General Medical Council

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20 September 2024

Ms Joanne Kearsley

HM Senior Coroner

Greater Manchester North

Sent by email: [redacted]

Dear Ms Kearsley

Regulation 28: Report to Prevent Future Deaths (ref: [redacted])

Thank you for your letter of 31 July 2024 enclosing your report into the death of Mrs Susan Pollitt. I am very sorry to hear of the tragic circumstances surrounding Mrs Pollitt's death and I extend my condolences to her family and friends. I am responding as the Medical Director and Director of Education and Standards at the GMC.

I have considered your report and the concerns it raises about the treatment Mrs Pollitt received at the Royal Oldham Hospital (ROH). The absence of statutory regulation of physician associates (PAs) may have contributed to the circumstances of her death. Regulation by the GMC, which will begin at the end of this year, should help address several of the issues you have highlighted. This should, in turn, bring benefits for patients, patient safety, PAs themselves and those that employ and work alongside them.

However, based on your report, there appear to be wider concerns about the clinical governance arrangements at the Trust including the roles, supervision and relevant policies supporting the use of ascitic drains and the deployment of PAs. I will return to this at the end of my response.

Lack of a regulatory body with oversight of PAs

The GMC agrees that statutory professional regulation of healthcare professionals involved in the treatment of patients better protects the public. PAs are not subject to such regulation at the moment but, as you note in your letter, the GMC will become the regulator of PAs and anaesthesia associates (AAs) in December this year.

I thought it would be helpful to outline the history of how the GMC was chosen to be the regulator of these professions, the work that we have done thus far to prepare for regulation and the next steps before we begin regulating PAs later this year.

In 2017, the Department of Health and Social Care (DHSC) consulted on which healthcare regulator would be most suitable to regulate one, some, or all the medical associate professions, which include PAs and AAs. Surgical care practitioners are the third profession in this group but are not included in those we will regulate. Following the consultation, the Government determined the GMC was most appropriate and formally asked us to take on the regulation of PAs and AAs which we agreed to do. The UK and Scottish parliaments approved the legislation (Anaesthesia Associates and Physician Associates Order 2024) earlier this year and it has been granted Royal Assent. This means the GMC will become the regulator of PAs and AAs from December 2024 and, from December 2026, they will have protected titles in law ('Physician Associate' and 'Anaesthesia Associate').

Regulation will bring many benefits and make an important contribution to assuring patients and employers that PAs are safe to practise and can be held to account if serious concerns are raised about their conduct or performance. PAs are part of the multi-disciplinary team and make decisions about patient care affecting diagnosis and treatment. Although they work in regulated healthcare settings and must be supervised by a registered and licensed doctor, at present there aren't any profession-specific mandatory standards for their pre-qualification education, training or conduct. Nor is there any professional accountability to a statutory body if their practice raises concerns that would warrant some action, and certainly not on a legally enforceable basis.

Once regulation by the GMC is fully in force, PAs will need to be registered with us and they will be required to adhere to *Good medical practice*, our core set of professional standards that all our registrants (which currently only includes doctors) are expected to follow. Regulation allows us to take action in the event that an individual registered with us falls significantly below the standards we set and poses a risk to the public or public confidence.

We recently consulted on the rules, standards and guidance needed to implement the legislation that gives us the power to regulate PAs and we're now considering the responses so that we can finalise our approach. Once regulation begins, we will have powers to:

- Set the standards of patient care and professional behaviours PAs need to meet.
- Set the outcomes and standards that students qualifying from PA courses must meet to achieve registration, and approve the curricula that courses must deliver.
- Set a two-part assessment of clinical knowledge and skills that a PA needs to pass before registration.
- Check who is eligible to work as a PA in the UK and that they continue to meet the professional standards we set throughout their careers.
- Give guidance and advice to help PAs understand what's expected of them.
- Investigate where there are concerns that patient safety, or the public's confidence in PAs, may be at risk, and take action if needed.

In summary, we agree that the current lack of a regulatory body for PAs represents a risk to patient safety and believe the concerns raised in your report will be addressed once the GMC takes on this role.

Existing voluntary register

The existence of a managed voluntary register offers some assurance to employers that PAs have passed a national exam designed, set and delivered by the Royal College of Physicians of London. However, it cannot assure the quality of the course they have studied, the outcomes they have achieved, or the clinical experience they gained during their studies. That is why we, the Faculty of Physician Associates (FPA) and many system partners welcome the introduction of a statutory register of PAs from December 2024.

We anticipate that employers will make GMC registration a condition for their PAs in the same way as they have done up to now in relation to voluntary registration. Although GMC registration doesn't become a legal requirement for practice until December 2026, we will strongly encourage all PAs to join our register as soon as possible.

I will leave it to the FPA to explain how they currently deal with concerns raised about a member of their voluntary register. The GMC currently has no power to investigate concerns raised about PAs as they are not yet regulated by us, and we have no role in determining the investigatory and disciplinary processes of the FPA. However, we can and will look at any outstanding concerns about an individual PA's fitness to practise when considering their application for registration with us from December this year.

It is also worth noting that, irrespective of whether a healthcare profession is regulated, each NHS trust has a duty to provide safe care to patients, and they also have a responsibility to ensure that standards are monitored and maintained.

Guidance on training, supervision and assessing competence

The issue of a perceived lack of national guidance surrounding the safe deployment of PAs has been raised in recent months. Several organisations have been working to develop guidance appropriate to their specialty or responsibility.

For example, NHS England has issued guidance to NHS Trusts and primary care providers in England on the safe and effective integration of PAs into departmental teams and GP practices respectively. It may also be helpful to see NHS England's supervision guidance for primary care network multidisciplinary teams, which sets out in some detail the key principles for effective supervision within GP practices, including how to meet the regulatory requirements set by the Care Quality Commission (CQC). For their part, the CQC has also recently issued guidance on supervising and overseeing PAs in general practice, and Health Education England's Core Capabilities Framework for Medical Associate Professionals has been in place since 2022.

We have also published our own advice for doctors who supervise PAs, and earlier this year we updated our clinical governance handbook to set out our expectation that organisations who employ PAs should make appropriate arrangements for their deployment and supervision.

Regarding PA education and training - once regulation begins in December 2024, we'll have powers to set the standards for course providers and regularly check that they're being met. We have already published a range of guidance to support PAs student PAs and course providers pending the implementation of regulation. From December 2024 we will be able to formally approve courses and curricula to ensure that PAs will have the clinical knowledge and skills needed to work safely once they qualify.

In preparation for the start of regulation we have already asked course providers to update their courses, including their syllabus and assessments, using the relevant curriculum as a guide, and we are checking that this has been done through our education quality assurance process. We are also finalising updated guidance for PA students on professional standards and the process for approving PA curricula.

Finally, we have been supporting the work that individual royal colleges, and the Academy of Medical Royal Colleges, are currently leading on developing a range of guidance on supervision and how PAs can safely develop their skills and competencies over time once they have qualified and registered with us. The Royal College of Physicians is currently consulting on their guidance and the Royal College of General Practitioners plans to do so shortly. We are also encouraging colleges, NHS employers and others to ensure that all guidance being produced is aligned and consistent so as not to cause confusion for employers, supervisors or PAs themselves.

Limited understanding and awareness of the PA role

We agree it is vital that patients must always be clear about who is treating them and their role within the team. While PAs have been part of the UK healthcare workforce for around 20 years, the numbers are relatively small, so it is even more important that they are always clear about their roles and responsibilities with the patients they treat.

Once again, regulation will be helpful in this context. Our professional standards say that PAs will have a responsibility to clearly communicate who they are and their role in the team, just as doctors must do now.

In March this year we also announced that we would implement an alphabetical prefix for PA and AA GMC reference numbers and ensure the prominent labelling of profession type on our public-facing registers. This means that in future when patients search our registers it will be very clear whether an individual is a doctor, a PA or an AA not only because of the use of a prefix for PAs and AAs but also because the face of the register will actually spell out in full the professional title of each individual ('Doctor', 'Physician Associate', 'Anaesthesia Associate').

The FPA also has guidance on 'titles and introduction' which provides a standardised way of using the PA title and highlights the importance of explaining it to patients and colleagues.

The issue you raise about the need for distinct uniforms to help patients distinguish between professionals is for the NHS and employers to address.

Clinical governance

Regulation is an important part of patient safety, but it alone cannot prevent future deaths. Good clinical governance by healthcare providers remains the most important factor. Your report raises significant questions that cannot be answered by those to whom the report is currently addressed, and are better explained by the trust:

- How was it possible for a junior doctor to decide a drain was required after the consultants had deemed it not to be required?
- Why was it decided Mrs Pollitt should remain on a respiratory ward (where likely there was little or no experience of managing the drain or of the nursing care required), rather than moved to a gastroenterology ward?
- How was the decision made to delegate this task to the PA without seeming to assess the competence of the PA or give clear instructions as to how it should be managed once inserted (i.e., not clamped and only left in situ for six hours)?
- What is the local policy for the use of ascitic drains that would address the above?
- What was the role of the consultant in overseeing the overall care of Mrs Pollitt?

The FPA will be able to explain the purpose and intended usage of the competency form that was used to assess the skills of the PA in this case.

We are pleased to note from your report that the NCA has put a local trust framework in place and will be writing to them to request sight of this document and seek our own assurances around clinical governance at the ROH.

Thank you for the opportunity to comment on this report. I hope this information provides reassurance around the work we are doing to bring PAs into regulation. We hope that work, along with action from others, will help ensure a similar incident does not happen again.

Yours sincerely

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Medical Director and Director of Education and Standards
General Medical Council

cc. [redacted], Secretary of State for Health and Social Care
[redacted] and [redacted], DHSC
[redacted], President, FPA