



Department
of Health &
Social Care

From Neil O'Brien MP
Parliamentary Under Secretary of State for Primary Care and Public Health

39 Victoria Street
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Ms Alison Mutch
Senior Coroner
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23 January 2023

Dear Ms Mutch,

Thank you for your letter of 15 June 2022 about the death of Mrs Marjorie Walker. I am replying as Minister with responsibility for Primary Care and Public Health at the Department of Health and Social Care.

Firstly, I would like to offer my sincere condolences to the family of Mrs Walker. I was very saddened to read the circumstances of her death and I am grateful to you for bringing these matters to my attention.

In preparing this response, Departmental officials have made enquiries with NHS England, the Medicines and Healthcare products Regulatory Agency (MHRA) and the Care Quality Commission (CQC).

Regarding your concern about significant delays to access specialist pain clinics, the pandemic has put enormous pressures on the NHS with elective waiting lists growing to over 7 million patients, but we remain committed to ensuring people get the right care at the right time. That is why we are delivering record staffing numbers, and putting in record levels of funding, to help the NHS recover and transform services. Having virtually met our target to eliminate long waits of two years or more for elective procedures in July 2022, our next ambition is to eliminate waits of eighteen months or more by April 2023.

To support this elective recovery, the government plans to spend more than £8 billion from 2022-23 to 2024-25, in addition to the £2 billion Elective Recovery Fund and £700 million Targeted Investment Fund already made available to systems last financial year, to help drive up and protect elective activity. Taken together, this funding could deliver the equivalent of around nine million more checks and procedures and will mean the NHS in England can aim to deliver around 30% more elective activity by 2024-25 than before the pandemic.

A significant part of this funding will be invested in staff, both in terms of capacity and skills. However, the Department has also committed to a £5.9 billion investment in capital for new beds, equipment and technology. The Department will also continue to work closely with NHS England to deliver the 'Delivery Plan for Tackling the COVID-19 Backlog of Elective Care', providing the necessary support and challenge to make sure it benefits patients and delivers value for money.

Turning specifically to pain clinics, it is within the remit of Integrated Care Boards (ICBs) to commission services within their geographical area and NHS England expects ICBs to commission appropriate services to meet the needs of the population they serve, including services that can

support people with chronic pain. NHS England is only responsible for the commissioning of highly specialist pain services in line with a published service specification.¹ There are currently eight adult NHS England specialist pain providers and access to these will depend on meeting the eligibility criteria.

Your other concern addressed a lack of understanding and recognition of monitoring kidney function, including clearance of test results by pharmacists and doctors alongside prescribing, that created a risk of overdose particularly in vulnerable patients. You may wish to know that the NHS Medicines Safety Improvement Programme, which forms a key part of the NHS Patient Safety Strategy, has launched a focussed programme of work relating to the improved care of people with chronic pain and a reduction in the use of prescribed opioids.² The programme has been in place since January 2021 and is supporting Integrated Care Systems to learn from, adapt and adopt effective practice using a whole-system improvement approach. As of 2022/23, 18 Integrated Care Systems are receiving intensive support to develop and implement improvements in care and a further 15 are participating in shared learning events.

In addition, the National Overprescribing Review report evaluated the extent, causes and consequences of overprescribing and made 20 recommendations to address it.³ Led by NHS England, a cross-organisational implementation programme brings together lead organisations, along with partners from across the health system, to implement the review's recommendations. The programme aims to achieve long term sustainable reductions to overprescribing via delivery of systemic and cultural improvements within the NHS. One of the key deliverables of the programme is a national resource to help practices improve the consistency of repeat prescribing processes and supported by appropriate training. Additionally, as part of the Dependence and Withdrawal Forming Prescribed Medicines Implementation programme, the National Institute for Health and care Excellence (NICE) has published guidance on Chronic pain assessment and management.⁴

Further to this, the MHRA monitors the safety of medicines and endeavours to ensure that up-to-date information on the benefits and risks of a medicine is available for healthcare professionals and patients. The Summary of Product Characteristics (SmPC) for a medicine provides information for healthcare professionals (HCPs) about the medicine, including warnings and precautions of use in higher risk situations. Gabapentin is a controlled medicine under the Misuse of Drugs Regulations 2012 and is regularly reviewed for signals of adverse effects to be included in the SmPC. The current SmPC for gabapentin contains detailed guidance on the administration of gabapentin in patients with compromised renal function and / or those on haemodialysis. The MHRA also published a Drug Safety Update article in 2019, concerning prescribing medicines in renal impairment.⁵

Also in 2019, the MHRA sought advice from the Opioids Expert Working Group (EWG) of the Commission on Human Medicines on the risks of dependence to opioids in the treatment of non-cancer pain. The review included an examination of worldwide clinical guidance on dose recommendations where risks exceed benefits, and the available evidence on conversion factors and calculations for the different opioids into morphine equivalent values. The EWG concluded that available values are not precise as they can be influenced by the individual patient past experience of opioid use as a patient can develop tolerance to their opioid medicine. The issue of tolerance has been reflected in the SmPC. The MHRA worked closely with the Faculty of Pain and the issues of tolerance and dose calculation has been highlighted in the Opioids Aware pages.

¹ <https://www.england.nhs.uk/publication/adult-highly-specialist-pain-management-services/>

² <https://www.england.nhs.uk/patient-safety/patient-safety-improvement-programmes/#MedSIP>

³ <https://www.gov.uk/government/publications/national-overprescribing-review-report>

⁴ <https://www.nice.org.uk/guidance/NG193>

⁵ Drug Safety Update volume 13, issue 3: October 2019: 3.

The British National Formulary and the Opioids Aware pages provide approximate conversion values to enable calculation of an appropriate dose to be used with a recommendation that a lower dose be used when switching between opioids.

The MHRA also issued a Drug Safety Update article for pregabalin, which is similar to gabapentin in its mechanism of action and side effects. The article highlights a European review of all reports of severe respiratory depression thought to be associated with pregabalin alone. Therefore, healthcare professionals were advised to consider dose adjustments in patients at a higher risk of respiratory depression, such as those with compromised respiratory function or renal impairment.⁶

Finally, the MHRA continue to monitor the benefits and risks of gabapentin and opioid medicines and will take further prompt regulatory action when needed to ensure that product information is clear and consistent.

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



NEIL O'BRIEN

⁶ Drug Safety Update volume 14, issue 7: February 2021: 2