Agenda Item 5

Enclosure 1

Health and Care Professions Council
07 December 2017

Consultation on the regulation of medical associate professions

For discussion and approval

From Michael Guthrie, Director of Policy and Standards

Council, 7 December 2017

Consultation on the regulation of medical associate professions

Executive summary and recommendations

Introduction

The Department of Health is consulting on the regulation of medical associate professions in the UK. A copy of the consultation document and our draft response is attached.

The consultation has been promoted via the website, social media, issues brief, the 'In Focus' newsletter and a stakeholder email. At the time of writing, the Chief Executive and Chair are scheduled to meet with the President of the Faculty of Physician Associates of the Royal College of Physicians.

We plan to issue a statement when we respond to the consultation highlighting our views.

Decision

The Council is invited to:

- discuss and agree the text of the consultation response (subject to any changes agreed at this meeting and minor editing amendments);
- discuss the key messages we might communicate in a statement.

Background information

- The consultation runs to 22 December 2017.
- The full risk profiles for each group are available here: https://www.gov.uk/government/consultations/regulating-medical-associate-professions-in-the-uk

Resource implications

None as a result of this paper

Financial implications

None as a result of this paper

Appendices

None

Date of paper

24 November 2017

December 2017

Health and Care Professions Council response to Department of Health consultation on 'The regulation of Medical Associate Professions in the UK'

1. Introduction

1.1 We welcome the opportunity to respond to this consultation.

1.2 The Health and Care Professions Council (HCPC) is a statutory regulator of health, social work, and psychological professions governed by the Health and Social Work Professions Order 2001. We regulate the members of 16 professions. We maintain a register of professionals, set standards for entry to our register, approve education and training programmes for registration and deal with concerns where a professional may not be fit to practise. Our role is to protect the public.

2. Our responses to the consultation questions

Physician associates (PAs) – assessment of risk

Q1. What level of professional assurance do you think is appropriate for PAs?

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

2.1 We consider that a persuasive case is made in the consultation document for the statutory regulation of PAs.

2.2 PAs are the only medical associate profession (MAP) to be rated as high risk against the Professional Standards Authority's (PSA's) criteria of intervention, context and accountability. Widespread direct entry into PA training means that few PAs have accountability to an existing statutory regulator. In addition, the growth in PA training numbers indicates a secure and expanding role for PAs in the future workforce.

Physician assistants (Anaesthesia) (PA(A)s) – assessment of risk

Q2. What level of professional assurance do you think is appropriate for PA(A)s?

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

2.3 We consider that statutory regulation may be appropriate for PA(A)s, but note that the consultation is seeking further evidence before a final decision is made.

2.4 The level of autonomy of this role is clearly articulated in the consultation document. Autonomy appears comparable to other statutory regulated professions who work in the operating theatre environment, including nurses and operating department practitioners. It seems to us that the primary reservation in the consultation to the statutory regulation of this group is its size and slow projected rate of growth.

2.5 An argument can be made for the statutory regulation of PA(A)s on the basis that, unlike the remaining MAP groups, direct entry into training means that some PA(A)s will not have accountability to an independent professional regulator.

2.6 There is also the practical question of protection of title. 'Physician assistant' is the professional title used in the United States for the profession now called 'physician associates' in the UK. Arguably, if physician associates were to be regulated in the UK, consideration would also need to be given to protecting 'physician assistant' to prevent an obvious evasion of regulation. This may therefore necessitate the regulation of PA(A)s in any event.

2.7 If PA(A)s were to be brought into statutory regulation, advance consideration might also be given (in partnership with the professional body) to introducing an alternative professional title. The title 'Physician Assistant (Anaesthesia)' may be confusing for members of the public, particularly given 'physician assistant' is used elsewhere in the world to describe what in the UK is a physician associate. In addition, 'Assistant' may not accurately convey the level of decision making autonomy involved in the role, one of the past drivers, we understand, for the renaming of the PA role in the UK.

Surgical Care Practitioners (SCPs) and Advanced Critical Care Practitioners (ACCPs) – assessment of risk

Q3. What level of professional assurance do you think is appropriate for SCPs?

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

2.8 We consider that voluntary registration or accredited voluntary registration, with employer controls, are likely to provide appropriate professional assurance for SCPs. We note that accredited voluntary registration would rely on a voluntary register being willing to seek (and to pay for) accreditation.

2.9 The lack of direct entry into this role, meaning that practitioners are accountable to a professional statutory regulator, indicates that statutory regulation of this group is unnecessary. We also note the small numbers of this group and the lack of national plans for expansion.

2.10 In the absence of 'direct' statutory regulation of SCP's as a distinct group, consideration might be given to the means by which practitioners can be required to maintain their original professional registration, for example, through guidance to NHS employers. The risk that practitioners will allow their 'base' registration to lapse after having moved into a new role is cited frequently as a limitation of a lack of direct regulation.

Q4. What level of professional assurance do you think is appropriate for ACCPs?

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

2.11 We consider that voluntary registration or accredited voluntary registration, with employer controls, are likely to provide sufficient professional assurance for ACCPs. However, we do note the assessment that this role performs high-risk interventions with high levels of decision-making autonomy. We note that accredited voluntary registration would rely on a voluntary register being willing to seek (and to pay for) accreditation.

2.12 The lack of direct entry into this role, meaning that practitioners are already accountable to a professional statutory regulator, would indicate that statutory regulation of this group is unnecessary. We also note the lack of national plans for expansion.

2.13 In the absence of 'direct' statutory regulation of ACCPs as a distinct group, consideration might be given to the means by which practitioners can be required to maintain their original professional registration, for example, through guidance to NHS employers. The risk that practitioners will allow their 'base' registration to lapse after having moved into a new role is cited frequently as a limitation of a lack of direct regulation.

Prescribing responsibilities

Q5. 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**

2.14 Don't know.

2.15 We consider that the MAP groups and service providers are better placed to answer this question.

2.16 Patient Group Directions (PGD), exemptions to sell, supply and/or administer medicines and prescribing entitlements are currently limited only to those professions that are statutory regulated. Subsequent consideration of extension of such mechanisms to PAs if they were regulated might realise the full potential of this role to healthcare delivery.

2.17 We are actively involved in ongoing NHS England-led work that considers extension of these mechanisms to other professions. We would be keen to ensure that any future consideration of the needs of the MAP groups does not delay progress for other groups. For example, operating department practitioners have been regulated by us since 2004 but are still unable to use PGDs.

Consideration of the appropriate professional regulator

Q6. Which healthcare regulator should have responsibilities for the regulation of any or all of the four MAP roles?

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

2.18 Don't mind.

2.19 We do not offer a view on which regulator should have responsibilities for the regulation of PAs (or the other MAP roles); it is right that this decision is made independently of either potential regulator. The identity of the regulator matters far less than that appropriate regulation is put in place.

2.20 However, we consider we are well placed to regulate PAs (and any of the other MAP groups) if we are asked to. The consultation document highlights a number of considerations that might inform the choice of regulator. We have highlighted our suitability against these areas below.

- **Existing scope of the regulator**. We are a multi-professional regulator, with experience of regulating a diverse range of professions. Our model of regulation, underpinned by generic and professions-specific standards, is well able to take account of both the similarities and the individuality of the different professions we regulate.

- **Speed of delivery**. We have a successful track record of bringing further professions into statutory regulation: operating department practitioners (2004), practitioner psychologists (2009), hearing aid dispensers (2010) and social workers in England (2012). As an existing multi-professional regulator, our rules, standards and systems are already designed in a way that would allow us (with relatively minimal changes required) to accommodate easily further professions. For example, our governance arrangements are able to accommodate further professions. Whilst the needs and challenges of every new profession are unique, we estimate that we would be able to open the Register within approximately 12 months of the publication of legislation.

- **Cost**. Our model of regulation outlined above means that the set-up costs to the taxpayer of extending professional regulation would be minimised. We benefit from economies of scale and currently have the lowest renewal fee of all the nine UK regulators overseen by the PSA - £90. This would keep the ongoing cost to practitioners who pay for the day-to-day costs of regulation as low as possible.

Costs and benefits analysis

Q7. 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**

2.21 Yes.

2.22 The consultation document includes an accurate summary of the main costs and benefits of each form of assurance.

Equality considerations

Q8. 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**

2.23 No.

2.24 We have not identified any positive or negative impacts on the public sector equality duty.

Department of Health

The regulation of medical associate professions in the UK

Consultation document

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Target audience: Physician Associates Physicians' Assistants (Anaesthesia) Surgical Care Practitioners Advanced Critical Care Practitioners Medical practitioners Healthcare professionals Healthcare regulatory bodies Royal colleges Unions Employee representatives Employer representatives General public Patients/service users Higher education institutions
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Executive summary

Across the UK, an increasing need for medical treatment and advances in clinical care requires a coordinated approach and a greater skill mix within healthcare teams. This includes the enhancement of existing roles and the introduction of new roles. As a result, the NHS has seen the emergence and increased use of new professional roles within multi-disciplinary teams as part of a continuing drive to provide safe, accessible and high quality care for patients.

Four of these roles can be grouped under the heading of 'Medical Associate Professions' (MAPs). Whilst there are significant differences in their clinical scope of practice, they share similarities in their career framework and education and training. The four roles are:

- Physician Associate (PA)
- Physicians' Assistant (Anaesthesia) (PA(A))
- Surgical Care Practitioner (SCP)
- Advanced Critical Care Practitioner (ACCP)

All four UK health departments recognise the important contributions that can be made to the delivery of healthcare through the enhancement of existing roles and the introduction of new roles. As these professionals become more widely employed in the health service, it is necessary to explore the options for professional regulation.

The medical associate roles, as part of the wider healthcare workforce, are trained to the medical model to augment service delivery alongside doctors. They are competent to practise in a range of specialties and can offer continuity of care, particularly in acute settings and GP practices. As such, they are dependent practitioners working within their sphere of competence, releasing doctors to focus on more complex patient pathways and care whilst bolstering the healthcare team.

In England, the Government has committed to increasing the primary and community care workforce by at least 10,000 by 2020. This will include an estimated 5,000 more doctors working in general practice, as well as more practice nurses, district nurses and pharmacists. As part of this, there is a commitment to make 1,000 physicians' associates available to work in general practice.

In Scotland, the Scottish Government has a manifesto commitment to produce more General Practitioners by the end of this Parliament. The Scottish Government will be publishing part 3 of the national health and social care workforce plan later this year which will have a focus on general practice and primary care.

In Wales the wider workforce roles are recognised as having the potential to contribute to the wider health care system. However if the contribution is to be maximised, there needs to be a planned approach to changes in models of care.

In Northern Ireland, *Health and Wellbeing 2026: Delivering Together* sets out a 10 year vision for transformation of the health and social care system including a commitment to seek opportunities to introduce new job roles.

Health Education England (HEE), through its MAPs Oversight Board, has worked in partnership with representatives of the devolved administrations, a number of Medical Royal Colleges[1] and their affiliated faculty representatives[2], to identify common themes and establish a core level of knowledge, skills and behaviours across all four MAP roles. The work aims to provide clarity around role definition to employers, patients and the public in support of all four professions, allowing easier movement of such professionals between employers whilst ensuring patient safety.

Ministers in the four UK health departments have long been supportive of examining the possibility of professional regulation for physician associates in terms of patient safety considerations. As a result, in November 2016, the Secretary of State for Health, Jeremy Hunt, announced his intention to consult on whether physician associates should be regulated[3].

Subsequently, HEE undertook an additional strand of work with members of the MAP Oversight Board to collate information on the scope of practice for each MAP role, assessing the evidence of the degree of risk of harm to patients. This informed the completion of risk profiles[4] and forms part of an assessment as to whether these groups should be regulated based upon the Professional Standards Authority's (PSA) criteria for right touch assurance[5]. The completed risk templates have been published alongside this consultation document to aid your consideration.

The four UK health departments have considered HEE's assessment of risk alongside a number of additional factors. This includes the current number of professionals in each role (which impacts on the subsequent scale of the risk) and the level of professional assurance currently in place.

On the basis of this analysis, the four UK health departments are now making the following proposals and are keen to seek views as part of this consultation:

- To introduce statutory regulation for PAs
- To seek further evidence on the most proportionate level of regulation for PA(A)s
- To seek views on the position that statutory regulation of the SCP and ACCP roles is not proportionate, and whether alternative options for professional assurance should be considered.

This consultation also seeks initial views on prescribing responsibilities and on the most appropriate healthcare regulator should the four UK health departments decide to take forward statutory regulation for any or all of the MAP roles.

If, following this consultation, a decision is made to introduce statutory regulation for any of the MAP roles, a further consultation would be required once the detailed drafting of the necessary secondary legislation had been completed.

[1] Royal College of Anaesthetists; Royal College of Physicians; Royal College of Surgeons; Royal College of Emergency Medicine
[2] Association of Physicians' Assistants (Anaesthesia); Faculty of Physician Associates; Faculty of Intensive Care Medicine
[3] https://www.gov.uk/government/speeches/nhs-providers-annual-conference-keynote-speech
[4] HEE developed risk profiles by completing template for each role against the PSA risk criteria.
[5] http://www.professionalstandards.org.uk/what-we-do/improving-regulation/right-touch-regulation

The regulatory framework for health and social care professionals in the UK

The purpose of professional assurance is to protect the public by ensuring that anyone providing healthcare is doing so safely. There is a continuum of professional assurance in relation to health and social care professions. The types of professional assurance range from routine employer controls to voluntary systems of registration through to statutory regulation. The level and type of assurance should be based on the level of risk connected to a particular profession.

There is therefore a mix of regulated and non-regulated health and care professions in the UK. There are currently 35 regulated health and social care professions across 12 statutory regulatory bodies. An individual wanting to practise in one of these professions is required by law to register with the relevant regulatory body. A number of other professions are not regulated including health care assistants, counsellors and the medical associate professions. Those professions that are not subject to statutory regulation will still be subject to employer checks and controls. Organisations that represent these professions can set up voluntary registers or accredited voluntary registers [6] which professionals can join if they adhere to certain requirements, but are under no obligation to do so.

The options for professional assurance of health and social care professions in the UK, and the specific attributes of each type of assurance, are set out in detail in Annex A of this document. The Annex only sets out those means of assurance that are currently used in the UK. However, alternative forms of regulation are used in other countries around the world, such as the use of prohibition orders[7] in Australia.

Statutory regulation is the most thorough form of assurance. The 12 regulatory bodies which regulate health and social care professionals across the four nations of the UK are the gatekeepers to the professions which they regulate. They set the educational requirements needed to enter a profession and the standards required to practise safely and effectively in each profession. They keep registers of people who meet these standards and are qualified and

[6] http://www.professionalstandards.org.uk/what-we-do/accredited-registers

[7] A prohibition order scheme, also referred to in different contexts as a 'negative registration scheme' or a 'barring scheme' allows individuals to be barred from practising a specified profession or from carrying out specific activities, through the use of prohibition or barring orders. This is in contrast to 'positive registration', where individuals are first vetted for their suitability to be registered, are placed on a list of registrants who are deemed fit to practise a particular occupation, and may then be removed from the list if they are found to have breached the standards of practice or conduct required (PSA Initial evaluation of the feasibility of prohibition order schemes for unregulated health and care workers in the UK Dec 2016)

fit to practise. The regulators also set the standards of conduct, performance and behaviour required of professionals and take action where these standards are not met.

There are a number of costs associated with regulation including the set-up costs of implementing statutory regulation with the chosen professional regulator and recurring costs such as administrative costs. The operating costs of the regulator are met by the fees paid by professionals.

Statutory regulation can impose constraints on the ability of employers and professionals to respond flexibly to the changing needs of service users or to deploy staff in a way that better suits different local contexts. On the other hand, the absence of regulation can make employers less confident about utilising a role, limiting the ability of the profession to develop and maximise its potential.

The introduction of statutory regulation for a profession requires changes to be made in law by introducing new legislation. This process is often lengthy and can take up to two years to complete.

Assessing the risks

As a result, any decision to extend statutory regulation to a professional or occupational group must be based on a solid body of evidence demonstrating a level of risk to the public which warrants the costs imposed by statutory regulation and which cannot be effectively addressed through other means of professional assurance, such as those mentioned at the start of this chapter. As such, for professions whose scale of risk can be managed and where operational numbers are low, a proportionate approach needs to be taken in considering the appropriate means of assurance.

In many cases, the risk to patients and service users posed by groups of unregulated health and social care professionals is not considered to be such that statutory regulation is necessary. This may be because existing safeguards within the system and the regulation of health and social care service providers are deemed to be at a sufficient level to manage the risk posed by a particular profession. For example, employers can sign up to the Disclosure and Barring Service in England and Wales, the Protection of Vulnerable Groups (PVG) scheme in Scotland and Access NI in Northern Ireland.

The Professional Standards Authority (PSA) published its paper 'Right-touch assurance: a methodology for assessing and assuring occupational risk of harm' in October 2016[8]. The paper sets out a proposed model for assessing the relative risk of harm presented by different health and care professions. In order to assess the right level of regulation that is required the first stage of the PSA's methodology creates a risk profile against specific criteria to assess the risk of harm. The criteria include:

- **Intervention** – are the interventions the professionals perform invasive or high-risk, or involve specific patient diagnostic or care functions?

[8] Professional Standards Authority – Right Touch Assurance : a methodology for assessing and assuring occupational risk of harm – 3 Oct 2016 - http://www.professionalstandards.org.uk/publications/detail/right-touch-assurance-a-methodology-for-assessing-and-assuring-occupational-risk-of-harm

- **Context** – do they practise outside managed environments such as a hospital or clinic, are they alone with patients, how clear is their chain of delivery?

- **Accountability** – do they make decisions which impact on individual mortality or morbidity, what degree of autonomy and delegated responsibility do they have from senior professionals?

The PSA methodology also sets out that extrinsic factors should be considered. Accordingly, the four UK health departments have considered the criteria set out above alongside a number of other factors such as the current numbers in each profession and the level of professional assurance currently in place.

This document is concerned with four medical associate professional roles in particular (physician associates, physician assistants (anaesthesia), surgical care practitioners and advanced critical care practitioners). The remainder of the document sets out an overview of the four roles and an assessment of the risks associated with each role based on the PSA methodology outlined above.

Medical Associate Professions

Across the UK, an increasing need for medical treatment and advances in clinical care requires a coordinated approach and a greater skill mix within healthcare teams. This includes the enhancement of existing roles and the introduction of new roles. As a result, the NHS has seen the emergence and increased use of new professional roles within multi-disciplinary teams as part of a continuing drive to provide safe, accessible and high quality care for patients.

Following the publication of the Shape of Training Review report[9] in 2013 there is widespread recognition amongst the healthcare sector that the shape and composition of the medical workforce needs to adapt to deliver the medical care more appropriate for a growing, changing and ageing population.

Four of these professional roles can be grouped under the heading of 'Medical Associate Professions' (MAPs). Whilst there are significant differences in their clinical scope of practice, they share similarities in their career framework and education and training. The four roles are:

- Physician Associate (PA)
- Physicians' Assistant (Anaesthesia) (PA(A))
- Surgical Care Practitioner (SCP)
- Advanced Critical Care Practitioner (ACCP)

The following section gives a high level overview of each role, approximate numbers in each profession and existing professional assurance arrangements.

Summary of medical associate professional roles

- **Physician Associates (PAs):** Work in hospitals and general practice. Carry out a number of tasks including taking medical histories, examinations and managing and diagnosing illnesses under the supervision of a doctor. Individuals complete a two year post graduate diploma or MSc. Entrants are usually graduates with a biomedical science degree but some courses accept individuals who have health related degrees or are registered healthcare professionals such as nurses.

- **Physicians' Assistants (Anaesthesia) (PA(A)s):** Work in hospitals as deliverers of anaesthesia and critical care in the anaesthetic team, performing pre and post-operative assessment and intervention and providing anaesthesia under the supervision of a consultant anaesthetist. Individuals complete a 27 month post graduate diploma and entrants are either graduates with biomedical or biological science degree, or registered healthcare professionals such as nurses or operating department practitioners (ODPs) with at least three years clinical experience and/or degree level studies.

[9] https://hee.nhs.uk/our-work/developing-our-workforce/shape-training

- **Surgical Care Practitioners (SCPs):** Perform some surgical procedures and preoperative and postoperative care under the supervision and direction of a consultant. It should be noted that in order to be eligible for the postgraduate masters course, individuals must be registered as a nurse, ODP or other allied health professional (AHP) and have at least 18 months experience in a clinical perioperative background.

- **Advanced Critical Care Practitioners (ACCPs):** Work in critical care units where they diagnose and treat patients and refer to an appropriate specialist if needed. They make high-level clinical decisions and will often have their own caseload. In order to be eligible for an appropriate postgraduate diploma or master's degree individuals must be registered healthcare professionals who are non-medical prescribers as this is a fundamental part of the role.

Table 1: Numbers, assurance arrangements and entry routes

	Approximate number	UK countries they practise in	Existing assurance arrangements	Entry route to training
PAs	400	England, Scotland, Wales, NI	Voluntary register operated by the Faculty of Physician Associates. Some PAs are already regulated healthcare care professionals, such as nurses.	Allow direct entry for post graduates. Usually required to have a degree in biomedical science
PA(A)s	165	England, Scotland, Wales	Voluntary register operated by the Association of Physicians' Assistants (Anaesthesia). Some PA(A)s are already regulated healthcare care professionals, such as nurses or operating department practitioners	Allow direct entry for post graduates.
SCPs	212	England, Scotland, Wales	SCPs can join the Faculty of Perioperative Care but there is no register specifically for SCPs. Professionals must already be a regulated healthcare professional.	Individual must be a regulated healthcare professional – usually nurses, operating department practitioner or allied health profession.
ACCPs	108	England, Wales	Voluntary register held by the Faculty of Intensive Care Medicine. Professionals must already be a regulated healthcare professional.	Individual must be a regulated healthcare professional. All ACCPs are required to register with the Faculty of Intensive Care Medicine (FICM) after starting training.

The following four chapters of this document set out more information in relation to the four MAP roles including HEE's assessment of the risk of harm from clinical practice for each profession. The full set of risk profiles collated by HEE is published alongside this consultation.

The document then sets out the four UK health department's views and seeks your opinions on our proposals.

Physician Associates

Background

PAs were introduced to the UK in 2003. Initially they were known as physician assistants, to mirror the name of the same profession in America, where the role was developed in the 1960s. The name was changed to physician associate in the UK in 2014.

The UK Association of Physician Associates (UKAPA) was established in 2005, acting as a professional body for physician associates. In 2015 the body was replaced by the Faculty of Physician Associates (the Faculty).[10]

What is a physician associate?

A PA can be defined as:

"a new healthcare professional who, while not a doctor, works to the medical model, with the attitudes, skills and knowledge base to deliver holistic care and treatment within the general medical and/or general practice team under defined levels of supervision".[11]

PAs carry out a number of tasks as part of their role including:

- taking medical histories from patients
- carrying out physical examinations
- seeing patients with undifferentiated diagnoses
- seeing patients with long-term chronic conditions
- formulating differential diagnoses and management plans
- performing diagnostic and therapeutic procedures
- developing and delivering appropriate treatment and management plans
- requesting and interpreting diagnostic studies
- providing health promotion and disease prevention advice for patients.

PAs are not able to request CT scans or X-rays. PAs do not currently have prescribing responsibilities. Historically professions cannot prescribe without being subject to statutory regulation because prescribing is such a high risk activity.

However not every profession that is subject to statutory regulation is given prescribing responsibilities and the process of regulating a profession and the process of giving a profession prescribing responsibilities are two separate legislative processes.

[10] www.fparcp.co.uk/about-fpa
[11] Competence and Curriculum Framework for the Physician Assistant 2012, http://www.fparcp.co.uk/document-library/?resources_page=2

Training and education

A biomedical science degree is usually required for entry to a PA training course. The majority of PAs enter the profession following completion of their postgraduate studies, although registered healthcare professionals, for example a nurse or allied health professional, can also apply to train as a PA.

PAs undergo two years (full-time) postgraduate training based on the Faculty's Competence and Curriculum Framework for physician associates[12]. There are currently 30 accredited education programmes running in the UK.

Training consists of theoretical learning in medical sciences, pharmacology and clinical reasoning as well as over 1,400 hours of clinical placement experience in community and acute care settings. Newly graduated PAs also complete a third year internship with a doctor to solidify and deepen their skills[13].

Although there is no legal requirement on employers to do so, the Faculty strongly recommend that employers only consider recruiting PAs who:

- are registered on the Physician Associate Managed Voluntary Register;
- hold a diploma or masters in Physician Associate Studies from a recognised UK or US programme; and
- have passed the UK Physician Associate National Exam.

The Faculty also requires professionals on the register to complete a recertification every six years[14].

PAs and the healthcare workforce

PAs can be found working in GP surgeries, accident and emergency departments, and inpatient medical and surgical wards throughout the UK.

They are a valuable addition to the healthcare team and increase access to quality care for patients and service users. They act in a generalist role, helping to meet the healthcare team's workload and add to the skill mix within teams. In primary care settings PAs typically see people with acute minor illnesses, helping to free up consultation time for doctors to focus on patients with multiple and complex health needs. Although PAs work under the supervision of a doctor, this does not mean that every patient they see needs to be reviewed by the supervising doctor, or that they cannot make decisions independently.

As there is a direct entry route into PA training for postgraduate students the role increases workforce numbers and brings new talent into the NHS. While trainee doctors rotate through different specialties, PAs can offer continuity and stability both for patients and for the team in which they work as they are permanent members of a team rather than being on rotation.

[12] www.fparcp.co.uk/about-fpa/Who-are-physician-associates
[13] www.fparcp.co.uk/pa-students/student-faqs.
[14] http://www.fparcp.co.uk/examinations/recertification

As of May 2017 there were approximately 400 PAs working in primary and secondary care in England, Scotland and Wales, with a small number working in Northern Ireland. An exact figure cannot be obtained as registration with the Faculty is voluntary. There has been a marked expansion across the UK in the number of PA training courses in recent years with over 1,200 students in training. In June 2015 the Secretary of State for Health, Jeremy Hunt, announced a commitment for 1,000 PAs to be available to work in general practice in England by 2020[15].

The further growth of this profession is a key part of the four UK health department's policy to develop a more effective, strong and expanding general practice to meet future need. HEE has been working with experts in the field to commission additional PA training courses in England and the number of PAs is expected to rise rapidly. In Wales, two Welsh Government funded pilot post graduate programmes were launched in 2016 and an additional cohort will be available from September 2017.

Increasing access to the profession

Due to the level of demand for PAs in different parts of the UK, work is being undertaken to explore whether an apprenticeship could also be a suitable entry route into the profession. As part of apprenticeship reform, 'trailblazer' groups of employers work together to design new apprenticeship standards for occupations within their sectors. In England, HEE is supporting a trailblazer group to develop an apprentice standard for the PA role.

Current regulatory arrangements for PAs

The Faculty oversees and administers the Physician Associate Managed Voluntary Register (PAMVR).

The Faculty reviews applications to join the register and establishes whether the professional applying is fit to practise in the UK. The Faculty reviews and sets standards for:

- the education and training of physician associates;
- the accreditation of university programmes; and
- physician associate national certification and recertification examinations.

A Competence and Curriculum Framework is in place for PAs and they are required to complete 50 hours of continuing professional development (CPD) per year to remain on the register.

However registration of practitioners with the Faculty is entirely voluntary[16] and approximately 75% of practitioners are currently registered. Although the Faculty operates a fitness to practise procedure to ensure good standards of practice and may independently investigate concerns raised about a PA on its register, this is not set out in legislation.

The Faculty may remove an individual from the voluntary register and highlight concerns to an employer but it does not have any powers to prevent an individual continuing to practise as a PA or use the title PA even if the Faculty has concerns about their fitness to practise safely.

[15] www.gov.uk/government/speeches/new-deal-for-general-practice
[16] www.fparcp.co.uk/employers/pamvr

Physicians' Assistants (Anaesthesia)

Background

PA(A)s were introduced to the UK in 2004. Originally called anaesthesia practitioners, a change in title to physician assistants (aneathesia) was agreed in 2008.

The Association of Physicians' Assistants (Anaesthesia) (the Association) is the representative body for PA(A)s in the UK.

What is a PA(A)?

A PA(A) is trained both in the underlying scientific and medical knowledge relevant to anaesthesia and in the skills of administering anaesthesia.

An agreed scope of practice for PA(A)s was drawn up by the Royal College of Anaesthetists (RCoA) and the Association in 2016. This sets out the types of interventions and level of supervision which should be followed by PA(A)s[17].

They perform duties delegated to them by their medical anaesthetic supervisor which include:

- pre and post-operative patient assessment and care;
- maintenance anaesthesia; and
- induction into and emergence from anaesthesia (under direct supervision).

PA(A)s will also deputise for anaesthetists in a variety of situations where their airway and venous cannulation skills will assist in patient care and where medically qualified anaesthetists are not available, such as in Accident and Emergency departments and critical care.

On completion of training, PA(A)s are ***not*** qualified to undertake:

- Regional anaesthesia/regional blocks
- Obstetric anaesthesia or analgesia
- Paediatric anaesthetic practice
- Initial airway assessment and management of acutely ill or injured patient (except when the PA(A) is part of a multidisciplinary hospital resuscitation team called to attend a patient and is first to arrive)

However, a number of PA(A)s work to an extended scope of practice managed within the local governance structures in organisations. This extended scope can include performing sedation and regional anaesthesia for acute pain.

[17] http://www.rcoa.ac.uk/anaesthesia-related-professionals/physicians-assistant-anaesthesia

Training and education

There is a single defined route of entry to the profession through a post graduate diploma. There is currently only one approved training course in the UK run by the University of Birmingham. The course content is developed and overseen by the RCoA and the Association. The 27 month course combines workplace teaching and competency assessment with distance learning and teaching in small groups.

The RCoA has reported that there are around 65 PA(A)s in training. The rollout of the PA(A) programme is currently 'demand led' by organisations who are required to secure funding to meet the cost of commissioning the required number of places on the course based on their workforce needs[18].

PA(A)s and the healthcare workforce

PA(A)s are generally employed in hospital surgical units but some organisations use their specialist skills in Accident and Emergency departments and critical care. PA(A)s can offer continuity and stability both for patients and for the team in which they work as they are permanent members of a team rather than being on rotation.

As of July 2016 there are approximately 165 PA(A)s in the UK. As registration with the RCoA is voluntary, the exact number of PA(A)s working in the UK is not known. Given that there is only one approved training course in the UK, growth of the profession is slow with demand being driven by specific gaps in the workforce in certain organisations across the UK.

As there is a direct entry route for postgraduate students into PA(A) training the role increases workforce numbers and brings new talent into the NHS.

Current regulatory arrangements for PA(A)s

The Association holds a voluntary register of qualified PA(A)s and a list of those currently in training. As set out in a joint statement issued in April 2016, the Association of Anaesthetists of Great Britain and Ireland (AAGBI) and RCoA will only recognise PA(A)s who have qualified having completed the approved UK training programme and have subsequently been entered on the voluntary register. The AAGBI and RCoA recommend that only individuals who appear on the voluntary register should be employed in the PA(A) role. However, there is no legal requirement for employers to follow this advice[19].

[18] http://www.rcoa.ac.uk/anaesthesia-related-professionals/physicians-assistant-anaesthesia - Planning the introduction and training for physicians' assistants (anaesthesia)
[19] http://www.anaesthesiateam.com/general-info/about-us/

Surgical Care Practitioners

Background

Assistants in surgical practice have been a part of the NHS since 1989. The role has been extended as nurses and operating department practitioners (ODPs) for example have demonstrated their increasing contribution in the surgical environment.

What is a surgical care practitioner?

A Surgical Care Practitioner (SCP) is a registered healthcare professional (nurse, ODP or other allied health professional) who has extended the scope of their practice to work as a member of a surgical team. They perform surgical intervention and preoperative and postoperative care under the supervision and direction of a consultant.

The role encompasses pre-, intra- and post-operative care. Under the direction of a consultant surgeon, the SCP may participate in:

- Preoperative assessment, including clinical history taking and physical examination
- Enhancing the communication link between theatre, patient and ward
- Involvement in the team completion of the 'Five Steps to Safer Surgery'
- Assisting with the preparation of the patient, including urinary catheterisation, venepuncture, patient positioning and preparation
- Providing assistance with surgical procedures
- Some technical and operative procedures according to their scope of practice
- Facilitating the training of trainee surgeons
- Arranging appropriate pre- and post-operative investigations
- Post-operative care – including wound assessment and management
- Evaluation of care, including the discharge process, follow-up care and outpatient activities.

Training and education

There are currently four masters' courses which are accredited by the Royal College of Surgeons (England) linked with the curriculum framework (2014). However in the past there have been a number of "in house" education programmes which had less quality assurance.

SCPs and the healthcare workforce

There are approximately 200 SCPs working in England, Scotland and Wales. The role is restricted to practising in acute and secondary care. SCPs are employed as a member of the extended surgical team and are clinically responsible to the consultant surgeon who delegates aspects of perioperative care to the SCP.

There are currently no central initiatives to increase the number of SCPs.

Current regulatory arrangements for SCPs

Entrants into training for this role must already be an established regulated healthcare professions, such as a registered nurse.

A faculty at the Royal College of Surgeons (Edinburgh) has been established and SCPs may also become members of the Association of Perioperative Practice.

Advanced Critical Care Practitioners

Background

Advanced roles in intensive and critical care have been operational in hospitals pre-2000. Many critical care units introduced new roles or extended the scope of practice of nurses, technicians, physiotherapists and clinical pharmacists in response to increasing complexity of care pathways and maximising opportunities to prevent or reduce the risk of critical illness in medical and surgical patients in general ward areas.

To reduce variation in the role's scope of practice and training pathway, the Department of Health in England defined the ACCP role in 2008 and published a National Education and Competence Framework for Advanced Critical Care Practitioners[20].

What is an advanced critical care practitioner?

ACCPs are experienced members of the care team working in intensive care units. They are able to diagnose and treat health care needs or refer patients to an appropriate specialist. They are empowered to make high-level clinical decisions and will often have their own caseload.

ACCPs can:

- Undertake comprehensive clinical assessment of a patient's condition
- Request and perform diagnostic tests
- Initiate and manage a clinical treatment plan
- Provide accurate and effective clinical handovers
- Undertake invasive interventions within the scope of practice
- Provide professional leadership and support within a multi-professional team
- Work autonomously in recognised situations
- Demonstrate comprehensive knowledge across a range of subject areas relevant to the field of critical care
- Critically analyse, evaluate and synthesise different sources of information for the purpose of assessing and managing the care of a critically ill patient
- Apply the principles of diagnosis and clinical reasoning that underlie clinical judgement and decision making
- Apply theory to practice through a clinical decision-making model
- Apply the principles of therapeutics and safe prescribing
- Understand the professional accountability and legal frameworks for advanced practice

[20] https://www.ficm.ac.uk/sites/default/files/National%20Education%20%26%20Competence%20Framework%20for%20ACCPs.pdf

- Function at an advanced level of practice as part of the multidisciplinary team as determined by the competency framework
- Apply the principles of evidence-based practice to the management of the critically ill patient
- Understand and perform clinical audit.

A key part of the ACCP role is the ability to prescribe, having undergone appropriate and ongoing training.

Training and education

Entrants into training for this role must already be an established regulated healthcare professions, such as a registered nurse.

Trainees must complete a programme with a Higher Education Institution (HEI) leading to an appropriate postgraduate diploma or master's degree. ACCP training programmes are run locally by hospital trusts in conjunction with HEIs. The two year training programme consists of clinical modules delivered within the local Critical Care unit and academic modules.

The Faculty of Intensive Care Medicine has published a Curriculum for Training for ACCPs which describes the context in which they work: https://www.ficm.ac.uk/sites/default/files/ACCP%20Curriculum%20v1.0%20(2015)%20COMPLETE_0.pdf

ACCPs and the healthcare workforce

Currently there are approximately 100 ACCPs working in England and 8 in Wales. Seventeen trusts now have trained ACCPs working on medical rotas in their intensive care units.

ACCPs work on medical rotas in replacement of medical trainees. Supervision varies dependent upon the situation and skill of the ACCP and ranges from distant to direct.

There are currently no central initiatives to increase the number of ACCPs.

Current regulatory arrangements for ACCPs

As set out above, trainees must be from established regulated healthcare professions, such as nursing.

All trainee ACCPs are also required to register with the Faculty of Intensive Care so that they are able to monitor the ACCP workforce.

Assessment of risk

Patient safety and risk of harm to patients is the key determinant for whether a profession should be subject to statutory regulation.

Understanding the degree of risk and potential for harm to patients and the public from a healthcare profession requires a comprehensive assessment of education, training, continued professional development, scope and scale of practice, how the role is deployed and the nature of the working environment.

The information collated by HEE, which has been summarised in this document, and the completion of risk profiles[21], in collaboration with MAP Board members, has informed an initial assessment of the risk of harm from clinical practice for each of the four MAP roles.

The assessment of risk is based upon the PSA's criteria for Right–Touch Assurance (detail of which is set out in the chapter - *Regulatory framework for health and social care professionals in the UK* on pages 6-8).

In brief, the PSA recommends a two stage methodology. First, by creating a risk profile of a profession which takes into account the risks of harm arising from practice, such as the level of autonomy or invasiveness of interventions. Second, looking to apply external factors to assess the level of assurance needed to manage the potential risk of harm. These external factors include considerations around the size of the patient and professional group, clinical governance arrangements and employer policies and procedures. Consideration has also been given to the levels of professional assurance already in place for each of the roles.

Table 2 on page 22 summarises HEE's assessment of the risk of harm from clinical practice for each of the four professions based on the completed risk profiles. The full risk profiles are published alongside this consultation.

[21] HEE developed risk profiles by completing a template for each role against the PSA risk criteria.

Table 2: Outcome of assessment of risk of harm from clinical practice

RISK OF HARM TO PATIENT FROM:	PSA Criteria 1: INTERVENTION (e.g. are the interventions they perform with patients invasive or high-risk, do they involve specific patient diagnostic or care functions)	PSA Criteria 2: CONTEXT (e.g. do they practise outside managed environments such as a hospital or clinic, are they alone with patients, how clear is their chain of delivery)	PSA CRITERIA 3: ACCOUNTABILITY (e.g. do they make decisions which impact on individual mortality or morbidity, what degree of autonomy and delegated responsibility do they have from senior professionals)
Physician Associate	HIGH	HIGH	HIGH
Physicians' assistant (anaesthesia)	HIGH	LOW	MEDIUM
Surgical care practitioner	HIGH	LOW	MEDIUM
Advanced critical care practitioner	HIGH	LOW	HIGH

The four UK health department's initial assessment of risk in relation to the four MAPs is set out below along with the proposed appropriate level of professional assurance. This assessment is based on the information collated by HEE, HEE's assessment of risk and a range of external factors including the level of professional assurance currently in place and the number of professionals in each role.

PAs – assessment of risk

HEE's assessment of risk reflects the wide ranging scope of the PA role including the provision of direct and interventional care to patients, the environments they work in (particularly primary care) and the level of direct supervision they are subject to. For example, PAs are often alone with vulnerable patients and service users and can make autonomous diagnostic and treatment decisions without the immediate direct supervision of a doctor. In addition, the types of intervention they undertake can also be invasive such as performing diagnostic investigations.

The Secretary of State for Health in England's commitment to have 1,000 PAs available to work in general practice in England by 2020 will mean that a higher proportion of PAs will be working without immediate direct supervision in a primary care setting. The proposed increase in the PA workforce will also mean an increase in the scale of the risk of harm as the number of patients being treated by PAs increases.

Although there is a voluntary register for PAs which does provide a level of assurance to employers in relation to those that are on it, the four UK health departments do not consider this to be sufficient given the above considerations. In addition, as there is a direct entry route into training for postgraduate students, the majority of PAs are not part of a profession that is already regulated. The absence of statutory regulation means that persons who have not

undergone the recognised training, and who have not met the standards expected of PAs, can use the PA title.

Having considered the available evidence, the four UK health departments propose that the introduction of statutory regulation for PAs is necessary and proportionate. However, we are keen to hear your views on this and to seek further evidence as part of this consultation. Information on the different types of professional assurance can be found in Annex A of this document to aid your consideration.

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

PA(A)s – assessment of risk

It is clear that the types of intervention PA(A)s make on a routine basis are high risk. For example a PA(A) could be required to make urgent autonomous decisions critical to a patient's care during surgical procedures before their supervising consultant is available.

The scope of practice agreed by the RCoA and the Association requires that a consultant anaesthetist should be present within the same operating suite as a PA(A). Most PA(A)s work to the recommended 2:1 ratio supervision with a consultant which means that the consultant may be supervising another member of staff in an adjacent theatre.

However, the evidence relating to PA(A) practice and the level of clinical autonomy is not clear cut. Specifically, we understand that a proportion of PA(A)s work beyond the agreed scope of practice for the role, performing additional tasks with limited supervision, such as regional anaesthesia blocks and undertaking sedation lists. Although this extended practice is managed under local governance structures - and therefore subject to controls and standards established by individual trusts - there are no universal standards or training in these extended practices as part of the approved PA(A) training course. This creates the potential for inconsistency across the profession and could pose a risk to patient safety.

A further factor for consideration when assessing the risks, is the route of entry into the profession. Some PA(A)s enter the profession directly following postgraduate study and are therefore not already a regulated healthcare professional. On the other hand, there are a small number of PA(A)s and the relatively slow rate of projected growth means that the proportion of patients who may come into contact with a PA(A) is small.

The four UK health departments believe that there is insufficient evidence at present to make a decision about whether PA(A)s should be regulated or whether other forms of professional assurance are more proportionate. Further evidence, for example on the level of clinical autonomy and scope of practice, is required in order to make a decision about the appropriate level of assurance. Information on the different types of professional assurance can be found in Annex A of this document to aid your consideration.

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

SCPs and ACCPs – assessment of risk

SCPs

It is clear that some of the tasks SCPs undertake are high risk. This includes carrying out preoperative assessments including physical examinations and carrying out technical and operative procedures dependent on their scope of practice.

However, in order for an individual to begin training as a SCPs they must already be a registered healthcare professional subject to statutory regulation, such as a registered nurse. SCPs also work solely in secondary care where professionals are more likely to be working within a team of healthcare professionals.

In addition, there are only around 200 SCPs, who predominantly practise in England and Scotland with a very small number in Wales. There are no central initiatives to increase the number of SCPs which suggests that the number of patients treated by SCPs is likely to remain small.

ACCPs

As with SCPs, ACCPs carry out some tasks as part of their scope of practice which, as set out in the table on Page 22, are deemed to be high risk. This includes performing diagnostic tests and undertaking invasive interventions.

As with SCPs, ACCPs are also required to be registered healthcare professionals subject to statutory regulation before they begin training.

There are also small numbers of ACCPs (approximately 100 working in England and 12 in Wales) and no centrally-planned initiatives to expand their numbers. This again means that small numbers of patients are being treated by ACCPs.

Whilst the four UK health departments recognise the benefits of the development of medical associate professions we are not persuaded by the case for introducing statutory regulation for the SCP and ACCP roles at this time. SCPs and ACCPs are required to be registered healthcare professionals, and therefore already subject to statutory regulation, before they begin training. Although working to extended practice in different roles, the protection afforded through accountability to the regulator the individual is registered with still applies.

We would however still like to seek your views on what you think is the appropriate level of assurance for these two roles. Information on the different types of professional assurance can be found in Annex A of this document.

Question 3:

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

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

Please provide further information to support your answer

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

Prescribing responsibilities

Under UK law a regulated healthcare professional can supply or administer medicines to patients in a number of ways.

- Exemptions: Some professions are allowed under medicines regulations to supply particular medicines directly to patients as clinically required. This mechanism is known as “exemption” and is usually for immediate treatment. Paramedics use exemptions to provide immediate pain relief when needed.

- Patient Group Directions (PGDs) allow particular healthcare professionals to be trained to assess a patient within stated parameters. A separate direction is needed for each different medicine to be supplied. The PGD is a set of instructions which directs the healthcare professional in their assessment of the patient and working through the protocol produces a clear indication of whether the patient should or should not recieve the medicine concerned.

Only "appropriate practitioners" can prescribe medicine. An appropriate practitioner is described as:

a. an independent prescriber: someone able to prescribe medicines under their own initiative. They include, amongst others, doctors, dentists and nurse independent prescribers;

b. a supplementary prescriber: someone able to prescribe medicines in accordance with a pre-agreed care plan that has been drawn up between a doctor and their patient. Supplementary prescribers include, amongst others, nurses, midwives and pharmacists[22].

Registrants from these professions need to complete an approved post-registration training programme to become independent or supplementary prescribers.

Whilst there is no legal requirement for a profession to be subject to statutory regulation before it can be given prescribing responsibilities, all healthcare professions that have prescribing responsibilities in the UK are regulated. This is because prescribing is a high risk activity which should only be carried out by individuals operating in a regulated context.

The process required to expand prescribing responsibilities to a profession is set out below:

- NHS England, working in partnership with the Department of Health in England, the devolved administrations, the Medicines and Healthcare products Regulatory Agency (MHRA) and other health and care system partners lead the development of any proposals to expand prescribing responsibilities.

[22] www.nhs.uk/chq/Pages/1629.aspx?CategoryID=68

- Public consultation on proposals to expand prescribing responsibilities explaining how the new prescribing group would work in practice, what their levels of training should be and how public safety would be protected.

- The Commission on Human Medicines make recommendations to ministers on any proposals to expand the list of regulated health professions able to prescribe medicines, taking account of the results of public consultation (outside the scope of this consultation).

- Once any further expansion of professions' roles in relation to medicines has been agreed, MHRA lead on making the necessary changes to legislation.

This process can take a number of years to complete and the expansion of prescribing responsibilities is a separate process to the introduction of statutory regulation for a profession and would be subject to a separate consultation. The four UK health departments are therefore using this consultation to seek initial views.

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 specific which professions and your views on the appropriate level of prescribing responsibilities (e.g an independent prescriber or a supplementary prescriber)

Consideration of the appropriate professional regulator

Should the four UK health departments decide to proceed with the introduction of statutory regulation for any or all of the MAP roles, then a decision will have to be made as to which regulatory body should regulate them.

The principal considerations in deciding where to place the MAPs include:

- The existing scope of the regulator
- Cost
- Views of key stakeholders such as the relevant professional group(s)
- Speed of delivery (e.g. establishing rules and standards for the new group(s))

Of the 12 UK health and social care regulators the General Medical Council (GMC) and the Health and Care Professions Council (HCPC) appear to be the most suitable potential regulator given their current registrant bases, however the considerations set out above will need to be factored into any decision.

The GMC (gmc-uk.org) helps to protect patients and improve medical education and practice in the UK by deciding which doctors are qualified to work here, setting the standards that students and doctors need to follow, and taking action to prevent a doctor from putting the safety of patients, or the public's confidence in doctors, at risk.

The HCPC (hcpc-uk.co.uk) maintain a Register of health and care professionals who meet its standards for their training, professional skills, behaviour and health. The HCPC has expanded over the years to regulate a diverse range of healthcare professionals including occupational therapists, paramedics and physiotherapists.

Either of these regulators could be suitable to take on the regulation of these groups and we welcome your views on which regulator would be most appropriate.

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**

Please provide further information to support your answer

Costs and benefits analysis

As part of the development of our proposals, we have done an initial assessment of the potential costs and benefits for a profession of:

1. Voluntary registration
2. Accredited registration[23]
3. Statutory regulation

We intend to use this consultation to seek further evidence to consider in our impact assessment, and to inform the final recommendation on the appropriate level of assurance for MAPs.

Voluntary registration

Costs
• There is usually a fee to the professional, both to join a professional voluntary register and in relation to annual renewal of registration. This fee can vary between professions, for example the annual fee for the Faculty of PAs voluntary register is £200. The fee level is often dependent in part on the number of professionals registered due to economies of scale.
• In order to be accepted on to the voluntary register it is likely that an individual would need to hold a certain level of qualification and potentially complete periods of CPD which could incur additional costs for the individual and the employer, both in monetary terms and in time taken to complete the requirements.
Benefits
• Voluntary registers tend to be run by organisations who are experts in a particular profession. There are therefore sometimes requirements for professionals to meet standards or hold a particular level of qualification in order to be registered. Employers might therefore be more likely to employ a professional who meets the requirements of a voluntary register.
• The voluntary nature of the register is beneficial to those professionals that wish to practise but do not wish to join the register and pay the registration fee.
• Benefits also accrue to patients/service users as the voluntary register enables them to identify professionals who meet certain standards

[23] Registers that are accredited by the PSA - http://www.professionalstandards.org.uk/what-we-do/accredited-registers

Accredited voluntary registration

Costs
• In addition to the costs of a voluntary register set out above, there is a further (mandatory) monetary cost attached to becoming an accredited voluntary register. In order for a voluntary register to be accredited by the PSA, an assessment against a series of standards is required. If a voluntary register is accredited there is then an annual fee based on the register maintaining the same standards. Some or all of this fee will need to be collected via registrant fees meaning fees may be higher than if a voluntary register was not accredited. The PSA currently charges: ➢ £12,735 for the initial accreditation; and ➢ £9,550 for the Annual renewal process
• As with voluntary registration, in order to be accepted on to the voluntary register it is likely that an individual would need to hold a certain level of qualification and potentially complete periods of continued professional development which could incur additional costs for the individual and the employer, both in monetary terms and in time taken to complete the requirements.
Benefits
• As with voluntary registers, a professional on an accredited voluntary register is subject to set standards of behaviour and competence. In addition, to voluntary registers, accredited voluntary registers must also meet standards set by the PSA such as ensuring that there is a complaints mechanism in relation to its registrants.
• A 'kite mark' of accreditation from a national organisation can also provide an additional level of assurance to the public that a professional is maintaining their standards to a certain level.
• As with voluntary registration, the voluntary nature of the accredited register is beneficial to those professionals that wish to practise but do not wish to join the register and pay the registration fee.

Statutory regulation

Costs
• Professions that are statutorily regulated are required to pay an annual fee to initially join the register and an annual renewal fee to stay on the register order to practise in their chosen profession. Current fees for statutory regulation range from £90pa for professionals registering with the HCPC, £425pa for doctors registering with the GMC, to £890pa for dentists registering with the General Dental Council. For those professions who already have well utilised voluntary registers where the majority of professionals already pay an annual fee the monetary cost to the individual of statutory regulation might have little to no impact. • There will also be a loss to the taxpayer as registration fees are tax deductible. (It should be noted that the fees for some accredited voluntary registers are also tax deductible).
• Additional costs to registrants could include, but are not limited to: ➢ time costs needed to engage with, and meet the requirements of the regulator ➢ time, monetary and professional costs associated with fitness to practise procedures
• There will also be transition costs such as one off set-up costs relating to the implementation of statutory regulation with the chosen regulator. These costs are often high and may therefore present financial implications for the UK government.
Benefits
• Statutory regulation allows for assurance processes which can have legal consequences. Whilst standard assurance, CPD and complaints processes may exist as part of a voluntary register and are more likely to exist with an accredited voluntary register, because an individual can legally practice in their chosen profession without registration, any actions taken by the voluntary regulatory are non-mandatory.
• Statutory regulation will remove a potential barrier to extension of scope of practice, possibly to include medicines supply, administration and/or prescribing responsibilities (subject to the process set out on pages 27-28), enabling employers to maximise the potential of the role.
• Formal, fitness to practise procedures can benefit service users by establishing whether a registrant's practice is impaired and taking action in order to protect the public. Having cases dealt with by a body independent of the employer and the profession provides transparency and clarity for patients.
• Increased demand for profession from employers due to the additional reassurance provided by statutory regulation.

Through this consultation we are seeking further information on the potential costs and benefits of the professional assurance options and how they might impact on the MAP roles. **We are particularly keen to gain evidence on the cost and time incurred on professionals and education providers as a result of statutory regulation, the expected**

growth in numbers for each of the professions and the split between public and private employment to help quantify the Impact Assessment.

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

Please provide further information to support your answer

Equality considerations

The Department of Health is covered by the Equality Act 2010, and specifically, the Public Sector Equality Duty. The Duty covers the following protected characteristics:

- age
- disability
- gender reassignment
- pregnancy and maternity
- race (includes ethnic or national origins, colour or nationality)
- religion or belief (includes lack of belief)
- sex
- sexual orientation

There are three parts to the Duty and public bodies must, in exercising their functions, have due regard to them all. They are:

- the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010;
- advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it;
- foster good relations between persons who share a relevant protected characteristic and persons who do not share it.

Section 75(1) of the Northern Ireland Act 1998 requires all public authorities in carrying out their functions relating to Northern Ireland to have due regard to the need to promote equality of opportunity between:

- persons of different religious belief, political opinion, racial group, age, marital status and sexual orientation
- men and women generally
- persons with a disability and persons without
- persons with dependants and persons without

In addition section 75(2) of the 1998 Act requires public authorities without prejudice to their obligations under subsection (1) to have regard to the desirability of promoting good relations between persons of different religious belief, political opinion and racial group.

The Department of Health in England has completed an initial assessment of the potential impact of our proposals on protected characteristics covered by the Public Sector Equality Duty. As part of our assessment we have sought data on the protected characteristics from NHS Digital in relation to PAs. The available data[24] suggested that:

- there are more female than male PAs
- over half of PAs are aged between 25 and 39
- over half of PAs state their ethnicity as ‘white’

[24] It must be noted that this data only covers PA working in the NHS Hospital and Community Health Services and that the individuals are not required to provide equalities information.

There is minimal available evidence on the protected characteristics of PA(A)s, SCPs and ACCPs. This is because these roles do not currently have a specific code on the Electronic Staff Register (ESR) therefore data cannot be obtained by NHS Digital. As part of this consultation we are seeking evidence on whether any changes to the level of professional assurance could impact (positively or negatively) on any of the protected characteristics.

It must also be noted that if a decision was made to introduce statutory regulation for any of the MAP roles a professional healthcare regulator would be given legal responsibility for regulating them. All healthcare regulatory bodies are required to adhere to the Public Sector Equality Duty when developing processes and policies. The GMC, for example, has an Equality and Diversity Strategy which applies to their work as both an employer and a regulator.

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

How to Respond to the Consultation

This consultation is undertaken on behalf of the four UK health departments and will be published on the Gov.UK website by the Department of Health in England.

The consultation will run for a period of 10 weeks from 12th October 2017 to 22nd December 2017.

In order to analyse the responses we receive most effectively, we would encourage you to use the online portal Citizen Space to respond: https://consultations.dh.gov.uk/workforce/regulation-of-medical-associate-professions

If you do not have internet or e-mail access, then please write to:

MAPs Regulation Consultation
Professional Regulation Branch
Department of Health
2W06 Quarry House
Leeds
LS2 7UE

A paper copy of this consultation document is available on request at the following e-mail address: mapsregulation@dh.gsi.gov.uk

Please note that we may use your details to contact you about your response or to send you information about our future work.

Comments on the Consultation Process

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact:

Consultations Coordinator
Department of Health
2E26, Quarry House
Leeds
LS2 7UE
e-mail: consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health's Information Charter.

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department of Health will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.

Next Steps

The Department of Health will collate and consider all responses to this consultation. The outcome will usually be published within three months of the consultation closing date at: www.dh.gov.uk/consultations

Annex A – Overview of options for professional assurance in the UK

	Employer-led regulation	Voluntary registration	Accredited voluntary registration (AVR)	Statutory regulation
Overview	There is no legislation setting out what is required to practise in the profession. Professionals are able to work in their chosen profession without being on a register.	Organisations that represent a health and / or care profession are able to set up voluntary register(s) that relevant professionals can join. Professionals not subject to statutory regulation are able to work in their chosen profession without joining a voluntary register.	Organisations that represent a health and / or care profession are able to set up voluntary register(s) that relevant professionals can join. Subsequently, they can apply for accreditation of the register by the Professional Standards Authority (PSA).	Legislation sets out which health and care professions are subject to statutory regulation and which regulatory bodies are responsible for regulating them.
Standards required for the profession	Standards, education and training may vary across professionals. Employers may also have particular requirements for professionals relating to their practice and training.	Standards, education and training may vary across professionals. Employers may also have particular requirements for professionals relating to their practice and training. Those on the voluntary register may be required to meet set standards to remain on the register.	Standards, education and training may vary across professionals. Employers may also have particular requirements for professionals relating to their practice and training. Those on the accredited voluntary register may be required to meet set standards to remain on the register. The PSA require the voluntary register to meet 11 accreditation standards as set out on Page 39.	The regulatory bodies main purpose is to protect the public by holding registers of professionals who meet their standards of education, training, professional skills, behaviour and health. Professionals must meet these standards to register with the regulatory body and they must be registered to work in their chosen profession.

	Employer-led regulation	Voluntary registration	Accredited voluntary registration (AVR)	Statutory regulation
Standards required for the register	Not applicable as there is no register.	Voluntary registers have no legal basis and there is no legislation setting out what is required to practise in the profession. There may be more than one voluntary register for the same profession. In order to join a voluntary register a professional may, or may not, need to meet registration standards covering training, education, competence and conduct. There is little consistency across voluntary registers.	In order to gain accreditation a voluntary register must meet all 11 standards set by the PSA, as set out below: • Hold a voluntary register of health and care practitioners • Be committed to protecting the public • Understand, monitor and control risks • Be financially sound • Inspire public confidence • Develop your knowledge • Provide strong and effective governance • Set good standards for practitioners on your register • Ensure appropriate education and training for practitioners • Run your register well • Manage complaints fairly and effectively Further details about the PSA's accreditation standards are available on its website - http://www.professionalstandards.org.uk/	Nine of the UK's health and social care regulatory bodies are overseen and their performance scrutinised by the PSA.[25] Regulators have four key responsibilities: • Set standards of competence and conduct that health and care professionals must meet in order to be registered and practise • Check the quality of education and training courses to make sure they give students the skills and knowledge to practise safely and competently • Maintain a register of professionals that anyone can search • Investigate complaints about a professional's fitness to practise and decide if they should be allowed to continue to practise or should be struck off the register

[25]The PSA do not oversee the three social work regulators in the devolved administrations.

	Employer-led regulation	Voluntary registration	Accredited voluntary registration (AVR)	Statutory regulation
Fitness to practise	There are no formal fitness to practise processes in place. However, if a professional is in employment they will be subject to their employers' disciplinary procedures. Employer's disciplinary procedures could lead to dismissal from a specific job however the individual would not be prevented from applying to work in the same profession elsewhere.	There are no formal fitness to practise processes in place. However, if a professional is in employment they will be subject to their employers' disciplinary procedures. Employer's disciplinary procedures could lead to dismissal from a specific job however the individual would not be prevented from applying to work in the same profession elsewhere. The organisation responsible for the voluntary register can remove professionals from their register, but they do not have the power to prevent them from practising.	There are no formal fitness to practise proceedings. However, if a professional is in employment they will be subject to their employers' disciplinary procedures. In addition, organisational processes for handling more serious complaints can have parallels with formal fitness to practise proceedings. The organisation responsible for the voluntary register can remove professionals from their register, but they do not have the power to prevent them from practising. The PSA independently gathers evidence and conducts an annual review of the register's compliance with its 11 standards. If a register does not improve to meet the required standards, for example if it were registering professionals who were not fit to practise, the PSA has the power to remove a register's accreditation.[26]	The regulatory bodies are responsible in law for carrying out fitness to practise processes where concerns are raised about a registrant's practise. Fitness to practice procedures vary between regulators but all involve investigating complaints about registrants' personal and professional conduct and competence and taking appropriate action following the conclusion of the investigation. Investigations are undertaken by the regulator or an independent tribunal service on its behalf. Fitness to practise cases can have a number of outcomes ranging from dismissal of a case with no further action taken to permanent removal of a professional from the register in the most serious cases meaning that the professional would no longer be able to practise in the UK.

[26] http://www.professionalstandards.org.uk/publications/detail/accredited-registers-annual-renewal-consultation

	Employer-led regulation	Voluntary registration	Accredited voluntary registration (AVR)	Statutory regulation
Requirements for employment	As part of pre-employment checks employers can apply to the Disclosure and Barring Service (DBS)* before making appointments.	Employers can require their employees to be registered with a voluntary register and may list this as a condition of employment. As part of pre-employment checks employers can apply to the Disclosure and Barring Service (DBS)* before making appointments.	Employers can require their employees to be registered with an accredited voluntary register and may list this as a condition of employment. As part of pre-employment checks employers can apply to the Disclosure and Barring Service (DBS)* before making appointments.	Employers are responsible for ensuring that a person's registration allows them to be employed in a particular role before they start work, and that they maintain appropriate registration to practise. As part of pre-employment checks employers can also apply to the Disclosure and Barring Service (DBS)* before making appointments.

*Protection of Vulnerable Groups scheme in Scotland