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HM SENIOR CORONER
COUNTY OF YORK

Dear Mr Coverdale,

Thank you for your letter of 27th January 2014, concerning the death of Judith Lesley Marshall.

In your letter you helpfully set out the events surrounding the incident. Mrs Marshall, was a 72 year old lady, correctly prescribed *"Morphine Sulphate M/R Capsules 10mg BD SIXTY CAPSULES Quant: sixty (60) capsule".*

Unfortunately a community pharmacy dispensed 60 capsules of Morphine Sulphate at 60mg strength and not 10mg as prescribed. You shared that the box of capsules carried numerous clear references to 60mg capsules. A trainee dispensing technician checked the medication dispensed by the community pharmacist.

Mrs Marshall took the capsules as dispensed to her, twice a day as prescribed (taking 120mg of Morphine per day rather than 20mg). She was found by her husband dead in her bed in the morning.

You asked the following questions:

1) **The Pharmacy's Errors Book shows a number of drug errors (including higher or lower dose tablets and the wrong drugs) over a number of years. It is not clear whether and to what extent such internal records are policed.**

Community pharmacies are required to record patient safety incidents that caused harm or have the potential to cause harm in a pharmacy errors log. They should also report these incidents to the National Reporting and Learning System (NRLS). The aim of recording and reporting incidents is to identify risks to patient safety and ensure that they are addressed both locally and nationally. Community pharmacists and their staff have responsibility to reflect on patient safety incidents that occur and identify safer practice to address these risks. Health care teams and governance systems should be in place to ensure this occurs. In a community pharmacy the responsible pharmacist and superintendent pharmacist have a particular responsibilities in this regard.

Pharmaceutical inspectors from the General Pharmaceutical Council also have a responsibility to review the error log when they inspect a community pharmacy to promote a patient safety culture and ensure that identified risks have been addressed.

I wasn't able to determine, from the information available to me, which of the above safeguards did not operating effectively in the community pharmacy involved in this case. I hope that in sharing your concerns you also contacted the General Pharmaceutical Council, as they will have an invaluable perspective on these issues.

2) Despite a system of checking by a colleague it is apparent that there can be a mistake in dispensing medication which in this case was a controlled opiate drug. The consequences were fatal.

Yes that is true and why we always must review checks in place to determine if they can be improved. Human factors science indicates that a double checking system is never infallible and where the risks resulting from a checking error are high, additional systems are required to further minimise the risks of serious harm.

In a review of medication incidents reported to the NRLS from 2005 to 2010, the largest numbers of incidents resulting in death or severe harm involved errors of prescribing, dispensing and administering opioid medicine, including morphine.

3) It is not clear whether there is any software, obtainable from the Department of Health or elsewhere, that could read prescriptions and raise an alert if the label sought to be created or if the drug sought to be dispensed is wrong in identity or amount. This would be of particular significance when a high risk drug is dispensed or when a drug is dispensed in an unusual quantity, dosage or form.

We are not aware of any such software to check doses of opioids when dispensing. The safe opioid dose is dependent on the patients height, weight, age, clinical condition and other medicines they are taking at the time and very dependent on the dose of opiate that they have previously taken.

The former National Patient Safety Agency issued a Rapid Response Report on Reducing opioid Dosing Errors to the NHS in 2008 recommending the following safer practice:

> *When prescribing, dispensing or administering opioid medicines the healthcare practitioner or their clinical supervisor should:*
>
> - *Confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed for the patient.*
> - *Ensure where a dose increase is intended, that the calculated dose is safe for the patient.*
> - *Check the usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, and common side effects of that medicine and formulation.*
>
> Healthcare organisations should review local medicines and prescribing policies, including Standard Operating Procedures, to reflect this guidance: http://www.nrls.npsa.nhs.uk/resources/?entryid45=59888

In the case of Mrs Marshall, it appears that this was not a dose error in labelling the medicine but a medicine pack mis-selection. However, we wouldn't recommend the practice followed in this case. The NPSA issued a Design for Patient Safety report on the dispensing environment in 2007. In this report it was recommended that selecting medicine packs from labels was unsafe practice and medicines should always be dispensed from the prescription:
.http://www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/?entryid45=59830

4) Mandatory procedures requiring a 'read-back' of the drug, its dosage, its frequency of administration and its total quantity may prevent such dispensing errors. In so far as the error in this case can be attributable to 'Human Error' it is concluded that the dispensing pharmacist focused on the figure of 60 and incorrectly attributed that to the dosage as well as to the number of capsules.

Although a 'read-back' procedures may be helpful. There are no such mandatory procedures in place. I understand that there is no definitive research evidence that this would further reduce dispensing errors.

5) A mandatory check, by a suitably qualified pharmacist or by a third party, at the end of the day after cashing up on the till, of records of each (prescription only) drug dispensed against the prescription would be a further precaution against a repetition of these circumstances.

Although some form of reconciliation of prescriptions and medicines dispensed particularly for Controlled Drugs may be helpful, there are no such mandatory procedures in place. I would welcome a system check such as this but it would require an evidence-base that this would further reduce dispensing errors.

6) There is evidently no central database of all prescription errors so there can be no central monitoring of such errors and no means of determining trends or particular repeat errors.

The National Reporting and Learning System is such a database and in 2012 received 155,000 medication incident reports. Unfortunately only 7,500 of these reports were from community pharmacy, which suggests they are underreporting incidents. Analysis of NRLS medication incident data has identified that dosing errors arising from the prescribing, dispensing and administering of opioid medicines were the largest cause of harm. Patient Safety Alerts have been developed since 2005 based on analysis of incident data in the NRLS.

Other information pertinent to this case.

Increasing reporting and learning from community pharmacy

a) NHS England is in the final stages of negotiating the community pharmacy Contract for 2014/15 and are planning to emphasise the requirement on community pharmacy to report patient safety incidents to the NRLS. We will look to achieve this by stipulating the minimum expected reporting rate and highlighting the requirement for prescribing error.

b) NHS England is preparing to publish a Patient Safety Alert on March 2014 to improve reporting and learning of medication errors from all sectors including community pharmacy. This will include the establishment of a National Medication Safety Network, the identification of medication safety officers in large healthcare provider organisations including community pharmacy companies and other measures into to increase the number, quality, timeliness and learning of medication error incident reports.

c) There have been bar codes on medicine packs for many years. There is research evidence that the use of bar code technology, linked to patient medicine records and electronic transfer of prescriptions in addition to all the existing safeguards could reduce moderately severe dispensing errors by 60%. (see Dean Franklin B, O'Grady K. Dispensing errors in community pharmacy: frequency, clinical significance and potential impact of authentication at the point of dispensing. IJPP 2007, 15: 273–281)

   Unfortunately, there is little use of bar codes in the dispensing process in community pharmacy at present. Greater use of this technology in dispensaries could improve patient safety. The Safe Medication Practice Team in NHS England, plan to undertake a review of community pharmacy incident data, together with relevant research and engage with stakeholders to prepare a Patient Safety Alert for possible publication in 2014. The proposed Alert would better describe the risks arising from dispensing medicines and safer practices to further minimise these risks, including better use of technology and checking systems. This guidance will help inform health care commissioners, providers and regulators of actions that they can take to further minimise risks arising from dispensing medicines.

I hope you find this letter helpful and if you require any further technical Information on this I would be very happy to help.

Please accept my best wishes

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Director of Patient Safety
NHS England