Medicines Optimisation Team

SPS QA Symposium

Care Quality Commission

Common Injectable Medicine Themes in CQC Inspections

Morag Ross

17th October 2024

CQC regulations

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

Regulations

12 (1) Care and treatment must be provided in a safe way for service users

12 (2) without limiting paragraph (1) the things which a registered person must do to comply with that paragraph include:

12(2) (f) *sufficient equipment and medicines*

12(2) (g) the proper and safe use of medicines

Common risks?

Medicines in Health and Adult Social Care -2019

Prescribing, Preparation & Administration

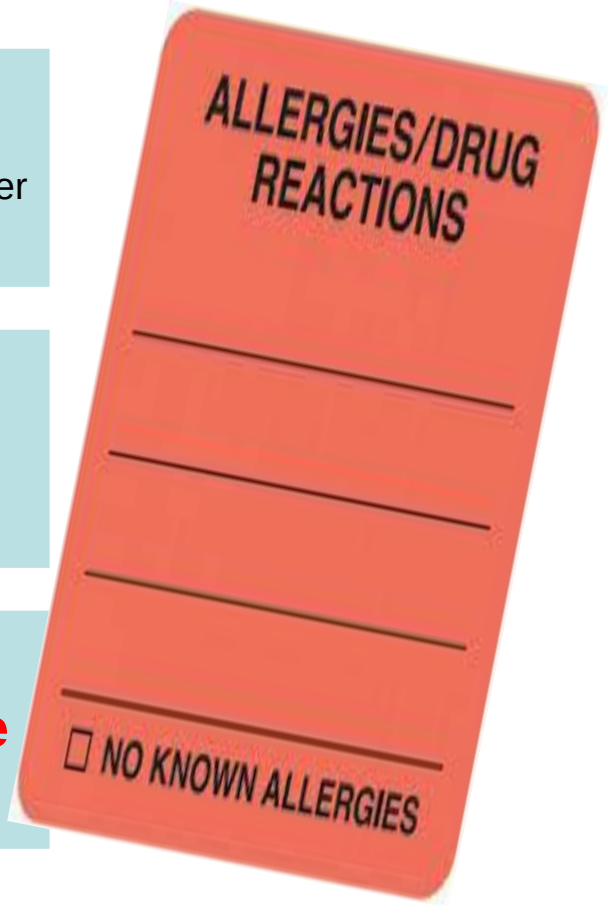
Care Quality Commission

- CONCENTRATION OR TOTAL QUANTITY OF MEDICINE IN THE FINAL INFUSION CONTAINER OR SYRINGE
- NAME AND VOLUME OF DILUENT AND/OR INFUSION FLUID
- RATE AND DURATION OF ADMINISTRATION
- **THE EXPIRY DATE OF THE FINAL PRODUCT**
- TYPE OF RATE-CONTROL PUMP OR DEVICE(S)
- **THE AGE AND WEIGHT OF ANY PATIENT UNDER 16 YEARS OF AGE, WHERE RELEVANT**
- **THE REVIEW DATE OR TIMEFRAME OF TREATMENT**
- FLUID BALANCE OR CLINICAL MONITORING SHOULD BE ON AN INDIVIDUAL PATIENT BASIS

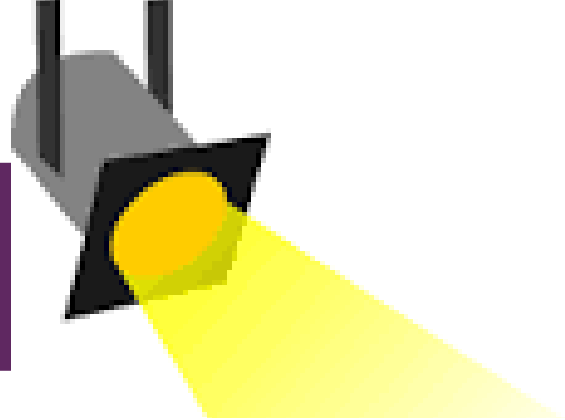
Prescribing

The prescription must include

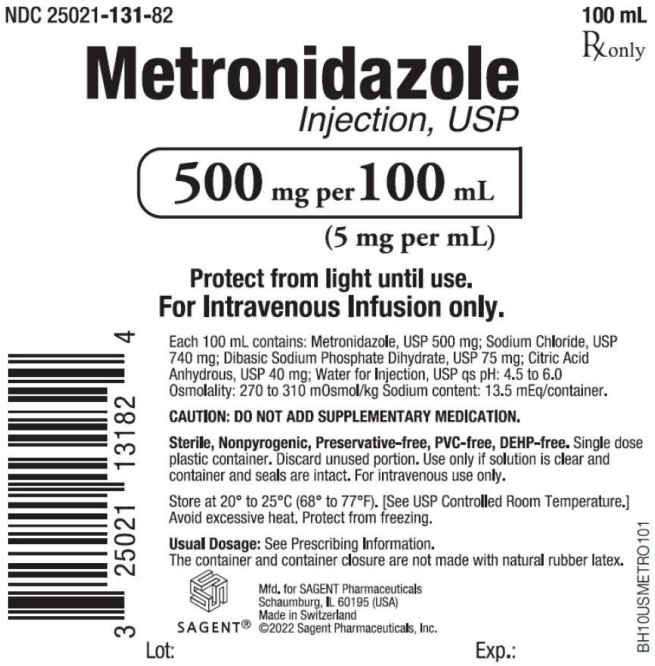
- patient's name
- patient's hospital/NHS number
- prescriber's signature
- the approved medicine name, in full, no abbreviations
- the dose and frequency of administration
- the date and route of administration, for example, intravenous, intra-muscular, sub-cutaneous or epidural
- site of administration where appropriate, for example IM injection
- **the allergy status of the patient**



Storage



Medicines not protected from light out on open shelving



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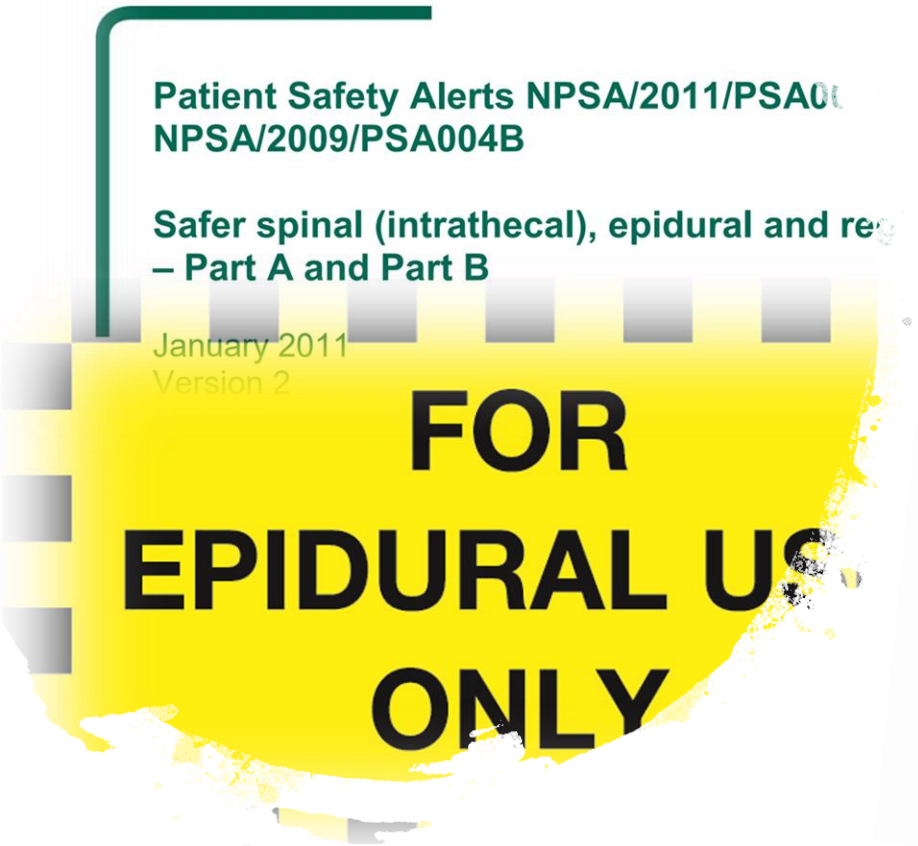
Preparation and Administration

Aseptic Services

- Shortages of trained staff
- Recruitment and retention
- Training

Syringe Drivers

Epidurals



National Patient Safety Alert – Transition to NRFit™ connectors for intrathecal and epidural procedures, and delivery of regional blocks

Published: 31/01/2024

A National Patient Safety Alert has been issued by the NHS England National Patient Safety Team, Royal College of Anaesthetists, Association of Anaesthetists and the Safe Anaesthesia Liaison Group. All NHS funded providers are instructed to complete the transition to NRFit™ connectors for all intrathecal and epidural procedures, and delivery of regional blocks by 31 January 2025.

The NHS has long used a range of medical devices with the universal Luer connector to administer medicines via different routes of administration, including the intravenous, intrathecal and epidural routes.

This commonality of connector carries significant risk of accidental wrong route administration of medication. The potential for a fatal outcome from this, especially if medication for intravenous administration is given via the intrathecal or epidural route, is well known, and previous patient safety alerts have been issued to support providers and staff to reduce this risk.

To overcome this issue a dedicated standard connector (NRFit™) for procedures and medicines administration involving the intrathecal and epidural route was developed. A full portfolio of these NRFit™ devices is now available for use across the NHS.

NRFit™ devices with this connector are not compatible with Luer connectors, reducing the risk of medication being delivered by the wrong route. For example, medication prepared for intravenous administration in a syringe with a Luer connector cannot be accidentally connected to a device that will deliver the medicine via the intrathecal or epidural route, as the cannula (in the patient) will have a NRFit™ connector preventing connection.

This National Patient Safety Alert instructs all relevant NHS funded organisations, to complete the transition to using these safer connectors by 31 January 2025, for all intrathecal and epidural procedures, and delivery of regional blocks.

EPMA Systems

Allscripts

Better

Cerner

CIS Chemocare

Civica

CMM

Dedalus

EMIS

EPIC

InterSystems

Dedalus - Lorenzo

Dedalus - Medchart

Meditech

NerveCentre

Quadramed

Servelec

System C

TPP

Uni of Birmingham UHB

York Teaching Hospital

Management of acute behaviour disturbance

Appendix 2- an example of a Rapid Tranquillisation protocol in Acute Behavioural Disturbance

Assessment by senior doctor:
- Patient lacks capacity.
- Patient represents a significant danger to him/herself or others.
- Patient requires emergency treatment / investigation.
- Patient is severely agitated.
- Doctor considers patient may have potentially life-threatening ABD.

De-escalation measures undertaken if possible:
- De-escalation techniques / exclusion
- Oral medication – lorazepam 1-2mg (max 4mg per day).

Preparation to ensure RT as safe as possible:
- Senior Doctor with critical care experience.
- Drug drawn up and prepared correctly (Antidotes available if applicable).
- Oxygen and high flow reservoir mask on patient/immediately ready.
- Monitoring equipment (ECG, pulse oximeter, BP, ETCO2).
- Equipment in case of complications (airways, suction, BMV).
- Short Safety Brief.
- Adequate number of personnel.

Choice of drug(s):
Either Ketamine 4mg/kg IM (or titrate to effect IV)
Or
Droperidol 5-10mg IM

If these agents are unavailable, midazolam (5-10mg IM), lorazepam (4mg IM) or haloperidol (5mg IM +/- 2mg lorazepam IM) could be considered. Higher concentrations than typically stocked may be required for IM injection. Large volume injections may need to be administered at multiple sites.

Once sedative taken effect:
- Establish and secure intravenous access.
- Monitor in a high dependency area (Resus Room).
- Maintain sedation with IV bolus medication until definitive management plan arranged.
- Correct electrolyte / glucose / acid-base abnormalities, correct hyperthermia, look for evidence of DIC or rhabdomyolysis.
- Institute other emergency treatments and investigations as necessary.

Document clearly in the clinical notes:
- Indication(s) for RT & any attempts at de-escalation.
- Mental capacity assessment.
- Restraint, Collateral history, Features consistent with ABD, Police involvement.

NOTES

- In general, dosages described are for 'average' sized adults, the dosage may need to be varied according to body habits, age (reduce dose by half in the over 65yrs) and according to other medication which may have recently been taken.
- **Flumazenil** should be available as a precaution if using parenteral benzodiazepines. Initial dose 200mcg slowly.

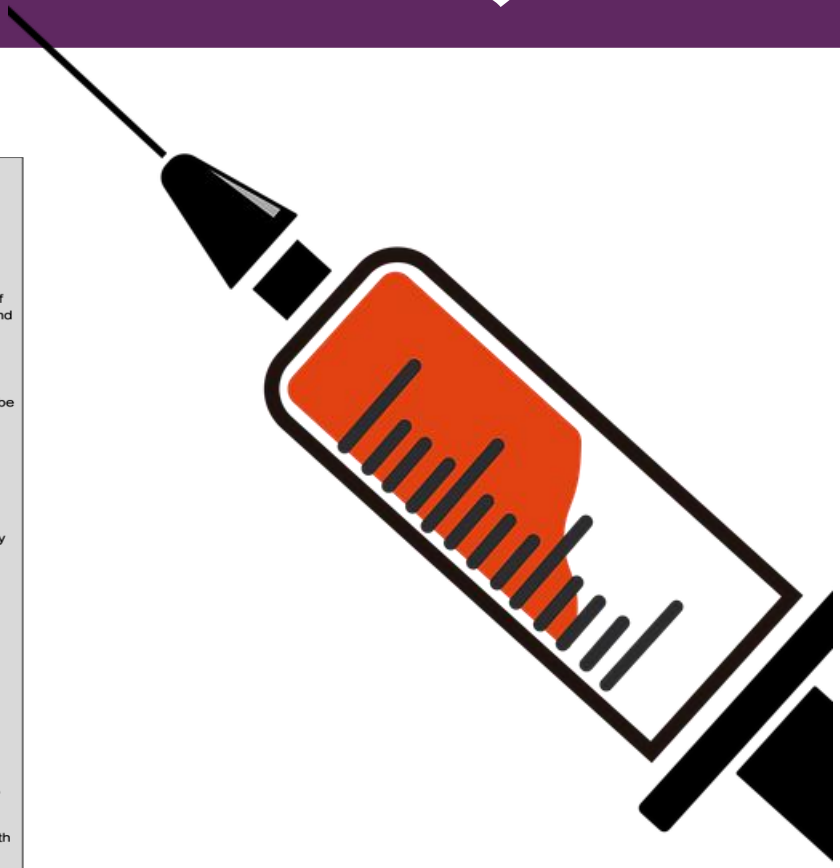
Flumazenil can be hazardous, particularly in mixed overdoses involving tricyclic antidepressants or in benzodiazepine-dependent patients.

- **Maintenance of Sedation**

Diazepam
0.3mg/kg IV

Lorazepam
0.03mg/kg IV

Consider:
Chlorpromazine 25-50mg IV in-addition to benzodiazepines for cases of **suspected serotonin toxicity** with severe psychosis or hyperthermia.



Care Quality Commission

Quarantine and recall

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

A Guide to Defective Medicinal Products

A Guide for Patients, Healthcare Professionals, Manufacturers and Distributors for reporting, investigating and recalling suspected Defective Medicinal Products.

Published August 2021

Medicines Optimisation Team

Clinical Homecare

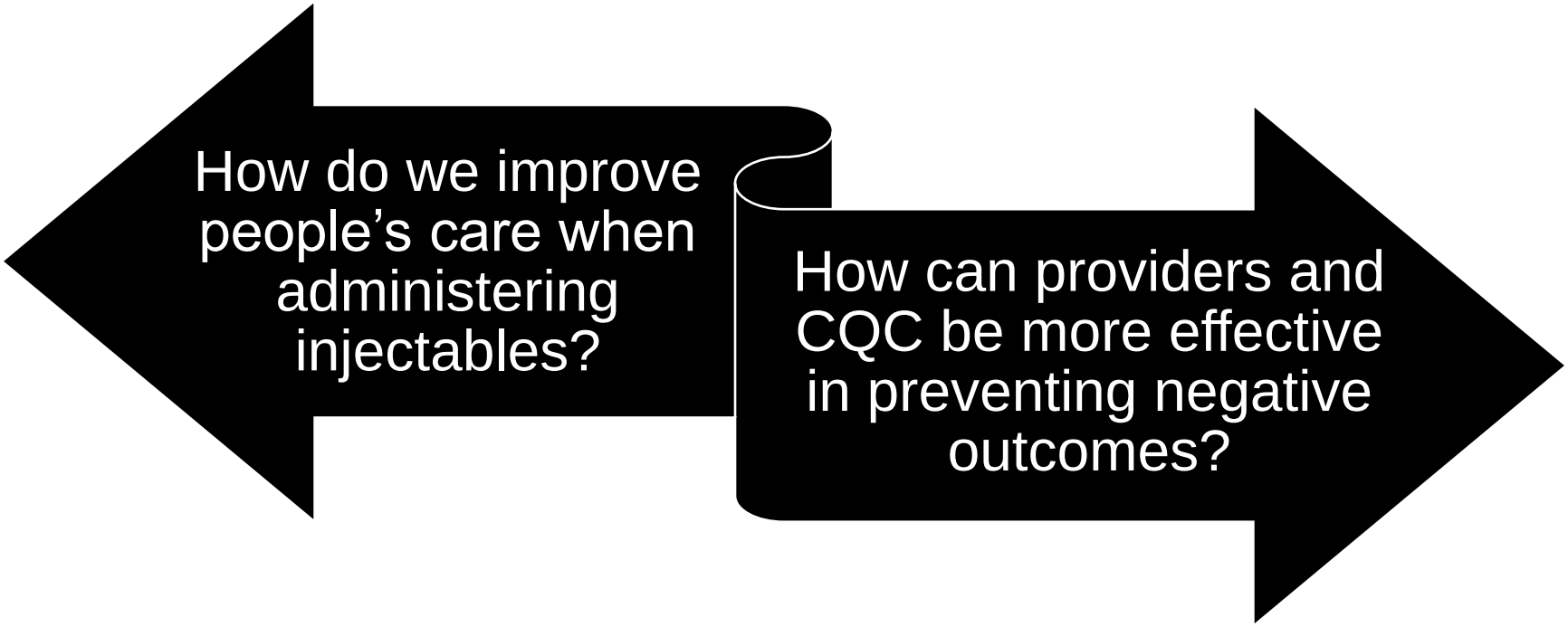
Care Quality Commission

Inquiry into Homecare Medicines Services

House of Lords Public Services Committee Inquiry

21 June 2023

What next?


How do we improve people's care when administering injectables?
How can providers and CQC be more effective in preventing negative outcomes?

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