Department of Health & Social Care

From Nadine Dorries MP
Parliamentary Under Secretary of State for Mental Health, Suicide Prevention and Patient Safety

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Your Reference: 8813
Our Reference: PFD-1193673

Mrs Maria Eileen Voisin
HM Senior Coroner, Avon
HM Coroner's Court
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23rd January 2020

Dear Mrs Voisin.

Thank you for your correspondence of 10 October 2019 to Matt Hancock about the death of Abdeslam Benelghazi. I am replying as Minister with responsibility for mental health services and patient safety and I am grateful for the additional time in which to do so.

Firstly, I would like to say how very saddened I was to read of the circumstances of Mr Benelghazi's death and I extend my deepest sympathies to his family and loved ones.

We must do all we can to learn from regrettable incidents such as these, especially when they involve vulnerable individuals detained under the Mental Health Act, to ensure the safety of health services and prevent future deaths. I am clear that the Avon and Wiltshire Mental Health Partnership NHS Trust must take forward the learning from this inquest in order to avoid another such tragic death.

In considering the concerns in your report, Departmental officials sought the advice of the Medicines and Healthcare products Regulatory Agency (MHRA) and the National Institute for Health and Care Excellence (NICE).

In relation to the prescribing of methadone beyond the normal limits and the continuing administration of clonazepam, a drug known to be associated with an increased risk of death when taken with opioids, I am advised as follows.

The increased risk of respiratory depression, coma and death when benzodiazepines and opioids are used together is known and changes to the product information highlighting these risks was recommended following an EU review in 2018. Wording for inclusion in the product information for both benzodiazepines and opioid medicines was published that year[1].

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The MHRA has reviewed all licences for clonazepam and methadone and noted that not all marketing authorisation holders (MAH) have applied the appropriate amendments. The MHRA is therefore contacting the MAH holders to request updates to the product information and the outstanding changes are expected to be implemented within three to six months.

In reviewing the product information for methadone, the MHRA has noted that several products contain information regarding respiratory depression and state that due to the slow accumulation of methadone in the tissues, respiratory depression may not be fully apparent for a week or two. The MHRA agrees that this important information should be included in all methadone products and has committed to working with MAH holders to update the product information within the timeframe above.

In addition, the MHRA will remind healthcare professionals of the risks of respiratory depression when benzodiazepines and opioids are co-prescribed via an article in its Drug Safety Update early this year.

The MHRA has added this case to its Yellow Card database (reference number ADR 24445672). The Yellow Card Scheme is the UK system for collecting and monitoring information on suspected adverse drug reactions (ADRs). The purpose of the Scheme, run by the MHRA, is to provide an early warning that the safety of a product may require further investigation.

As with all safety concerns, the MHRA will keep this particular issue under review and will update product information further if necessary.

Prescribing decisions are made by clinicians who are responsible for taking into consideration the dosage of medication prescribed and the combination of medicines administered.

Prior to offering treatment, healthcare professionals are expected to carefully consider information on the likely benefits of a treatment and balance these against possible adverse side effects, interactions and contraindications before making decisions appropriate to the circumstances of the individual (in consultation with them, and/or their families and carers/guardian).

Sources of information include the British National Formulary (BNF[2]) and, as already mentioned, a drug's summary of product characteristics (SmPCs). SmPCs contain information regarding the administration of medicines, and issues such as adverse side effects, contraindications and special warnings. SmPCs are available on the electronic

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https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Advice_from_CMDh/CMDh_372_2018_Rev0_02_2018.pdf

[2] https://bnf.nice.org.uk/?utm_source=evidence_bnf_redirect&utm_medium=(other)&utm_campaign=old_site_redirect

Medicines Compendium website[3] which contains up-to-date, easily accessible information about medicines licensed for use in the UK.

The NICE website hosts the BNF, which is a joint publication of the British Medical Association and the Royal Pharmaceutical Society. The BNF provides prescribers, pharmacists, and other healthcare professionals with up-to-date information about the selection, prescribing, dispensing and administration of medicines. A further source of advice is the General Medical Council's prescribing guidance[4].

In addition, healthcare professionals are expected to take account of NICE guidelines that offer advice on clinical care based on evidence of best practice. In 2014, NICE published *Psychosis and schizophrenia in adults: prevention and management* (CG178[5]), that includes recommendations on when to offer psychotic medication and how to initiate and monitor its use. NICE published technology appraisal guidance *Methadone and buprenorphine for the management of opioid dependence* (TA114[6]) in 2007, that recommends the treatments as options for maintenance therapy in the management of opioid dependence and highlights the potential risks, including of respiratory depression and interactions with other drugs. There are also NICE guidelines that make recommendations on the use of clonazepam[7] and gabapentin[8].

In summary, a healthcare professional is expected to consider the patient's circumstances and the possible benefits and risks before making an informed decision about what treatment might be appropriate for them.

In relation to the finding by the inquest jury of a failure to adequately monitor Mr Benelghazi and to identify signs of over sedation, the General Medical Council's (GMC) *Good practice in prescribing and managing medicines and devices*[9], is clear that prescribers must make sure that suitable arrangements are in place for monitoring, follow-up and review, taking into account the patients' needs and any risk arising from the medicines. This is particularly important where the medicines prescribed have potentially serious or common side effects.

The Nursing and Midwifery Council (NMC) is responsible for the standards of education of undergraduate nurses and works to ensure that registered nurses have the knowledge and skills they need to deliver high-quality, safe care on a consistent basis. The NMC's *Future*

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[3] https://www.medicines.org.uk/emc

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

[5] https://www.nice.org.uk/guidance/cg178/chapter/1-Recommendations#first-episode-psychosis-2

[6] https://www.nice.org.uk/guidance/ta114

[7] https://www.nice.org.uk/guidance/cg137

[8] https://www.nice.org.uk/guidance/cg173

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

Nurse: Standards of proficiency for registered nurses[10] specifies the knowledge and skills that registered nurses must demonstrate when caring for people of all ages and across all care settings.

It is expected that a registered nurse should be able to demonstrate the knowledge and ability to respond proactively and promptly to signs of deterioration or distress in mental, physical, cognitive and behavioural health and use this knowledge to make sound clinical decisions and contribute to a comprehensive clinical plan that is compliant with the employer's policy on monitoring and observing patients.

In response to changes to the National Early Warning Score (NEWS) parameters[11], Health Education England (HEE) is working in partnership with NHS England and NHS Improvement and others, to support learning needs for the health and care workforce. Learning resources have either been developed, are in development or are being planned for staff working in secondary care, primary care, ambulance settings and mental health settings. The resources consist of a number of case studies covering presentations common to particular care settings. In response to your report, HEE advises that it will ensure the development of a specific case study to cover opioid use and over sedation when it develops the early warning score learning resource for mental health settings.

I am further advised that HEE is providing education and training opportunities for mental health practitioners through the development of related competency frameworks and teaching initiatives. HEE is working with health system stakeholders, subject matter experts and people with lived experience, to develop guidance, endorsed by the Royal Pharmaceutical Society, that sets out additional guidance, support, resources and learning materials specifically related to prescribing in mental health.

On medicine safety more generally, the Government is committed to supporting the work of the Medicine Safety Improvement Programme[12], led by NHS England and NHS Improvement, which aims to increase safety across the medication pathway. The programme will bring together a variety of projects to support medicine safety, from improvements to technology and the roll out of electronic prescribing, to improved training for health and care professionals in the safe use of medicines.

The Government recognises the need to modernise the Mental Health Act 1983 to ensure it is used in a fair and just way and that people are not detained any more than is necessary. We want to make sure that people subject to the Act receive better care, that they have a much greater say in that care and that they are treated with the dignity and respect they deserve. We will publish a White Paper in early 2020, which will set out the Government's response to Sir Simon Wessely's Independent Review of the Mental Health Act. We will consult publicly on our proposals and will bring forward a Bill to amend the Act when Parliamentary time allows.

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[10] https://www.nmc.org.uk/globalassets/sitedocuments/education-standards/future-nurse-proficiencies.pdf

[11] https://www.rcplondon.ac.uk/projects/outputs/national-early-warning-score-news-2

[12] https://improvement.nhs.uk/resources/national-medicines-safety-programme/

Finally, I have asked Departmental officials to bring the matters of concern in your report to the attention of NHS England and NHS Improvement, the Care Quality Commission and the Healthcare Safety Investigation Branch.

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

Yours, Nadine.

NADINE DORRIES