Clinical Monitoring of Controlled Drugs

Background

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009, require organisations to have in place adequate and up to date standard operating procedures covering:

- Who has access to the controlled drugs;
- Where the controlled drugs are stored;
- Security in relation to the storage and transportation of controlled drugs;
- Disposal and destruction of controlled drugs;
- Who is to be alerted if complications arise; and
- Record keeping, including:
  - Maintaining relevant controlled drugs registers and
  - Maintaining a record of Schedule 2 controlled drugs that have been returned by patients.

The Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations (Northern Ireland) 2015[1] came into operation on 16 July 2015 and require procedures to now also include, best practice relating to:

- the prescribing, supply and administration of controlled drugs, and
- clinical monitoring of patients who have been prescribed controlled drugs.

This paper provides guidance to organisations regarding requirements for clinical monitoring of patients who have been prescribed controlled drugs.

Processes already in place to comply with the amended Regulations

Organisations across Northern Ireland have a range of procedures in place for managing controlled drugs which include aspects of clinical monitoring of patients prescribed controlled drugs. It is important that procedures are reviewed to incorporate the clinical monitoring requirements outlined below.

Clinical monitoring of patients who have been prescribed controlled drugs

The following points should be included within procedures for clinical monitoring of all patients prescribed controlled drugs:

- Who is responsible for carrying out the monitoring and within what timescales
- What should be monitored (and how). Examples of this include:
  - therapeutic benefit

    - dosage and compliance
    - effects of dose increases/medication changes
    - response in relation to treatment plan
    - adverse effects/toxicity
    - effect on driving/operating machinery
    - long term risks eg addiction
    - effects of other co-morbidities eg ckd
    - drug interactions/contraindications
    - continued appropriateness

- Action to be taken where necessary including where there are concerns

- Patient education including risks

- Clinical records of monitoring activity

- Reporting of adverse incidents for shared learning

A range of guidance documents is available to support the development of best practice clinical monitoring procedures. *See Appendix 1*.

Action

1. Review the guidance documents in Appendix 1 below as appropriate.

2. Develop your procedures for the clinical monitoring of all patients prescribed controlled drugs, ensuring that these procedures include the items above.

3. Keep these procedures under review, specifically with reference to changes to any of the guidance documents.

1. http://www.legislation.gov.uk/nisr/2015/278/contents/made

Appendix 1

The following guidance should be referred to where relevant in the development of best practice clinical monitoring procedures. (Note: this list is not exhaustive).

Regional Guidance

- Northern Ireland Guidelines on Converting Opioid Analgesics for adult use
- Reducing dosage errors with opioid medicines - incomplete cross tolerance - letter to GPs
- Guidance for the Management of Symptoms in Adults in the Last Days of Life (Regional Palliative Medicines Group)
- GAIN: General Palliative Care Guidelines for the Management of Pain at the End of Life in Adult Patients
- Primary and Secondary Care Opioid Substitute Treatment Guidelines
- Morphine first line strong opioid
- Opioids in Chronic Pain

HSCB Guidance

- Medication Review Guidance for Primary Care Prescribers
- Medicines Safety Advice Letters: Transdermal Fentanyl Patches, Risks with Buccal Midazolam, Prescribing and Dispensing Controlled Drugs http://www.medicinesgovernance.hscni.net/primary-care/medicines-safety-advice-letters/

National Patient Safety Agency (NPSA) Guidance

- NPSA RRR: Reducing risk of overdose with Midazolam
- NPSA RRR: Reducing dosing errors with opioid medicines
- NPSA Safer Practice Notice: High strength Morphine and Diamorphine

Other

- British National Formulary
- Product Summary of Product Characteristics
- National Early Warning Scores https://www.rcplondon.ac.uk/projects/outputs/national-early-warning-score-news
- British Pain Society Guidance https://www.britishpainsociety.org/british-pain-society-publications/professional-publications/
  The British Pain Society aims to produce up-to-date guidance, supported by available evidence, on clinical and other pain matters, for patients and healthcare professionals.
- The Pain Toolkit http://www.paintoolkit.org/

It is expected that the following will be updated in due course with guidance in relation to clinical monitoring of CDs:

- HSCB Guidance for Developing CD Procedures for Primary Care Prescribers
- DHSSPS Guidance for the Safe Management and Use of Controlled Drugs in Primary Care
- DHSSPS Guidance for the Safe Management and Use of Controlled Drugs in Secondary Care