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Karen Harrold Coroner's Office West Sussex Records Office Orchard Street Chichester West Sussex PO19 1DD

23rd January 2018

Dear Ms Harrold.

Regulation 28 Report: Inquest into the death of David JACKSON

I am responding to your letter of 10 November 2017 addressed to NHS England, with regard to the Inquest into the death of David Jackson, concluded on 17 October 2017 and noting that you have kindly allowed an extension for the required response date to 22 January 2018.

On receipt of this enquiry NHS England commissioned an independent clinical adviser (Dr Andrew Foulkes FRCGP) to meet with the practice, review the clinical notes and discuss the issues of concern. In order to inform this response, Dr Foulkes reviewed the coroner's regulation 28 report and the clinical record. The practice manager and Dr Yvonne Grant were interviewed, he reviewed the practice's prescribing policy and explored any existing local (Clinical Commissioning Group (CCG)) and national (General Medical Council (GMC) and National Institute for Health and Care Excellence (NICE)) guidance, regarding repeat prescribing and in particular controlled drugs prescribing. In addition he has reviewed the GP's NHS England contractual requirements.

By way of background, Mr Jackson would have been known to his former GP, but rarely attended the Practice. He last saw his GP on the 5th of August 2013 when his prescription for Botobarbital was discussed. Further review of this consultation and the appointment recorded on the computer system suggests that this was more likely to be a face to face consultation. He had been prescribed barbiturates (a controlled drug) for many years, for insomnia. This drug is no longer used in current practice but is still available on a named person basis. It is subject to controlled drug legislation and the guidance is that this drug should be prescribed in 30 days' instalments. A review of the records between 2013 and 2017 confirms that this guidance was followed. Mr Jackson did not have any other medical problems. He was prescribed a mild analgesic for long term back pain but there were no other known active problems.

Mr Jackson rarely attended the surgery. He was invited to attend for yearly influenza and faecal occult blood testing but did not respond to the invitations. There were no recorded medication reviews in 2013 or 2016. The repeat medication card was updated in 2012 but there was no recorded medication review in 2011 or 2012. There was a recorded medication review in 2010 but this was not face to face.

Dr McLeod and two of his partner colleagues either retired or resigned from the practice in 2015. He was allocated to Dr Grant but she never met him. He did have a medication

review on the 23rd of November 2015 and his prescription was continued.

There was no further contact with Mr Jackson. He continued on the same monthly prescriptions which he had taken for many years until his death. The cause of death as recorded by Her Majesty's Assistant Coroner, Karen Harrold was:

- 1(a) Severe pressure sores associated with sepsis, toxaemia and rhabdomyolysis
- 1(b) Prolonged immobility due to a fall and fracture of the hip
- 2 Hypertensive and Ischaemic heart disease

The coroner established that Mr Jackson had fallen, in the weeks before his death. He refused any help and declined any suggestion that he should see his doctor or attend hospital. He passed away on the 17th of July 2017.

Fitzalan Medical Group is a long standing group practice in Littlehampton. For many years it had been a training practice, although with the recent departure of partners this is no longer the case. The Care Quality Commission (CQC) inspected the practice and in January 2016 it gave the practice a 'Good' rating in all categories.

In reference to the coroner's concerns, NHS England's findings are as follows:

- a) Our investigations have established further clarity as to the last time Mr Jackson saw his GP. Further inspection of both the paper records and the computer audit trail indicate that Mr Jackson was likely to have been seen face to face in 2013 by Dr McLeod.
- b) The medication had been prescribed in 28-day quantities which is compliant with the guidance on prescribing controlled drugs. This review has confirmed that there is no definitive national guidance on how often patients taking controlled drugs should be reviewed, nor whether any reviews should be face to face or by telephone or by review of the patient record.

For example, NICE published guidance on controlled drugs in 2016. With regard to repeat prescriptions the guidance says:

When prescribing a repeat prescription of a controlled drug for treating a long - term condition in primary care, take into account the controlled drug and the person's individual circumstances to determine the frequency of review for further repeat prescriptions

The GMC Good practice in prescribing and managing medicines and devices (2013) states:

Whether you prescribe with repeats or on a one-off basis, you must make sure that suitable arrangements are in place for monitoring, follow-up and review, taking account of the patients' needs and any risks arising from the medicines.

There is no direction as to the frequency of such reviews, nor is there any direction on whether a medication review should be face-to-face. As clinical circumstances differ so much between patients, it could be difficult to write guidance that was prescriptive. However, the majority of General Practices recognise the importance of reviewing their patients on repeat medication on at least an annual basis, and their individual policies would normally specify that repeat medication reviews were

offered annually.

Of note, the Fitzalan Medical Practice prescribing policy indicates that 'all patients on a repeat prescription should be reviewed annually'. It doesn't say whether this should be done in the presence of the patient or remotely. In this particular case, there were medication reviews in 2013 and 2015, but none in 2016 or the first half of 2017.

The coroner identified inconsistencies in the arrangements for undertaking medication reviews at Fitzalan Medical Group. The practice has not been adhering to its own prescribing policy with regard to this and fully acknowledges this failing. In the absence of definitive national guidance, and given the difficulties indicated with developing such guidance to cover all patient circumstances, it would be reasonable to review the repeat prescriptions every 12 months, or more frequently as the clinical circumstances dictate. In this particular case, a medication review on an annual basis would have been appropriate bearing in mind this was a very long standing prescription and had remained unchanged for many years.

Finally, there is a question as to whether the medical practitioners involved have adhered to the GMC guidance outlined above. The fact that the opportunity to review the patient's medication was missed on a number of occasions and that Mr Jackson was not seen face-to-face since 2013 is a matter for concern in the context of the manner of his eventual death and does represent a patient safety issue with potential ramifications outside this case, given current guidance. In the first instance this case has been referred to NHS England's local Performance Advisory Group (PAG), the outcome of which, including the option of a referral to the GMC, is awaited. This process can take several months depending on the nature of the investigations and I cannot, therefore, indicate when the PAG will have concluded their enquiries.

c) With further reference to the specific medication Mr Jackson was prescribed, very few patients are now prescribed barbiturates for insomnia. This medicine had been prescribed for 45 years or more. During the 1970s and 1980s this was a commonly used medication to treat this condition. A consultation with Dr McLeod on the 18th of October 2007 records a consultation which notes that other medication (more commonly prescribed benzodiazepines) had been offered but were not favoured by the patient. Under this circumstance, the continuation of this medicine was reasonable and safe. There is no suggestion that barbiturates were linked to the cause of death.

The prescription of co-dydramol was also reasonable and is commonly used on the WHO analgesic ladder for the treatment of mild pain. The coroner has pointed out that there was unused medication in boxes in the house. It is not unusual for patients or their relatives to 'over order' prescription medication. It is not possible to detect non-concordance through routine repeat prescription monitoring.

- d) A review of the clinical system to detect ordering arrangements confirmed that no particular pharmacy was selected by the patient. This usually means that the patient or their representative prefers to collect the prescription from the surgery and take this to a chemist convenient to them. This is a common arrangement, although with electronic transfer of prescription (ETP) this is less common.
- e) The passing of Mr Jackson was not related to the prescriptions of either barbiturates or co-dydramol. The associated findings of hypertension and ischaemic heart disease had not been identified clinically nor had symptoms been reported by the patient. Even if face to face medication reviews had been undertaken annually it is

unlikely that these would have prevented this particular death. Although there have been some care and delivery problems identified, the root cause was a conscious decision undertaken by the patient not to seek medical advice during his final illness. This was consistent with other examples within the medical record where requests for other preventative interventions were declined.

f) Contributing Care and Delivery Factors

Repeat medication reviews

The practice acknowledges that there had been a failure of their repeat prescribing process in organising annual prescribing reviews on a consistent basis. Reviews were present in 2013 and 2015 but missing in 2014 and 2016. This has prompted the practice to undertake a review of their repeat prescribing systems and identify other patients who have not had a completed medication review.

At the time of writing this letter, NHS England is aware that there are a considerable number of patients who have not had it recorded on their medical records using the appropriate code to represent an annual prescription review; this is being analysed further by the practice. Currently the number of patients identified as requiring a review stands at 3,206.

In practice, very few patients on repeat prescriptions will not be reviewed within 12 months since many will be recalled for review of their condition through a separate disease specific recall mechanism. In this particular case, the patient was not on a disease register so he would not be recalled by this process.

2. Changes in partnership, recruitment difficulties and closure of a neighbouring practice

NHS England is aware that during 2015 three partners left the practice. Because of recruitment difficulties the GP practice had to rely on short term locums for much of 2015 and 2016. Their current list size is 17,150. This increased by 3000 in 2016 with the closure of a local practice. Many of those patients have long term physical and mental health issues and it has been challenging for the practice to manage a 20% increase in list size at the same time as such a significant loss of experienced GPs. NHS England accepts that the pressure on the Brighton primary care system has contributed to the recent inability of the practice to follow the standards it has declared for itself.

Regarding the coroner's Matters of Concerns 1 a) b) and c), the actions that NHS England has undertaken are as follows:

Fitzalan Medical Practice

- The Practice has implemented a plan for the backlog of medication reviews to be completed by end of January 2018;
- The review progress is being monitored and discussed at weekly Practice meetings;
- Practice policy for repeat prescribing is being reviewed to develop a more robust fail-safe system including how the prescribing administration team make a GP aware that the review is outstanding;

 Additional slots have been added to into morning surgeries where face to face appointments for medication reviews are deemed necessary;

5. The Practice will undertake audits of repeat prescribing of high risk drugs in 2018 to ensure that they have adequately dealt with them by the above process;

- Clinicians have been recently been updated on new guidance on opioid
 prescribing in non-cancer pain in an in-house educational session and will be
 considering how they can update our prescribing for these patients alongside
 reviewing benzodiazepine prescribing;
- 7. The practice is exploring ways of having more continuity of care for their patients;

8. There has been an award of funding for employing a pharmacist and will engage them to help with this work on an on-going basis;

NHS England provided input into a CQC inspection with a focus on prescribing scheduled for Tuesday 19th of December 2017.

In future, the practice will have a process in place to deal with medication reviews when clinicians leave or large numbers of patients are assigned to the practice.

CCG

- The CCG prescribing advisory team has met with the practice and conducted an independent review of the case. The findings of this review have contributed to this report;
- The findings have been reported to NHS England's Controlled Drug Accountable Officer (CDAO) as well as to the commissioners and the head of medicines management at Coastal West Sussex CCG;
- 3. A request for CCG support in reviewing the practice repeat prescribing system.

The practice intends to work with CQC and the CCG and accept the guidance that they may offer.

National actions

NHS England acknowledges that the issues highlighted in this case may represent a future risk to patient safety within primary care at large. NHS England will refer the arising issues, particularly with regard to the suitability of current guidelines for the issuing of Controlled Drugs prescriptions, to NHS England's national prescribing team for a decision upon whether or not current guidance needs to be amended. Should you require an update on this, I can report back to you by the end of summer 2018.

The above addresses matters of concerns 1a) b) and c)

Regarding the coroner's Matters of Concerns 2 a) b) and c), NHS England review has established that:

- a) Mr Jackson remained on repeat prescriptions for 45 years, having last been seen by a GP on 5 August 2013;
- b) It is most likely that Mr Jackson or his representative collected the prescription from the surgery to take to any pharmacy of their choice;
- c) There were no particular pharmacies selected by the patient with which to establish a regular arrangement.

Summary and Conclusions

NHS England acknowledges the risks to patient safety, particularly regarding the effective review of patient medication at practice level, exposed in your report, and that these risks exist independently of the finding that they are not directly linked to the cause of death in this case.

NHS England considers that there is a robust plan in place to address matters at the practice and CCG level and will request a national review regarding medication reviews for controlled drugs. We undertake to report progress on these issues to you by the end of summer 2018, should you indicate you require such an update.

I hope that my response is helpful to you and Mr Jackson's family.

Yours sincerely,

Professor Sir Bruce Keogh KBE, MD, DSc, FRCS, FRCP

National Medical Director

NHS England