Department of Health & Social Care

From the Lord Bethell
Parliamentary Under Secretary of State for Innovation

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[redacted]

Your Ref: [redacted]

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Mr James E Thompson
HM Assistant Coroner, County Durham & Darlington
HM Coroner's Office
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Bishop Auckland DL14 4FY

01 December 2020

Dear Mr Thompson

Thank you for your letter of 3 September to Matt Hancock about the death of Laura Eve Parsons. I am replying as Minister with responsibility for data and technology and medicines and I am grateful for the additional time in which to do so.

I would like to say how sorry I was to read of the circumstances of Laura Parsons' death and I offer my heartfelt condolences to her family and loved ones. I can appreciate how deeply upsetting Laura's death must be for her family and those who loved Laura and we must do all we can to learn from the circumstances of her death to prevent such tragedies from occurring again.

In preparing this response, my officials have taken advice from NHS England and NHS Improvement (NHSEI); NHSx, the body responsible for developing best practice for NHS technology, digital and data; the National Institute for Health and Care Excellence (NICE) and the Care Quality Commission (CQC).

First, it may be helpful if I explain that prescribers are expected to take account of NICE guidance when making treatment decisions with their patients. NICE National Guideline 46: *Controlled drugs: safe use and management*[1], gives recommendations on the prescribing of controlled drugs that include:

- Taking into account the benefits of controlled drug treatment and the risks of prescribing, such as dependency or overdose;

- Documenting the regimen (dosing and frequency, quantity to supply) in the patient's care record and including dosage instructions on the prescription (with the maximum daily amount or frequency of doses) so this can be included on the label when dispensed;

[1] https://www.nice.org.uk/guidance/ng46

- Checking a person's clinical needs and if appropriate, adjusting the dose until a good balance is achieved between benefits and harms; and,

- Discussing with the person the arrangements for reviewing and monitoring treatment.

The guideline recommends that when prescribing a repeat prescription of a controlled drug (such as morphine) for treating a long-term condition in primary care, the prescriber should take into account the person's individual circumstances to determine the frequency of review for further repeat prescriptions; and prescribe enough of a controlled drug to meet the person's clinical needs for no more than 30 days (and if, under exceptional circumstances, a larger quantity is prescribed, the reasons for this should be documented in the person's care record).

NICE National Guideline 46 also gives recommendations on governance arrangements and clear lines of accountability, as well as policies, processes and procedures in relation to safe management of controlled drugs. In addition, there are governance processes that should be followed in relation to patient safety incident reporting. For example, NICE National Guideline 5: *Medicines Optimisation*[2] gives several recommendations on systems for identifying, reporting and learning from, medicines-related patient safety incidents.

I am advised by NHSx that electronic clinical systems have the facility to create alerts or warnings linked to coded problems, conditions and diagnoses that launch when a patient record is opened. In some GP systems, additional capability enables the use of system protocols to create pop-ups that launch during the prescribing process. It is not clear if a flag on the risk of overdose was added to Ms Parsons' patient record. However, GP clinical system best practice is that:

- GP practice staff should ensure all incidences of overdose are added to patient GP clinical system records using the appropriate code;

- GP practice staff should utilise GP clinical system functionality to create warnings/alerts linked to coded entry;

- Repeat requests for Schedule 2 and 3 controlled drugs, such as morphine, should be subject to a strict Standard Operating Procedure within the GP practice with clear lines of accountability and responsibility for staff;

- GP practice staff should review all incoming hospital correspondence relating to incidences of overdose against a patients' list of repeat medications and remove the medication(s) to prevent the patient from ordering further repeat prescriptions;

- GP practice staff should not add controlled drugs to repeat prescribing where clinical risk of an overdose exists; and,

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[2] https://www.nice.org.uk/guidance/ng5

- GP practices should carry out an urgent structured medication review of all patients who have taken an overdose.

All GP practices are expected to have mechanisms in place to review patient safety incidents internally within their practice. In doing so, GP practices should ensure that they meet the recommendations set out in NICE guidance as described above. The findings of reviews into patient safety incidents will usually be shared with their local clinical commissioning group (CCG) and reported to NHSEI for the purposes of national learning[3].

I am informed by NHSEI that the GP practice where Ms Parsons was registered has advised that it has reflected carefully on the circumstances of Ms Parsons' death and the findings of your investigation. This includes a review of its prescribing processes to confirm they comply with NICE guidance, the General Medical Council's *Good Practice Guidance on Prescribing and Managing Medicines and Devices*[4], as well as the regional protocol on prescribing of controlled drugs. In addition to this, I understand that a report on the learning from Ms Parsons' death has been shared with the local clinical commissioning group (CCG), from which there may be further cascade of learning to the wider GP community.

I note that you copied your report to the CQC. As you may be aware, CQC is responsible for making sure that health and social care providers, and other regulators, maintain a safe environment for managing controlled drugs in England.

As part of its responsibilities under the Regulations[5], CQC reports annually on its findings through oversight activity and makes recommendations to help ensure the continuing effectiveness of the arrangements for managing controlled drugs in England.

I am advised by the CQC that it is aware through its analysis of prescribing data, attendance at controlled drug local intelligence networks (CDLINs), and its wider inspection and regulatory work, that patients need to be regularly monitored before repeat prescriptions are issued for controlled drugs across all Schedules.

In its *Controlled Drugs Annual Update for 2019*[6], CQC made the following recommendation to strengthen existing arrangements.

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[3] https://improvement.nhs.uk/resources/reporting-patient-safety-incidents-general-practice

[4] https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices

[5] Controlled Drugs (Supervision of Management and Use) Regulations 2013, amended on 1 April 2020 to the Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations 2020.

[6] https://www.cqc.org.uk/sites/default/files/The_safer_management_of_controlled_drugs_Annual_update_2019.pdf

The level of controlled drug prescribing continues to increase year on year. Unnecessary prescribing for long-term treatment can result in an accumulation of unwanted medicines in patients' homes, which increases waste and the associated risks of misuse. Furthermore, patients commonly do not fully understand the risk of dependence on long-term treatment with many of the scheduled controlled drugs and the importance of returning them to a community pharmacy once they no longer need them. To address this:

- *Prescribers should regularly review patients' clinical needs before prescribing and consider the quantity prescribed, particularly when issuing repeat prescriptions; and,*

- *CQC encourage healthcare professionals to fully explain patients' medicines at the point of prescribing and supply. This should include giving guidance and warnings of the potential for dependence and actions to take, appropriate to patient need.*

CQC will continue to recommend and support measures that strengthen the safe use of controlled drugs in all settings to help improve patient safety.

I hope this information is helpful. Thank you for bringing these concerns to my attention.

With my very best wishes,

Bethell.

LORD BETHELL