare to reduce errors

- Checklists
- CPOE SYSTEM

 (Computerized physician order entry)
- Color Coding of Medical gasses adaptor
- Barcode medication administration system.
- Forcing functions : Removal of concentrated potassium from general wards





Summary

- Define NMP prescribing roles
- Define opioid stewardship
- Discuss ORADEs and the need for opioid stewardship
- Discuss drivers for opioid use and misuse
- Discuss components of opioid stewardship
- Discuss new international, MHRA and GMC guidance



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Take home messages

- 1. Limit duration and agree end date (course of treatment)
- 2. No repeat prescriptions and no modified-release opioids
- 3. Regular assessment
- 4. Through SDM ensure patients are aware of BRAN
- 5. Promote safe storage and disposal
- 6. Avoid drug driving, opioid diversion
- 7. Work with others