National Patient Safety Agency

RAPID RESPONSE REPORT: NPSA/2008/RRR05

Reducing Dosing Errors with Opioid Medicines

July 2008

SUPPORTING INFORMATION

Background

Opioid medicines are invaluable for the treatment of acute and chronic pain. There are risks if members of the healthcare team who prescribe, dispense or administer opioid medicines have insufficient knowledge of dosage and the requirements of the patient concerned. Every member of the team has responsibility to check that the intended dose is safe for the individual patient.

Incidents have been reported to the National Reporting and Learning System (NRLS) concerning patients receiving unsafe doses of opioid medicines, where members of the clinical team have not checked current opioid dose and give an incorrect dose or formulation.

There is a wide variety of opioid medicines, and shortages may be one of the factors that result in products being used which are unfamiliar to practitioners. In addition, patients response to opioid medicines varies widely and is partly dependant on previous doses received.

While dose increments should be in line with this guidance, it is recognised that in palliative care higher than normal doses may be required. These recommendations are not designed to restrict clinical use of opioid medicines, but to ensure they are used in a way that is as safe as possible for patients.

For the purposes of this alert, the term 'opioid medicines' refers to the following medicines, including commercial brands.

- Buprenorphine
- Diamorphine
- Dipipanone
- Fentanyl
- Hydromorphone
- Meptazinol
- Methadone
- Morphine
- Oxycodone
- Papaveretum
- Pethidine

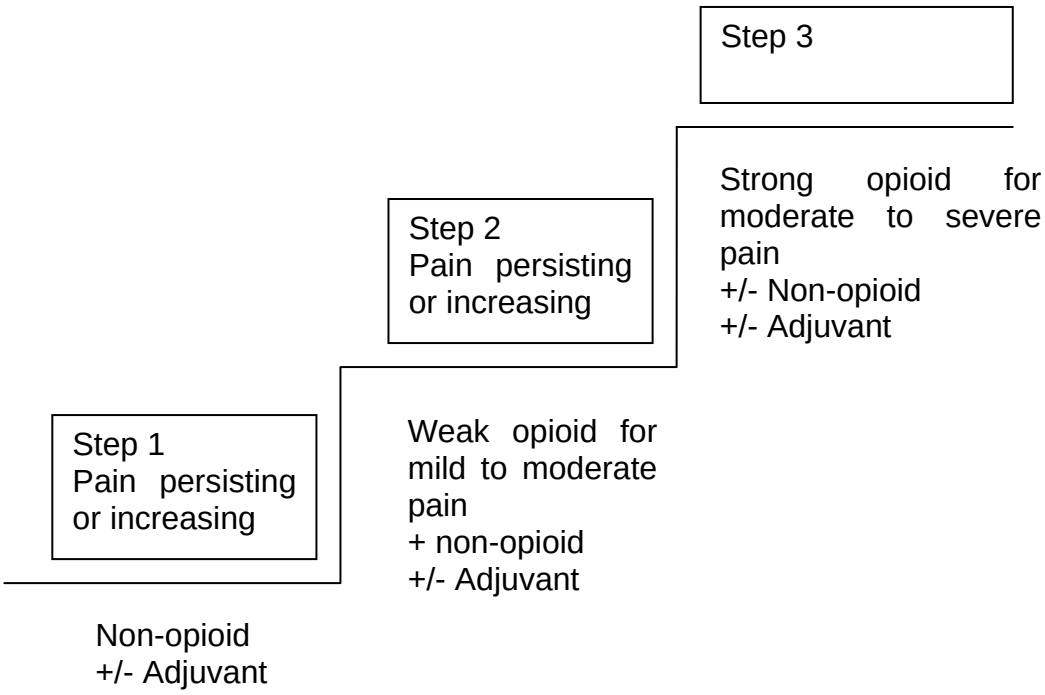
Usual starting doses for these medicines may vary depending on the type of patient e.g. doses in paediatric patients are likely to be very different to those in adult patients. Information relating to starting doses, dose conversion and formulations may be found in the following texts (other texts may also be relevant):

- British National Formulary (Individual product monographs and 'Prescribing in palliative care' section)
- British National Formulary for Children
- Palliative Care Formulary or www.palliativedrugs.com
- Local policies and guidance
- Summary of Product Characteristics (SPC) of individual products

As well as at initiation of treatment, errors can occur during dose conversion or with an unintended dose increase for a patient already on opioids. Where a change in formulation or medicine is required, practitioners inexperienced in the use of opioids should use references for dose conversion to aid calculation of a safe dose. Individualisation of opioid doses means that prescribing incidents may not be immediately recognisable.

WHO Pain Ladder

The following diagram shows the WHO pain ladder which describes a three step approach to administering the right medicine in the right dose at the right time to treat pain. More detailed guidance for specific patient groups may be available.



Particular care should be taken when checking the safety of increased doses. For example, for oral morphine or oxycodone in adult patients doses should not normally be more than 50% higher than the previous dose.

Review of evidence of harm

A review of incidents reported to the NRLS found 4,223 incidents involving opioid medicines and the 'Wrong / unclear dose or strength' or 'Wrong frequency' of medication, as at 18 June 2008[1].

Interpretation of data from the NRLS should be undertaken with caution. As with any voluntary reporting system, the data are subject to bias. A proportion of incidents that occur remain unreported, and those which are reported may be incomplete having been reported immediately and before the patient outcome is known.

Table 1: Patient safety incidents involving opioid medicines by care setting

Base: All medication incident reports contained in the NRLS as at 18 June 2008 involving opioid medicines and errors in frequency, strength or dose

Care Setting of Occurrence	Frequency	Percent
Acute / general hospital	3,341	79
Community nursing, medical and therapy service (incl. community hospital)	451	11
Mental health service	277	7
Community pharmacy	110	3
General practice	28	1
Ambulance service	12	0
Learning disabilities service	3	0
Community and general dental service	1	0
Total	**4,223**	**100**

Table 2: Patient safety incidents involving opioid medicines by degree of harm

Base: All medication incident reports contained in the NRLS as at 18 June 2008 involving opioid medicines and errors in frequency, strength or dose

PD09 (validated)	Frequency	Percent
No Harm	3,338	79
Low	629	15
Moderate	242	6
Severe	4	0
Death	5	0
Insufficient information	3	0
Missing/Blank	2	0
Total	**4,223**	**100**

Note: Incidents reported with a degree of harm 'death' or 'severe' have been reviewed and excluded or re-classified if appropriate.

[1]The NRLS was first set up in October 2003 and all NHS organisations were able to report to the NRLS by 1 January 2005. It is important to note that the volume of reports received by the NRLS has steadily increased since inception, and as the NRLS is a voluntary reporting system, the data may not be representative of the rates of incidents across England and Wales.

Table 3: Patient safety incidents involving opioid medicines by stage of medication process

Base: All medication incident reports contained in the NRLS as at 18 June 2008 involving opioid medicines and errors in frequency, strength or dose

Stage of Medication Process	Frequency	Percent
Administration / supply of a medicine from a clinical area	2,847	67
Prescribing	771	18
Preparation of medicines in all locations / dispensing in a pharmacy	402	10
Monitoring / follow-up of medicine use	123	3
Advice	20	0
Supply or use of over-the-counter (OTC) medicine	11	0
Other	49	1
Total	**4,223**	**100**

Table 4: Patient safety incidents involving opioid medicines by type of medication error

Base: All medication incident reports contained in the NRLS as at 18 June 2008 involving opioid medicines and errors in frequency, strength or dose

Type of Medication Process	Frequency	Percent
Wrong / unclear dose or strength	3,297	78
Wrong frequency	926	22
Total	**4,223**	**100**

Table 5: Patient safety incidents involving opioid medicines by medication involved

Base: All medication incident reports contained in the NRLS as at 18 June 2008 involving opioid medicines and errors in frequency, strength or dose

Medication (from search)	Frequency	Percent
Morphine	2,441	55
Fentanyl	544	12
Oxycodon	520	12
Methadon	371	8
Dianmorp	293	7
Buprenor	135	3
Pethidin	86	2
Hydromorphone	8	0
Meptazinol	6	0
Dipipanone	3	0
Total	**4,407**	**100**

Note: Incidents may involve more than one medication type, therefore totals may not match other tables

Example Incidents

The following are examples of dose related patient safety incidents concerning opioid medicines reported to the National Reporting and Learning System (NRLS), which the guidance in this Rapid Response Report could have helped to avoid.

Incident 1 – Prescribing error - inappropriate starting dose of morphine
A patient was started on MST (morphine) 60mg twice a day for arthritic pain as an initial dose. Prior to this the patient was using tramadol 50mg three times a day for analgesia. After taking four doses of the MST the patient was confused, hallucinating and drowsy. The patient was admitted to hospital where he remained for six days after receiving naloxone.

Incident 2 – Administration error – wrong strength fentanyl given
A patient was given 2 ½ times the requested amount IV fentanyl, leading to severe respiratory depression and admission to ICU.

Incident 3 – Prescribing error - product unfamiliarity - dose not matched to indication
At 04.00 hours a crash call was put out. Following assessment the patient was found to have a pulse and was still breathing. When doctors consulted the patient's treatment chart it became evident that the patient had received a greater concentration of methadone than was required for use as a cough suppressant. Naloxone was given as prescribed.

Incident 4 – Prescribing error compounded by lack of safety check during dispensing
A patient was given 100mg/ 5mls of Oramorph (morphine), instead of 10mg/5mls. The prescription was copied from the acute discharge note. The G.P. failed to notice the error and the pharmacy didn't question that the dose was different from that previously dispensed. The patient noticed and did not take the increased dose.

Incident 5 – Administration error – wrong formulation and route of administration
On the incident date, two staff nurses administered 2.5mg of oxycodone via subcutaneous injection. The patient was written up for 2.5mg Oxynorm via the oral route only. The patient was already receiving oxycodone via a syringe driver.

Incident 6 – Prescribing error – wrong medicine prescribed
Oxycontin was prescribed in error instead of oxybutinin . Several doses were given. The patient was also taking MST (morphine) 15mg twice a day. Safety checks on dispensing may have alerted the pharmacist to this error.

Incident 7 – Morphine administered at wrong rate
A morphine Patient Controlled Analgesia (PCA) background infusion was found to be running at 5mgs/hr. This should have been 1mg/hr. Patient became sedated, aspirated and was admitted to intensive care.

Incident 8 – 24 hour dose given as single injection
On admission, a patient had a respiratory rate 4/minute and was very sedated as a result of an Intra Muscular injection 40mg diamorphine given at home. This was in effect a dose equivalent to the previous total 24 hour morphine dose given as a single injection (not 1/6th of the total 24 hour dose as recommended).

Incident 9 – Morphine overdose
A patient was prescribed MST (morphine) 120mg daily. The patient normally takes MST 20mg twice a day. They received the incorrect dose for two days. Respiratory depression was recorded in the patient's notes. The patient required naloxone infusion.

Incident 10 – Multiple opioids
A patient admitted from another ward with respiratory depression following apparent opioid overdose on the ward. Epidural infusion, Fentanyl patch and MST (morphine) were all found to be given concurrently.

Evaluation

Implementation of this Rapid Response Report in England will be monitored through the Safety Alert Broadcast System (SABS) run by the Department of Health. Chief Pharmacists should ensure that their SABS office is kept up to date on implementation progress and that the SABS system is updated accordingly.

Implementation of this Rapid Response Report in Wales will be monitored through Regional Offices. It is also possible that monitoring bodies such as the Healthcare Commission and Strategic Health Authorities may require evidence of implementation as part of their routine monitoring and evaluation role.

References

British National Formulary Edition 54 September 2007. BMJ Publishing Group Ltd. And RPS Publishing.

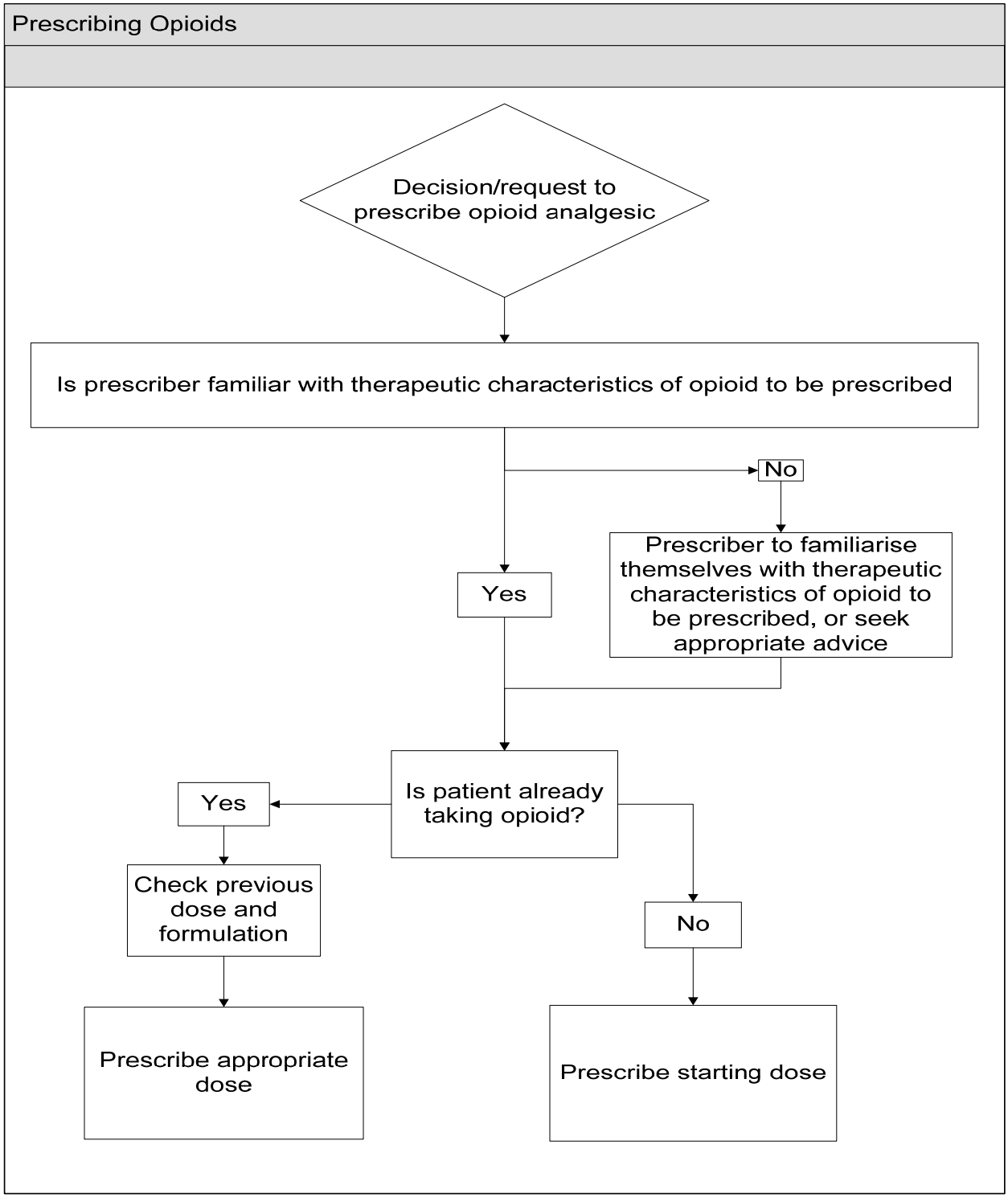
British National Formulary for Children 2007 - Published jointly by the British Medical Association, the Royal Pharmaceutical Society of Great Britain, the Royal College of Paediatrics and Child Health, and the Neonatal and Paediatric Pharmacists Group.

Twycross R, Wilcock A (2007) Palliative Care Formulary 3, Published by palliativedrugs.com LTD, Nottingham.

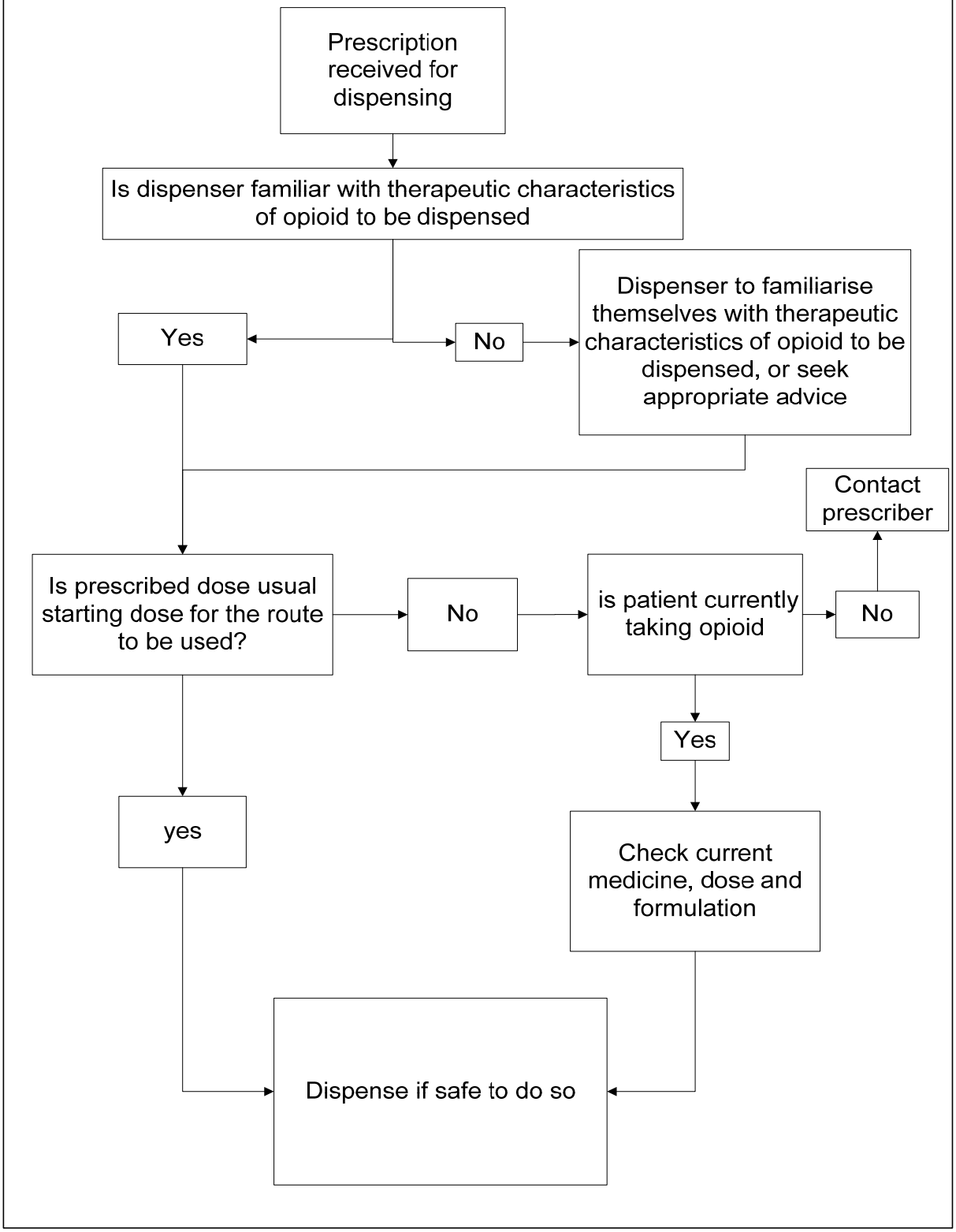
www.palliativedrugs.com

Implementing this guidance

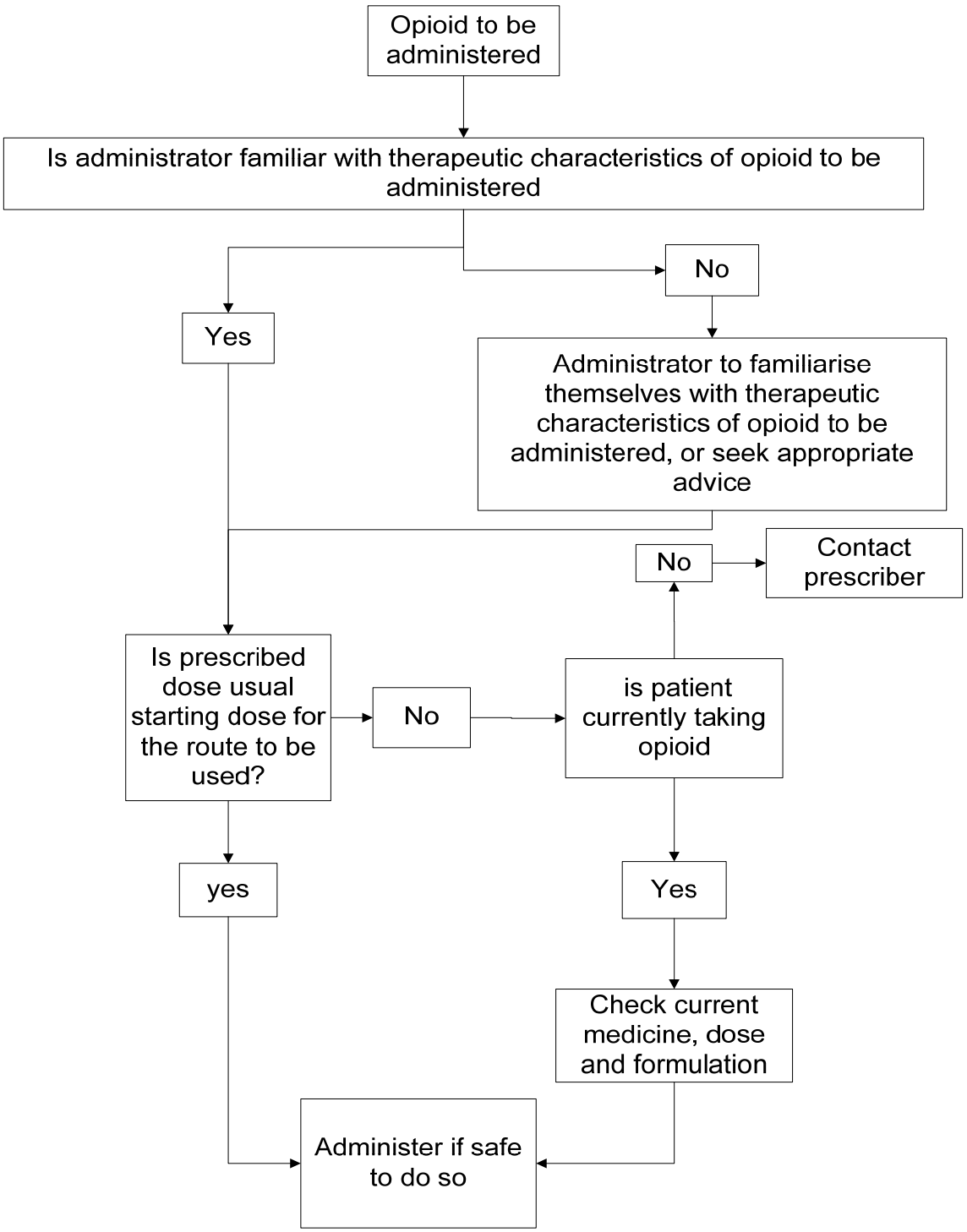
The NPSA has produced some possible algorithms which may be helpful for staff in reducing risks of dosing errors with opioid medicines.

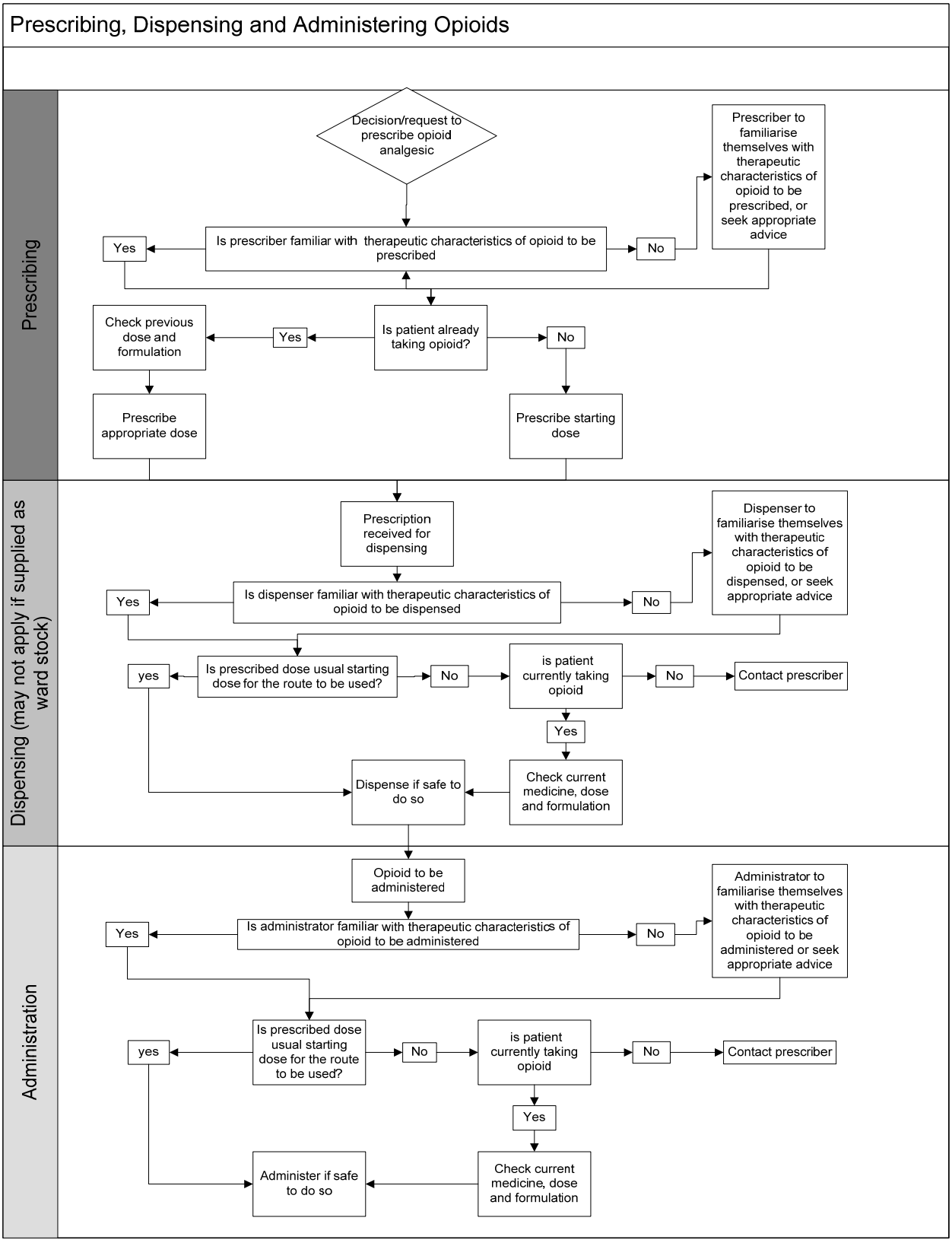


Dispensing Opioids (may not apply if supplied as ward stock)



Administering Opioids




Prescribing, Dispensing and Administering Opioids
Prescribing
Decision/request to prescribe opioid analgesic
Is prescriber familiar with therapeutic characteristics of opioid to be prescribed
Yes
No
Prescriber to familiarise themselves with therapeutic characteristics of opioid to be prescribed, or seek appropriate advice
Is patient already taking opioid?
Yes
No
Check previous dose and formulation
Prescribe appropriate dose
Prescribe starting dose
Dispensing (may not apply if supplied as ward stock)
Prescription received for dispensing
Is dispenser familiar with therapeutic characteristics of opioid to be dispensed
Yes
No
Dispenser to familiarise themselves with therapeutic characteristics of opioid to be dispensed, or seek appropriate advice
Is prescribed dose usual starting dose for the route to be used?
yes
No
is patient currently taking opioid
No
Contact prescriber
Yes
Check current medicine, dose and formulation
Dispense if safe to do so
Administration
Opioid to be administered
Is administrator familiar with therapeutic characteristics of opioid to be administered
Yes
No
Administrator to familiarise themselves with therapeutic characteristics of opioid to be administered or seek appropriate advice
Is prescribed dose usual starting dose for the route to be used?
yes
No
is patient currently taking opioid
No
Contact prescriber
Yes
Check current medicine, dose and formulation
Administer if safe to do so