Department of Health

From the Baroness Blackwood
Parliamentary Under Secretary of State (Lords)

Department of Health
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Your Ref: 8223/CH
Our Ref: PFD-1161533

21 FEB 2019

Ms Alison Mutch OBE
HM Senior Coroner, Manchester South
HM Coroner's Court
1 Mount Tabor Street
Stockport
SK1 3AG

Dear Ms Mutch

Thank you for your correspondence of 28 December to Matt Hancock about the death of Mrs Joan Wright. I am replying as Minister with portfolio responsibility for medicines.

Firstly, I would like to say how sorry I was to read of the circumstances of Mrs Wright's death. If you have the opportunity to do so, please pass my condolences to her family.

I have noted carefully the matters of concern in your report relating to the management of controlled drugs.

You mention the Shipman Inquiry in your report. In response to the Shipman Inquiry's Fourth Report[1], there have been significant changes in the governance arrangements for the use and management of controlled drugs.

The Home Office put in place tighter controls through Regulations covering prescribing, record keeping and safe custody of controlled drugs, and the then

[1] http://www.nicpld.org/nes/assets/4thShipmanreport.pdf

Department of Health, implemented The Controlled Drugs (Supervision of Management and Use) Regulations 2006 (the 2006 Controlled Drugs Regulations) (as amended)[2]. These Regulations mandated health care organisations to put in place standard operating procedures on the prescribing, supply and administration of controlled drugs and the clinical monitoring of patients.

The 2006 Controlled Drugs Regulations also require the appointment of a Controlled Drug Accountable Officer (CDAO). This Officer has statutory responsibility for the safe management and use of controlled drugs within their organisation. These Officers are required to work with healthcare providers, regulators and enforcement authorities, including Controlled Drug Liaison Officers (CDLOs), through local intelligence networks (CD LINS) to share any concerns about the use and management of controlled drugs.

The 2006 Controlled Drug Regulations were replaced by the current version of the Regulations in April 2013[3]. This replacement was largely due to the approval of the Health and Social Care Act 2012 by Parliament, which led to the removal of primary care trusts (PCTs) and therefore required the responsibilities and powers of PCT CDAOs to be transferred to the then-new NHS Commissioning Board (now NHS England). Under the 2013 Regulations, clinical commissioning groups are not 'designated bodies' but are named as 'responsible bodies'. The responsibilities of 'responsible bodies' are set out in the Regulations.

NHS England Area Teams are responsible for the appointment of a lead Controlled Drugs Accountable Officer to ensure that systems are in place for the safe and effective management and use of controlled drugs and that these systems are working effectively in their region.

A statutory post-implementation review of the revised 2013 Regulations will be undertaken and published before 31 March 2020. I hope this information is helpful and provides assurance that the Regulations will be reviewed to ensure their continued effectiveness.

More generally, the NHS has taken important steps towards improving the safety of medication.

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[2] http://www.legislation.gov.uk/uksi/2006/3148/contents/made

[3] https://www.legislation.gov.uk/uksi/2013/373/contents/made

The chief pharmacist role, following the report Pharmacy in England (2008)[4], was identified as the organisational lead for medicines safety, and a Patient Safety Alert in 2014 required all organisations to identify the role of Medicines Safety Officer to coordinate local medicines safety processes and work collaboratively nationally.

NHS Improvement and the Medicines and Healthcare Products Regulatory Agency (MHRA) jointly support a network of Medication Safety Officers and Medical Device Safety Officers.

In addition, as part of the Government's response to the World Health Organisation's patient safety challenge on medicines safety, we are developing a programme of work led by NHS Improvement to improve medicines safety. Work is underway to accelerate the roll-out of electronic prescribing to controlled drugs and medicines administration, and to deploy more clinical pharmacists in primary care and care homes. We have also introduced monitoring of the highest risk prescribing practice linked to hospital admissions.

Furthermore, in response to the Gosport Inquiry[5], NHS England has initiated the following actions:

- A review of the governance and leadership of the Controlled Drug Accountable Officer role in NHS England;

- A review of the operation of the lead Controlled Drug Accountable Officers in NHS England, including the effectiveness of Local Intelligence Networks; and

- An assurance process to assess how 'designated bodies' (which include NHS trusts and foundation trusts) are reflecting on the learning from the

[4] https://www.gov.uk/government/publications/pharmacy-in-england-building-on-strengths-delivering-the-future

[5] https://www.gosportpanel.independent.gov.uk/media/documents/070618_CCS207_CCS03183220761_Gosport_Inquiry_Whole_Document.pdf

Gosport Panel report and reviewing arrangements in their organisation in the light of it.

More broadly, system governance is provided by the Care Quality Commission (CQC), which ensures that health and adult social care providers maintain a safe environment for the management of controlled drugs in England. The CQC reports its findings through individual local inspection reports and by means of published annual updates to Government.

It is clearly of great concern that the maladministration of a controlled drug to Mrs Wright occurred at a time when the care home was being monitored by the local authority.

It is the registered provider and the registered manager's responsibility to ensure the proper and safe management of medicines and guidance is available to support them to achieve this. The National Institute for Health and Care Excellence (NICE) has produced a national guideline on the '*Safe use and management of controlled drugs* '(NG46)[6], published in 2016, and a social care guideline (SC1), published in 2014, provides guidance on '*Managing medicines in care homes* '[7]. Furthermore, the CQC has clear guidance on its website on '*Storing controlled drugs in care homes*'[8].

I note your comment about the definition of 'regular'. I am advised that guidance with regard to checking stocks is given within the NICE guidance NG46. This makes clear that providers should develop a controlled drugs policy and standard operating procedures for storing, transporting, destroying and disposing controlled drugs. Detailed guidance is provided on process and procedures for storage, stock checks and audits, including on the frequency of stock checks.

While no system can ever completely prevent the mismanagement or misuse of controlled drugs, we believe the measures that have been put in place mean that the inappropriate use of opioids and other controlled drugs can be detected more quickly and minimised, so that protracted poor practice is less likely to continue unchecked.

[6] https://www.nice.org.uk/guidance/ng46
[7] https://www.nice.org.uk/guidance/sc1

[8] https://www.cqc.org.uk/guidance-providers/adult-social-care/storing-controlled-drugs-care-homes

Department of Health

Your report raises concerns about the actions of Greater Manchester Police in responding to the potential safeguarding risks following the incident report of maladministration of Oramorph to Mrs Wright, and questions if learning from this incident has been shared at a national level.

The Health Act 2006 placed a greater emphasis on Controlled Drugs Liaison Officers being involved in not only the investigation of offences concerning controlled drugs in the health service, but also intelligence and partnership working; particularly through CD-LINs.

As CDLOs are employees of the police force, I would suggest taking up this point with the Home Secretary, the Right Honourable Sajid Javid.

Yours Sincerely

Nicola

NICOLA BLACKWOOD