For the attention of Coroner Sabyta Kaushal – [redacted], H.M. Coroner's Officer

Dear [redacted],

Ref. 28 McGauran M.S. 28112018; Alvaston Medical Centre response to 'Action should be taken'

The Coroner, as part of the 'lessons learned' from the inquest of Mrs McGauran, has requested we introduce an action plan to prevent/reduce the risk of future deaths occurring under similar circumstances to that of Mrs McGauran. We welcome any opportunity for improvement in the provision of clinical care.

The Coroner identified Mrs McGauran's 'hoarding' of Codeine as a matter of concern. As part of our ongoing programme of improvement:

1. Taking advantage of the expanding of job roles within primary care, over the period January to February 2021, Alvaston Medical Centre recruited two clinical pharmacists to undergo patient medication reviews. The clinical pharmacist's area of professional expertise means they are ideally suited to conducting structured medication reviews of patients – including extensive knowledge of controlled drugs. As part of the medication review, they explore the patient's compliance and understanding of their medication, along with addressing other concerns within their remit.

2. The structured medication reviews take a patient centred approach, whereby the patient is reviewed holistically, exploring both lifestyle and medication. This includes taking a social history alongside reviewing the compliance of their medication and outlining changes to the medication regime. Lifestyle suggestions are advised based on individual evidence base. The actions and changes proposed are agreed through a shared decision process. The effectiveness of the reviews is dependent upon patient honesty and clarity.

3. Alvaston has also made it good practice, to ensure wherever possible, any high risk scheduled drugs do not form part of the repeat prescription. Furthermore, we have a robust system in place to ensure the prescribing of medications is not automatically ordered too far in advance of their due date. This reduces the risk of any patients 'stock-piling' medication. This is an ongoing project that is constantly being reviewed and refined, and we continue to further assess which areas or medications would benefit from additional surveillance during the prescribing and issuing of the prescription.

None of the above actions have been taken as a response to Mrs McGauran's death (as said, these changes have come about as a result of our ongoing programme of improvement). Ultimately, the above will only reduce the risk of patients stockpiling prescription medications – there is no way to totally eliminate the possibility of a determined patient doing so. And we, of course, will continue to seek further opportunity to reduce that risk for our patients.

Our clinical pharmacists have asked me to clarify with you the point raised in the inquest on the combined toxicity of the two prescribed medications, Citalopram and Codeine. To their knowledge, prescribing these two medications conjointly – and taken to the recommended dosage - should not have led to drug toxicity. We are assuming, based on the concern you have raised, that the patient very significantly exceeded the recommended dosage of these 2 drugs (i.e. overdosed) and that was what caused the fatal level of toxicity?

You have mentioned "alternative pain management aids…(such as Fentanyl patches…)".

The Government's advice on Fentanyl patches Transdermal fentanyl patches for non-cancer pain: do not use in opioid-naive patients - GOV.UK (www.gov.uk) is as follows:

Advice for healthcare professionals:

- fentanyl is a potent opioid – a 12 microgram (µg) per hour fentanyl patch equates to daily doses of oral morphine of up to 45mg a day

- do not use fentanyl patches in opioid-naive patients
- **use other analgesics and other opioid medicines (opioids) for non-cancer pain before prescribing fentanyl patches**
- if prescribing fentanyl patches, remind patients of the importance of:
    - not exceeding the prescribed dose
    - following the correct frequency of patch application, avoiding touching the adhesive side of patches, and washing hands after application
    - **not cutting patches and avoiding exposure of patches to heat including via hot water (bath, shower)**
    - **ensuring that old patches are removed before applying a new one**
    - following instructions for safe storage and properly disposing of used patches or patches that are not needed (see advice issued previously); it is particularly important to keep patches out of sight and reach of children at all times
- **make patients and caregivers aware of the signs and symptoms of fentanyl overdose** and advise them to seek medical attention immediately (by dialling 999 and requesting an ambulance) if overdose is suspected
- **remind patients that long-term use of opioids in non-cancer pain (longer than 3 months) carries an increased risk of dependence and addiction**, even at therapeutic doses (see Drug Safety Update on risk of dependence and addiction with opioids); before starting treatment with opioids, agree with the patient a treatment strategy and plan for end of treatment
- **report suspected adverse drug reactions, including dependence, accidental exposure, or overdose associated with fentanyl patches**, via the Yellow Card scheme

Review of opioid medicines

Considerable concern has been raised regarding the prescribing of opioids in the UK (see Drug Safety Update on risk of dependence and addiction with opioids). In 2019, the Commission on Human Medicines (CHM) convened an Expert Working Group to examine the benefits and risks of opioids in the relief of non-cancer pain.

During this review it was noted that there have been reports of serious harm, including fatalities, associated with fentanyl patches in both opioid-naive patients and opioid-experienced patients. Up to May 2020, we have received 13 Yellow Card reports in which opioid-naive patients have experienced respiratory depression following use of fentanyl and additional Yellow Card reports in which respiratory depression was reported in patients switched from another opioid to an inappropriately high dose of fentanyl. There was no evidence of intentional overdose in these cases.

There is considerable risk of respiratory depression with the use of fentanyl especially in opioid-naive patients. There is also significant risk with too rapid an escalation of dose, even in long-term opioid users.

Fentanyl is a potent opioid analgesic – a 12 microgram (µg) per hour fentanyl patch equates to daily doses of oral morphine of up to 45mg a day. Because of the risk of significant respiratory depression, in non-cancer patients fentanyl patches should only be used in those who have previously tolerated opioids. **CHM has recommended a strengthening of the**

current warnings and a contraindication for use in opioid-naive patients in the UK for non-cancer pain.

The above guidance is reflected in NHS Nottinghamshire County medicines information for staff working in a social care setting (see attached) which advises that "Fentanyl is a strong opioid which is often used in the management of cancer pain". Specific training is required for staff administering fentanyl patches.

The Nottinghamshire guidance mentions 2 specific risks from Fentanyl patches:

- "Ensure the old patch is removed before applying a new one…..a new patch MUST only be applied if the staff are satisfied that the resident does NOT have remaining patches on them"
- Heat (e.g. hot baths, electric blankets, hot water bottles) should NEVER be applied over the top of the patch as it may enhance absorption of fentanyl"

In turn, this advice reflects the outcome of a Coroner's report in England 2011 regarding the death of a 67 year old lady who died after taking a hot batch while wearing 2 fentanyl patches; this led to the Regulation and Quality Improvement Authority reissuing warnings already presented by the Medicines and Healthcare products Regulatory Agency (MHRA) in response to earlier deaths related to the misuse of Fentanyl patches.

In light of the suggestion that Mrs McGauran's death was due to an overdose, pain relief options such as Fentanyl patches would not be considered as a viable safer option.

We hope this addresses the Coroner's concerns. If there is any additional follow up required, please do not hesitate to contact me.

Regards,

[redacted]
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Business Manager
Alvaston Medical Centre

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