

GMC response to the Department of Health (England) consultation on the regulation of medical associate professions in the UK

About the GMC

The General Medical Council (GMC) is responsible for the regulation of doctors and is one of the two statutory health and care professional regulators referenced in the consultation. At the centre of everything we do are our core functions:

- We set the educational standards for all UK doctors through undergraduate and postgraduate education and training.
- We decide which doctors are qualified to work here and maintain the public register of all those who are licensed to practise.
- We set the professional standards for doctors in the UK and we make sure that they demonstrate on a regular basis that they are up to date and fit to practise (the process known as revalidation).
- We take action when we believe a doctor may be putting the safety of patients, or the public's confidence in doctors, at risk.

It is only by continuing to deliver these functions to the highest standards that we are able, with others, to realise our vision of preventing harms and driving improvement in care across the health services.

Summary of our views

As new professional roles emerge to meet the changing needs of patients and the health services, it is vital that patients, employers and other health professionals are assured that those providing care are able to practise to appropriate professional standards, are supported to meet those standards and are held accountable against them. Regulation should operate to provide that assurance, support and accountability, while at the same time facilitating the development of these professional roles in order to meet the needs of the service.

We welcome the opportunity to comment on this consultation, particularly given that we have long argued that physician associates (PAs) should be subject to statutory regulation in order to provide an appropriate level of assurance about the safety of their practice to the public.

Although this consultation document discusses the medical associate professions (MAPs) as effectively four discrete professions (physician associates (PAs), physician assistants (anaesthesia) (PA(A)s, surgical care practitioners (SCPs) and advanced critical care practitioners (ACCPs), it is our strong view that MAPs should be considered as a single umbrella profession made up of four areas of practice. In considering MAPs in this way, i.e. treated as a single profession, we believe that development of MAP roles in other areas of practice, (particularly for key specialties with workforce shortages) will be better enabled. Statutory regulation of MAPs will also facilitate the future development and uptake in employment of the current MAPs.

The grouping of MAPs for statutory regulation together will also allow for a more coherent and co-ordinated approach to regulation and make it easier for patients and the public to understand the relationship between these roles and doctors.

Therefore, although the consultation encourages respondents to consider the four groups separately and in isolation, we have tried in our comments to look across professional boundaries. For the reasons set out in our response, we have concluded that all four groups should be subject to statutory regulation as a single umbrella profession – the Medical Associate Practitioner profession.

Furthermore, acknowledging our current regulatory remit and work relating to doctors, we believe there is clear regulatory coherence in the GMC taking on this role. Our discussions with key stakeholders have led us to conclude that there is a compelling case for the GMC to regulate MAPs and we are prepared to do so, noting the following elements:

- Doctors should not be expected to bear the cost of bringing these new professions into regulation. Therefore, the Government must provide transitional funding to cover the set up costs for regulating MAPs.
- Once MAPs have been brought into regulation the ongoing costs of regulating them would be borne by the GMC as an independent regulator, through collection of an annual retention fee (ARF) from the MAPs. However, this must be financially sustainable. Doctors cannot be expected to incur additional costs through their ARF for the ongoing regulation of MAPs.
- The timeline for the transition to introduce statutory regulation for the MAPs would need to be agreed. We see a strong case for the four MAP roles to be brought into regulation in stages rather than all at once, to ensure smooth transition and implementation.

- An appropriate new legislative framework to support MAP regulation must be agreed. The approach taken by the Government to the regulation of nursing associates has been to graft the term 'nursing associate' onto the existing NMC legislation. If the same approach was taken to the legislation for MAPs and it was decided that the regulator should be the GMC it would mean imposing on the MAP profession the prescriptive, inflexible and outdated framework that currently exists for doctors. The Government's current consultation on the reform of professional regulation acknowledges that the existing legislative framework is no longer fit for purpose. It would not make sense, and would be disproportionate, to inflict that regulatory model on MAPs.
- A new legislative framework should be drafted in such a way so that it is future proofed and does not preclude future emerging MAP roles.

Regulation is not just about that individual's accountability to a regulator as the consultation document references on page 25. If the direction of travel for regulatory reform, as proposed in the DH's consultation, *Promoting Professionalism, Reforming Regulation*, is moving beyond simply focussing on fitness to practise concerns, but rather, supporting good practice - it will be necessary to ensure that the proposed regulator for MAPs oversees all the key aspects of the role, including; education, training, standards, guidance and support throughout the professional's career.

Question 1:

What level of professional assurance do you think is appropriate for PAs?

- Voluntary registration
- Accredited voluntary registration
- ***Statutory regulation***
- Other

Please provide further information to support your answer

We have long argued, and continue to believe, that statutory regulation is the most appropriate level of professional assurance for PAs.

To determine whether a new professional group should be brought into regulation, a principled and evidenced case for regulation must be made. To explore this we have, building on the work of others, developed the following criteria:

- i The professional group must have a defined body of knowledge and standards.

- ii The profession must be a clearly definable and differentiated group and have a clear role.
- iii Statutory regulation is necessary to perform functions associated with the role (for example prescribing).
- iv There is a high level of complexity associated with the role.
- v There is a high level of risk associated with activities necessary to fulfil the role and therefore a need for accountability.
- vi Professionals have a significant degree of autonomy.
- vii Regulation is necessary to be able to command public confidence.
- viii Regulation is necessary to provide assurance of quality and reliability to other professional groups or agencies using the services of the profession.
- ix Statutory regulation must be supported by the proposed professional group and other key stakeholders.
- x The professional group must be of sufficient size and maturity to be able to support the requirements of regulation (for example, an established educational and professional infrastructure and professional standards. This might be demonstrated through voluntary regulation).

PAs represent a clearly identifiable group of professionals with a defined body of knowledge, skills and expected professional standards. They are dependent practitioners (supervised by consultants) and practice with a high degree of complexity and autonomy, which presents a significant potential risk to patients, including vulnerable patients. Public confidence in a profession, such as PAs requires assurance about standards of training and practice, and accountability. Furthermore, employers and other health professionals need to have the confidence and clarity about the individuals fulfilling these roles.

There is some evidence that the absence of statutory regulation is inhibiting the development of the PA profession. We are also aware of at least one case of a regulated professional who was erased from the register by their statutory regulator and subsequently sought to re-establish themselves as an unregulated PA in the same area of practice.

Question 2:

What level of professional assurance do you think is appropriate for PA(A)s?

- Voluntary registration
- Accredited voluntary registration

➤ **Statutory regulation**

➤ Other

Please provide further information to support your answer

As indicated in the preamble to this response, we believe that all four MAPs should be subject to statutory regulation. This includes PA(A)s.

Given the inherently medical nature of their scope of practice, and the continued risk to patient safety without regulation, we believe they should be regulated with statutory backing. The PA(A) role is complex in nature but there are no current standards for PA(A)s. Even though some, but not all, PA(A)s may be regulated, there may be little, to no connection between their scope of practice as a PA(A) and the scope of practice in the profession they are regulated in.

Whilst we recognise that the current number of practitioners in this area is currently small, there is some evidence to suggest that a lack of statutory regulation can limit the growth and uptake in employment of professions. Employers and other professionals may be reluctant to embrace the role of PA(A)s to realise their full potential, in the absence of better systems for assurance of standards and accountability.

We also acknowledge, in coming to this conclusion, the view of the Royal College of Anaesthetists (RCoA) and the AAGBI. In April 2016, they state that the earliest cohort of PA(A)s have more than a decade of experience and are fully integrated into the anaesthetic departments in which they work. They note, in saying this, that the predictions of the changing demographic of the UK indicates a need for a 25-40% expansion in the number of anaesthesia providers by 2035. RCoA and AAGBI both therefore believe that *'registered, regulated PA(A)s, supervised by medically qualified anaesthetists, can make a valuable contribution towards a suitable anaesthetic workforce'*.

Question 3:

What level of professional assurance do you think is appropriate for SCPs?

- Voluntary registration
- Accredited voluntary registration
- **Statutory regulation**

* Joint statement from the RCoA and AAGBI on the scope of practice of PA(A)s, April 2016, <https://www.rcoa.ac.uk/sites/default/files/JointStatementPAA2016.pdf>

- Other

Please provide further information to support your answer

We believe that statutory regulation is the most appropriate level of professional assurance for SCPs.

SCPs work within a medical environment and are clinically responsible to their consultant surgeon.

Given the nature of their scope of practice, (which extends to performing surgical intervention and pre-operative and post-operative care under the supervision and direction of a consultant), and the continued risk to patient safety without regulation, we believe they should be regulated with statutory backing.

The standards they must adhere to upon qualification by virtue of their existing registration, (for example with the NMC as a nurse, or HCPC as an operating department practitioner) are in relation to the profession that they are registered as, not practising in; a situation that is not ideal for supporting professionals in maintaining good practice and reducing risk of harm to patients.

We also acknowledge the Royal Colleges of Surgeons' (London and Edinburgh) assessment that these groups ought to be subject to statutory regulation *'in order for the NHS and patients to benefit fully'*. They note that the role has expanded greatly since it was first formally developed in 2006 and the scope of practise includes work in clinics, pre-operative environments and facilitating the continuity of patient care on the wards.

Question 4:

What level of professional assurance do you think is appropriate for ACCPs?

- Voluntary registration
- Accredited voluntary registration
- ***Statutory regulation***
- Other

Please provide further information to support your answer

* Royal College of Surgeons, press release October 2017, <https://www.rcseng.ac.uk/news-and-events/media-centre/press-releases/regulating-medical-associate-professions/>

We believe that statutory regulation is the most appropriate level of professional assurance for ACCPs.

ACCPS work within specialised intensive care environments and have been operational in hospitals for approximately two decades. Crucially, in terms of an assessment of risk and the appropriate level of professional assurance, they work in critical care units where they diagnose and treat patients, referring to the appropriate specialist if needed. They make high-level clinical decisions and will often carry their own patient caseload.

Similar to the training entry requirements for SCPs, a condition of entry to postgraduate programmes, as well as entry to the voluntary register, is a pre-existing and current registration with the relevant healthcare regulator (i.e. HCPC or NMC). So whilst some ACCPs are regulated by other bodies, there may be no connection between their actual scope of practice and the scope of practice in the profession they are regulated in. Registration as an ACCP would provide greater clarity and assurance for the public, employers, and the profession, if they are regulated in a way which reflects what they are actually doing.

Question 5:

In the future, do you think that the expansion of medicines supply, administration mechanisms and/or prescribing responsibilities to any or all of the four MAP roles should be considered?

Yes

No

Don't know

If yes, please specify which professions and your views on the appropriate level of prescribing responsibilities

Given that we believe that the MAPs should be subject to statutory regulation, it follows that all four MAP roles should have prescribing rights at some point in the future. Noting the roles that these groups already perform, and the future development of these roles, the assumption should be that they would, in due course, have prescribing responsibilities appropriate to the roles they are undertaking.

This would alleviate pressures on doctors and other professionals with prescribing rights, so that individual professional's skill sets are best utilised (i.e. doctors can focus on more complex, higher-risk patient needs).

Given that the process required for expanding prescribing responsibly to a profession can take a significant number of years, we believe that consideration of prescribing

responsibilities for all four MAPs should be at the point of bringing the group into statutory regulation. We appreciate that there is a level of risk inherent in this approach but this is ultimately a matter for the Medicines and Healthcare Products Regulatory Agency and partner organisations, acknowledging that any changes would require legislative amendments.

Question 6:

Which healthcare regulator should have responsibility for the regulation of any or all of the four MAP roles?

- **General Medical Council**
- Health and Care Professions Council
- Other
- Don't mind

It is a matter for the four UK governments to decide which of the MAPs groups should be regulated and by whom.

There is a strong case for all four roles to be regulated together as a single MAP profession, but also that it should be by the same regulator to avoid future unhelpful divergence of their regulation, education, training, standards and practice.

Whilst we appreciate there are many issues the government will want to consider in deciding who should have responsibility for the regulation of all four MAP roles, there is regulatory coherence in the GMC undertaking this role. The four MAP roles train and work to a medical or surgical model and have a supervisory relationship with doctors. There are clear synergies in terms of oversight of education and training for doctors, and taking on the regulation of the MAP group will help ensure a coordinated and coherent approach to our key regulatory functions.

In outlining this, and considering our current regulatory work and remit in relation to doctors, our discussions with key stakeholders have led us to conclude that there is a compelling case that can be made for the GMC to regulate the MAPs group. We would be prepared to do so, as long as the below key considerations are taken into account:

- Doctors should not be expected to bear the cost of bringing these new professions into regulation. Therefore, the Government must provide transitional funding to cover the set up costs for regulating MAPs.
- Once MAPs have been brought into regulation the ongoing costs of regulating them would be borne by the GMC as an independent regulator, through collection of an annual retention fee (ARF) from the MAPs. However, this must be financially

sustainable. Doctors cannot be expected to incur additional costs through their ARF for the ongoing regulation of MAPs.

- The timeline for the transition to introduce statutory regulation for the MAPs would need to be agreed. We see a strong case for the four MAP roles to be brought into regulation in stages rather than all at once, to ensure smooth transition and implementation.
- An appropriate new legislative framework to support MAP regulation must be agreed. The approach taken by the Government to the regulation of nursing associates has been to graft the term 'nursing associate' onto the existing NMC legislation. If the same approach was taken to the legislation for MAPs and it was decided that the regulator should be the GMC it would mean imposing on the MAP profession the prescriptive, inflexible and outdated framework that currently exists for doctors. The Government's current consultation on the reform of professional regulation acknowledges that the existing legislative framework is no longer fit for purpose. It would not make sense, and would be disproportionate, to inflict that regulatory model on MAPs.
- A new legislative framework should be drafted in such a way so that it is future proofed and does not preclude future emerging MAP roles.

Furthermore, it is worth noting that in so far as there are international precedents for regulation of MAPs - other jurisdictions that regulate PAs, such as the USA, Canada and the Netherlands, PAs and doctors are regulated by the medical regulator. PAs in those jurisdictions also have prescribing rights and the right to refer patients for ionising radiation.

Question 7:

Do you agree or disagree with the costs and benefits on the different types of regulation identified above? If not, please set out why you disagree. Please include any alternative cost and benefits you consider to be relevant and any evidence to support your views.

Yes

No

Don't Know

We agree with the costs and benefits analysis conducted on the different types of regulation identified in the consultation document at page 30-32. Were the GMC to regulate MAPs, it should not be assumed that we would apply the same fee model as we do for doctors. We would consider the appropriate fee levels in light of the operating model to be introduced.

We do, however, feel that there are numerous non-financial benefits to regulating MAPs on a statutory footing that are not included. Many of these benefits to statutory regulation have arisen from our conversations with relevant stakeholders, such as the Faculty of PAs:

- Uniformity of training and professional standards - We have heard in our discussions with PAs that their training and scope of practice can differ depending on the support provided by the relevant employer, training provider, and their supervising consultant or GP.
- Assurance that only those who have met the appropriate standards can practise within the profession, thus protecting patients.
- Aids driving improvement in standards for the benefit of patient care.

Please provide further information to support your answer

Question 8:

Do you think any changes to the level of professional assurance for the four medical associate professions could impact (positively or negatively) on any of the protected characteristics covered by the Public Sector Equality Duty, or by Section 75 of the Northern Ireland Act 1998?

Yes

No

Don't know

Please provide further information to support your answer

Whilst we do not consider that introducing a level of professional assurance for the MAPs would impact on any of the protected characteristics, the model that is put in place would need to demonstrate how the relevant regulator is meeting the requirements of the public sector equality duty.

For example, the data currently available from the Department of Health in England suggests that there are more female than male PAs, over half of PAs are aged between 25 and 39, and over half of PAs state their ethnicity as 'white'. In developing a regulatory model for any of the MAPs, PAs included, the relevant regulator must demonstrate how it is taking steps to meet the public sector equality duty, ensuring that, for example, education, and registration and revalidation requirements, do not negatively impact on these cohorts.