# Key risks and implications associated with managing patients with complex pharmaceutical (and medical) needs in the community

# A Case Study


**Julie McCann**
**Head of Pharmacy**
**Controlled Drug Accountable Officer**
**Medication Safety Officer**
**NHS England South (South Central)**

# Background; raising concerns

- Concerns were reported by a community pharmacist and general practitioner to their respective Controlled Drug Accountable Officers (CDAOs) in April 2016 about a **substantial loss** of a number of controlled drugs
- These losses occurred over a 3 months period post-hospital discharge, following a long term hospital stay
- Whilst the subsequent investigation was in relation to the controlled drug losses, it became clear that there were a **significant number of 'system failures'.** As CDAOs, our statutory responsibility was around CD management, but the implications apply much wider than just CDs
- As such, the focus today will be not be around the controlled drug loss but the wider multi-agency issues and concerns that were identified and steps that can be taken to both improve patient care and protect the patient, their families, carers and healthcare staff

# Overview of the case

- Patient with **extremely complex medical and pharmaceutical needs**
- Required vast quantities of injectable CDs for pain management
- Long-term in-patient (approx. 3 years) discharged into the community with a full Continuing Healthcare (CHC) package
- **No advance arrangements made for primary medical services or pharmaceutical services to support the patient**
- 4 months after discharge concerns were raised about the traceability of 100s of oxycodone ampoules
- During the investigation into the missing oxycodone, large discrepancies of morphine, tramadol and cyclizine ampoules were also identified and the investigation was widened to include these

# Additional background

- The patient had only recently registered with their GP practice (while they were still in hospital)
- GP was invited to the **discharge planning** meeting (Summer 2015) but was unable to attend and **no further communication** was made until November 2015 to inform of the planned discharge at the end of that month
- Following some home-leave sessions, the patient was discharged into domiciliary care with 24/7 nursing care support.
- **No formal arrangements or plans around medicines management were made between secondary care and those involved in the ongoing care in the community**
- **No medicines management standards around self-medication and controlled drugs were applied as there were no national/local guidelines or standards** that specifically met the circumstances of the care package

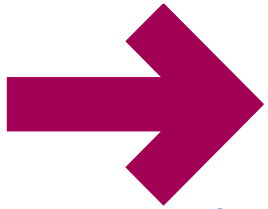
# Patient medication on discharge

The patient was discharged on the following medication regimen:

- **Tramadol 100mg IV Four times daily**
- **Oxycodone 12mg SC When required, weaning down dose - Max 12mg 2 hourly**
- **Cyclizine 50mg IV Four times daily**
- **Lorazepam 2-4mg IV Once daily**
- Paracetamol 1g IV Four times daily
- Hydrocortisone 50mg IV once daily (aim reducing dose)
- Fludrocortisone 100mcg At night via PEG
- Amitriptyline 10mg at night via PEG
- Omeprazole 40mg IV Once daily
- Ranitidine 50mg IV Three times daily
- Hysoscine butyllbromide (Buscopan®) 20mg IV Four times daily
- Midrodine 2.5mg Four times daily via PEG
- Ondansetron 4mg IV Three times daily
- Daltaparin (Fragmin®) 500 UNITS SC Once daily
- Chlorphenamine 10mg IV Four times daily
- Sodium cromoglicate 100mg Three times daily via PEG
- Teicoplanin
- Tazocin (Piperacillin with Tazobactam)
- Maxitrol® ointment once daily

# NHS Continuing Healthcare

- NHS Continuing Healthcare refers to a package of on-going care for adults that is arranged and funded solely by the NHS where the person has a 'primary health need'.
- This care is provided to meet needs that have arisen as a result of disability, accident or illness. NHS Continuing Healthcare provision might take the form of a care home placement, or a package of care in the individual's own home or elsewhere.
- In order for someone to receive NHS Continuing Healthcare funding, they have to be assessed according to a legally prescribed decision-making process to determine whether they have a 'primary health need'



# NHS Continuing Healthcare

- Individuals in receipt of ongoing or long-term care through NHS Continuing Healthcare are amongst the most vulnerable and dependent people in our society.
- Following a holistic assessment of the individual's needs, deciding whether someone has a 'primary health need' which makes them eligible for NHS Continuing Healthcare also requires consideration of the lawful limits of local authority powers.
- In order to do this Practitioners are required to use a **national Decision Support Tool** which records a individual's needs across 12 areas, known as domains.
- **Drug therapies and medication** are one of these domains

Is the focus too much on whether an individual's primary need is health or social care (and who will pay), rather than what care and support that individual requires?

Is sufficient consideration given to how complex healthcare will be delivered in the community settings, including the management of complex pharmaceutical need (often involving high risk medication)?

# Domain: Drug therapies and medication (symptom control)

- **No need**: Symptoms managed effectively, without problems and not resulting in unmanageable side-effects (no need)
- **Low need**: Requires supervision / prompting but shows compliance OR mild predictable pain
- **Moderate need**: Requires administration of meds due to non-concordance/ compliance or type of medication OR moderate predictable pain or other symptoms having a moderate effect on care
- **High need**: Requires administration and monitoring with specific training needs due to risks, BUT with monitoring, condition is usually non-problematic to manage, OR moderate pain or other symptoms having a significant effect on care
- **Severe need**: Requires administration and monitoring with specific training needs due to risks; EVEN with monitoring, condition is usually problematic to manage, OR severe recurrent pain that does not respond to symptoms OR risk of non-concordance with medication, with risk of relapse
- **Priority**: Drug regime that requires daily monitoring by a nurse to ensure effective symptom and pain management associated with a rapidly changing and/or deteriorating condition OR unremitting and overwhelming pain despite all efforts to control pain

# Investigation summary

It was not possible to determine what happened to a large number of controlled drugs, or why or how the discrepancies have occurred. However, in the course of the investigation, the following issues were identified:

- Health care professionals **did not always follow best practice** or their processes with respect to the handling of Controlled Drugs (the handling of non-CDs was not investigated)
- There were **gaps where processes were not in place**. This applied to all aspects of the care including in the hospital as a long-term in-patient and during subsequent short-term admissions, at discharge and care provided by the GP, community pharmacist and nursing staff in the domiciliary setting
- **Conflicts between patient preferences** (when in their own home) over care provision **and the requirements of healthcare professionals** to work within their codes of practice were identified
- The case has highlighted the need to ensure that **all aspects of medicines management are specifically considered** when patients are discharged into a domestic setting.

In all, 26 recommendations were made regarding the use of controlled drugs in the home environment in order to provide additional governance and provide protection to the patient, family and healthcare professionals providing care.

# GP and community pharmacy issues

- The GP acted proactively and promptly in trying to manage the complex needs of the patient BUT difficult to manage the care due to large volume of letters, communications and prescription issues
- Safeguards were put in place in the home but were not being used as expected by GP and CCG
- Presence of 24 hour care led to a further false sense of security
- The GP provided additional prescriptions due to false assurance of stock and records
- The pharmacist should have had closer oversight clinically to the quantity being provided. The complexity of the prescriptions most likely contributed to this oversight

# Agency Management & Nursing Staff issues (CHC Commissioned 24/7)

Sometimes, nurses were sent home because the patient (or family member) did not want them in the house. This made **formal monitoring of care standards and processes by nursing staff difficult**

Specific concerns, issues and complaints regarding the provision of care were reported by 4 individual nurses to their agency during the 4 month period of investigation

Concerns raised specifically regarding medicines and clinical care included:

- **Excessive self administration** of cyclizine
- Asked to confirm broken boxes of oxycodone, that hadn't been witnessed
- **Lack of professional oversight** regarding medicines management, particularly CDs
- Exclusion from the room so **unable to observe** medicines administration
- Refusal of other medicines
- **Requests to work contrary to NMC code**
- **Lack of support and direction** from agency with regard to medicines management

These concerns were responded to verbally by the agency. The agency made it clear that **the care preferences and choices of the patient should be paramount within the confines of safe and acceptable professional practice.**

They agreed there was **a fine balance between providing managed care as would be expected in other care settings and the provision of care in the home environment where the patient has the capacity to take decisions and make their own choices**.

# Key themes around medicines management provided by nursing care

- **Disagreements between nurses and the patient** regarding administration of medicines.
- Nurses **unable to manage medicines in line with their usual standards** due to domestic environment and patient autonomy
- **Lack of control or oversight** of medicines administration
- No control over storing and record keeping
- Self administration by the patient made **monitoring difficult**
- Requests that nurses sign the CD register to 'witness' broken or lost ampoules
- Multiple staff with different ways of working made **consistency in approach** and lines of communication very difficult
- **No clarity over expectations regarding medicines management** in the home environment.
- The **chaotic and inadequate management of CDs** in the domestic environment was primarily due to a **lack of standards and guidance**.
- **Record keeping and medicines storage were not considered acceptable** and in line with NMC standards
- Nursing staff were placed in difficult situations whereby normal standards of professional practice around medicines management were compromised by the wishes of the patient to self-manage in their own home.

# Conclusions

- The **discharge planning** for the complexity of this patient with regard to medicines management, governance and medication supply routes was **inadequate with insufficient involvement of all the primary stakeholders** who would be involved in the ongoing care
- The GP recognised that the case was outside his competency and asked for support. Process was not always followed and there were some issues with managing information across the interface
- **CD management was inadequate and chaotic** in the domestic environment. A lack of process and protocol for CDs for this patient was a contributory factor.
- Provision of NHS funded CHC in this specific domiciliary environment **created tensions** between professional standards and the aspiration to put the patient and their wishes at the centre of the care package.
- The **large quantities of controlled drugs and complexity of the case** were a **specific risk with respect to medicines management**. This was not recognised by all parties involved and insufficient safeguards were in place to monitor the supply and administration of medicines.
- The contracting arrangements and associated care standards for the provider meant that it was not **possible to adequately monitor the delivery of care services** to the patient.

# Recommendations for Wider Dissemination and Learning

**Commissioners:**

- Ensure that **all patients in receipt of CHC services have their needs regarding medicines management properly assessed prior to discharge**.
- There should be **appropriate standards for care**, assessment thresholds for service provision and escalation processes should patient needs change.
- Where **complex pharmaceutical needs are identified**, consider commissioning enhanced primary care medical and pharmaceutical services to support CHC patients as part of the overall care package. Where CDs are involved, adherence to CD legislation must occur
- Ensure there is **clarity and agreement between provider agencies, healthcare professionals, patients, and commissioners regarding the medicines management arrangements expected for each CHC case**. This should include clear lines of responsibility for monitoring and/or administering of high risk medicines and effective communication processes with lead clinicians
- Ensure that primary care contractors are aware **how to report concerns** regarding CD use and management with systems in place to ensure prompt assessment and appropriate response to concerns or intelligence.
- **Care for highly complex patients should be co-ordinated by a clinician competent to undertake the clinical decisions required** to ensure the best possible outcome for the patient. This should be a named clinician who coordinates and is accountable for the multidisciplinary care.

# Recommendations for wider dissemination and learning

**Providers of NHS funded CHC**

- Should **risk assess the medicines management requirements of the patient before the start of any care package** and ensure that their systems and processes are appropriate and effective, particularly for CDs
- Ensure that **regular review of medicines management requirements** for patients receiving NHS funded care is included within the routine assessment of the patient
- Have **SOPs for all aspects of medicines management relevant to each care scenario**, including a specific CD management SOP in line with NMC standards
- Ensure that there are **appropriate mechanisms in place for staff to raise concerns** regarding the provision of care, how concerns will be addressed and how actions will be reported

# Recommendations for wider dissemination and learning

**Healthcare Professionals**

Community pharmacists:

- Should maintain **auditable records when supplying and delivering CDs**.
- Should ensure they carry out a **clinical check on each prescription** ensuring the care, well-being and safety of the patient is paramount
- Where there are significant quantities of controlled drugs or other high risk medicines, consideration to be given to additional recording

Prescribers:

- Should consider prescribing CDs with **reduced intervals** where doses or quantities may be considered as higher than standard practice levels.

All Healthcare professionals:

- Should provide advice and information to people who are prescribed controlled drugs about **how to store controlled drugs** safely taking into account all risk factors and patient preference

# On a positive note

- At an early stage, the GP requested advice from the CCG Medicines Management team regarding the management of medicines for this patient. Concerns centred on destruction of unused controlled drugs and the large quantities involved. This resulted in additional safeguards being put into place and enabled the discrepancy to be identified
- The GP acted proactively and promptly in trying to manage the complex needs of the patient
- The pharmacist provided a very customer focused service beyond that normally expected
- The GP and pharmacist undertook a joint initial investigation when concerns were first highlighted and escalated these concerns promptly