The Regulation of Medical Associate Professionals in the UK

Consultation Response

Published 7 February 2019
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1. Executive summary

1.1 Across the UK 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); and
- Advanced critical care practitioner (ACCP)

1.2 The Department of Health and Social Care (‘the Department’), on behalf of the four UK health departments, went out to public consultation between 12th October and 22nd December 2017 on proposals relating to the regulation of the four MAP roles.

1.3 The consultation:

- proposed to introduce statutory regulation for PAs;
- sought further evidence on the most proportionate level of regulation for PA(A)s; and
- proposed that statutory regulation of the SCP and ACCP roles was not proportionate given their current assurance arrangements.

1.4 Over 3,000 responses to the consultation were received. This report presents a summary of the views that were expressed and the response of the four UK health departments. As such, the four UK health departments will be referred to as ‘the Government’ throughout the remainder of this report where collective responses or actions are referenced.

1.5 As well as considering the views expressed by respondents, the Government also considered a number of extrinsic factors including the scale of risk around scope of practice, current entry routes and the existing level of assurance in place for each of these roles in order to reach its conclusion on the most proportionate approach.
PAs

1.6 The majority of respondents supported our initial proposal that statutory regulation is proportionate for PAs. A recurrent theme from the comments we received was that respondents noted that PAs are often alone with vulnerable patients, making autonomous diagnostic and treatment decisions, without the direct supervision of a doctor. These circumstances, particularly when coupled with a direct entry route to training and a planned increase in numbers in the primary care workforce in England, create a compelling case for statutory regulation for this group.

PA(A)s

1.7 The consultation process has provided additional clarity on the practices and the level of clinical autonomy afforded to PA(A)s. For example, we understand that there is potential for PA(A)s to have a high level of autonomy at critical points in a patient’s care pathway. This, together with the high-risk interventions that they perform and the lack of assurance currently in place given the direct entry route into the role, means that we are persuaded that statutory regulation is proportionate for PA(A)s.

SCPs and ACCPs

1.8 The consultation responses showed clear support for the introduction of statutory regulation for SCPs and ACCPs. Although it is acknowledged that these professionals may be performing some high-risk interventions, SCP and ACCP training is only open to regulated healthcare professionals such as nurses, operating department practitioners and physiotherapists. There is no direct entry route available. Given the pre-requisite to be a regulated healthcare professional, SCP and ACCP roles exemplify the broad range of advanced practice roles that are increasingly being deployed to meet workforce need.

1.9 Anyone who is registered with a healthcare professional regulator must abide by its Code of Conduct, regardless of their scope of practice. A breach of this Code may bring a practitioner's fitness to practise into question which could result in regulatory proceedings being taken against them. Therefore, we maintain our position that further regulation would be disproportionate and burdensome.

1.10 We are aware that relevant professional bodies are exploring the potential for SCPs and ACCPs to become direct entry professions. Direct entry would mean that applicants for these roles would no longer have to be regulated healthcare professionals before entering training, which could have implications for patient safety. In this case, the Government would consider reviewing the appropriate level of regulatory oversight.
Regulator

1.11 The consultation sought views on which healthcare professional regulator would be most appropriate to regulate one, some, or all the MAP roles, suggesting that the General Medical Council (GMC) or the Health and Care Professions Council (HCPC) would be the most suitable given their current registrant bases. Respondents were also given the opportunity to suggest other appropriate regulators however the vast majority of responses indicated that the GMC or the HCPC were likely to be best placed.

1.12 We are currently carrying out further scoping work to ascertain the most appropriate body to take forward the regulation of the PA and PA(A) roles. This will include assessing the potential set-up costs to Government and ongoing fees to registrants as well as further consideration of which regulator would be the ‘best fit’ for the two professions. The views put forward by respondents will feed into this work.

Prescribing responsibilities

1.13 The consultation sought initial views in relation to extending prescribing responsibilities to the MAP roles in the future, should regulation be introduced for any. The majority of respondents agreed that extension of prescribing responsibilities should be considered for a number of, or all four, MAP roles. There was particular support for the extension of these responsibilities to PAs.

1.14 As set out in the consultation document, the process to extend prescribing responsibilities is subject to separate consideration and consultation. We will, however, ensure that the views obtained during this consultation will be fed in to any future proposals around extending prescribing responsibilities to these groups.

Costs and benefits

1.15 The consultation sought views on the potential costs and benefits of different levels of professional assurance. Similar proportions of respondents either agreed with our assessment or had no view either way. Only 4% of respondents said they disagreed with our assessment.

1.16 A number of respondents considered the benefits of statutory regulation outweighed the financial costs involved citing improved patient safety, quality assurance, professional accountability and increased employer confidence.

1.17 A full impact assessment will be produced and published alongside any draft legislation that is developed. Information provided through this consultation will inform the development of the impact assessment.
Equalities considerations

1.18 Finally, the Government sought views on whether changes to the level of professional assurance for the four MAP roles 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.

1.19 Most respondents either had no view or thought there would be no impact upon protected characteristics. However, 20% of respondents thought there would be an impact on protected characteristics, including gender, race, disability and socio-economic background.

1.20 Of those that provided additional comments, the majority felt that the introduction of statutory regulation would have a positive impact as it would facilitate more robust monitoring of adherence to the duties and increase commitment to them. Some respondents suggested that those working in MAP roles tend to be female and/or from ethnic minority groups, often working flexible hours. They argued that statutory regulation would benefit these equality characteristics through the resulting expansion of the MAPs workforce potentially providing increased job opportunities for groups such as working mothers. A small number of respondents commented that there may be a negative impact in terms of the financial burden of registrant fees, especially on those working part-time.

1.21 Again, we will consider the impacts on equalities identified by respondents during the next stage of the process.

1.22 In conclusion, after careful consideration of the views presented during the consultation, alongside other relevant evidence and extrinsic factors, the Government plans to take the following next steps:

- Introduce statutory regulation for PAs and PA(A)s.

- Continue work to evaluate which of the two preferred regulators (the General Medical Council (GMC) or the Health and Care Professions Council (HCPC)) would be most appropriate to take on the regulation of these two roles.

1.23 Once a decision has been made regarding which regulator should be responsible for regulating PAs and PA(A)s, the Government will work with relevant stakeholders to develop the legislation needed to bring PAs and PA(A)s into statutory regulation. As part of this process, we will look to develop a framework to which other MAP roles could be added at a later date as the case arises. A public consultation on the draft legislation will be required and the legislation will be subject to the agreement of the health ministers across the UK in advance of it going before Parliament.
1.24 The appropriate level of regulatory oversight for different professional groups remains a key issue for the Government. The consultation on regulatory reform sets out future possibilities in this area, including the development of risk profile models for all professional groups and the consideration of alternative regulatory approaches.
2. **Background to the consultation**

2.1 The Government recognises the important contributions that can be made to the delivery of healthcare through the enhancement of existing roles and the introduction of new roles. In particular, there has been support for examining the possibility of introducing statutory regulation for physician associates (PAs). As a result, in November 2016, the Secretary of State for Health and Social Care, Jeremy Hunt, announced his intention to consult on whether PAs should be regulated.

2.2 Subsequently, Health Education England (HEE) worked with representatives of the four MAP roles to collate information on the scope of practice for each role. HEE then assessed the evidence of the degree of risk of harm to patients and produced risk profiles based upon the Professional Standards Authority’s (PSA) criteria for Right Touch Assurance ©.

2.3 The Government considered HEE’s assessment of risk alongside a number of additional factors including the current number of professionals in each role and their projected growth, entry routes and the level of professional assurance currently in place.

2.4 Based on this analysis, the Government launched a public consultation on proposals to introduce statutory regulation for PAs. In addition, the consultation asked respondents for further evidence on the most proportionate level of regulation for PA(A)s and to provide views on our initial position that statutory regulation of the SCP and ACCP roles is not proportionate.

2.5 The consultation also opened the discussion around whether it would be appropriate to extend prescribing responsibilities to these roles in the future, should regulation be introduced for any of them, and sought views on which healthcare regulator would be the most appropriate to take on responsibility for regulating any or all of the MAP roles.
3. Consultation process and overview

Consultation process

3.1 The public consultation ran from 12th October 2017 to 22nd December 2017 and was undertaken by the Department of Health and Social Care on behalf of the Government. The consultation was taken forward in accordance with the Cabinet Office Consultation Principles.

3.2 The consultation was made available on the GOV.UK website.

3.3 The Department received 3,066 consultation responses submitted via the digital platform ‘Citizen Space’, by email or by post. Of these, 95% (2,901) responded as an individual with the other 5% (165) responding on behalf of an organisation. A breakdown of how respondents identified themselves is provided in this section.

3.4 In three cases we were unable to extract quantifiable answers to the consultation questions. Therefore, the data in the statistical tables presented in this report are based on a total respondent figure of 3,063. However, all responses were considered during our analysis.
Overview of respondents

Individuals

3.5 Figure 1 below shows the breakdown of individuals who responded and how they identified themselves.

Figure 1: Individuals by type

*Those who identified as ‘other’ includes students (subject not defined), non-clinical professional roles (e.g. NHS management and administration), social care workers, academics and retirees.

3.6 Table 1 below lists the high-level role descriptions selected by the 78% who identified as a healthcare professional. A more detailed breakdown of role descriptions can be found at Annex A of this document.

Table 1: Type of healthcare professional

<table>
<thead>
<tr>
<th>Category</th>
<th>Number of respondents</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical practitioner</td>
<td>1,050</td>
<td>47%</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>17</td>
<td>1%</td>
</tr>
<tr>
<td>Dental practitioner</td>
<td>8</td>
<td>0.4%</td>
</tr>
<tr>
<td>Allied health professional</td>
<td>149</td>
<td>7%</td>
</tr>
<tr>
<td>Nurse</td>
<td>273</td>
<td>12%</td>
</tr>
</tbody>
</table>
The Regulation of Medical Associate Professionals in the UK - Consultation Response

<table>
<thead>
<tr>
<th>Category</th>
<th>Number of respondents</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Midwife</td>
<td>3</td>
<td>0.1%</td>
</tr>
<tr>
<td>Other</td>
<td>754</td>
<td>33%</td>
</tr>
<tr>
<td>Not answered</td>
<td>2</td>
<td>0.1%</td>
</tr>
<tr>
<td>Total</td>
<td>2,256</td>
<td>100%</td>
</tr>
</tbody>
</table>

Note: Some percentages have been rounded and therefore may not total 100%

Organisations

3.7 We received responses from 165 organisations. Figure 2 below shows the percentage of responses received by organisation type.

3.8 The majority of organisational responses came from regulatory and professional bodies, royal colleges, NHS trusts, higher education institutions (HEIs) and medical schools. We also received responses from a number of arm’s length bodies (ALBs), charities, hospitals and hospital departments, clinical commissioning groups (CCGs), GP practices, health teaching boards and trade unions.
Those who identified as ‘other’ includes health agencies (ALBs), charities, hospitals and hospital departments, clinical commissioning groups (CCGs), GP practices, health teaching boards and trade unions.

Geographical location

3.9 Figure 3 below breaks down the percentage of respondents (individuals and organisations) by geographical location, where they provided this information.

3.10 We received the most responses from individuals and organisations living, or based in, England (85%), followed by Scotland (9%), Wales (4%) and Northern Ireland (1%). A further 1% of respondents were based outside of the UK. 0.2% of respondents did not identify their geographical location.
3.11 All comments made by respondents have been considered. Where comments made did not directly relate to the question being asked, we considered them under the most relevant question.

Summary of responses

3.12 The consultation sought views on the appropriate level of assurance for each of the MAP roles. The four options presented were:

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

3.13 The consultation responses received demonstrated a high level of support for the introduction of statutory regulation for all four MAP roles as shown in Table 2 below.
Table 2: Summary of responses - preferred level of assurance for MAP roles

<table>
<thead>
<tr>
<th>Response</th>
<th>Physician associates</th>
<th>Physicians’ assistants (anaesthesia)</th>
<th>Surgical care practitioners</th>
<th>Advanced critical care practitioners</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of respondents</td>
<td>%</td>
<td>Number of respondents</td>
<td>%</td>
</tr>
<tr>
<td>Statutory regulation</td>
<td>2,909</td>
<td>95%</td>
<td>2,544</td>
<td>83%</td>
</tr>
<tr>
<td>Voluntary registration</td>
<td>28</td>
<td>1%</td>
<td>69</td>
<td>2%</td>
</tr>
<tr>
<td>Accredited voluntary registration</td>
<td>69</td>
<td>2%</td>
<td>232</td>
<td>8%</td>
</tr>
<tr>
<td>Other</td>
<td>24</td>
<td>1%</td>
<td>83</td>
<td>3%</td>
</tr>
<tr>
<td>Not answered</td>
<td>33</td>
<td>1%</td>
<td>135</td>
<td>4%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>3,063</strong></td>
<td><strong>100%</strong></td>
<td><strong>3,063</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

Note: Percentage figures have been rounded and therefore may not total 100%

**Key themes**

3.14 Comments made by respondents covered a number of key themes across all four MAP roles, specifically:

- Patient protection and safety;
- Accountability (including fitness to practise processes and professional indemnity);
- Quality assurance (of training, continuing professional development and standards of practice);
- Credibility (amongst peers, employers and patients);
- Workforce pressures (regulation may facilitate roles to work to their full potential and increase uptake by employers); and
- Pursuit of prescribing responsibilities.
3.15 The remaining sections of this document mirror the order of the questions as they were asked in the consultation. In each section we have provided background to the question, set out response data and given a summary of comments made by respondents and a selection of quotes. It should be noted that the summary of comments in this report represent respondent views and are not necessarily the view of the Government.
4. Physician associates (PAs)

Background

4.1 PAs were introduced to the UK in 2003 and can carry out a number of tasks including:

- Taking medical histories from patients and carrying out physical examinations;
- Seeing patients with undifferentiated diagnoses or 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; and
- Provision of health promotion and disease prevention advice for patients.

4.2 PAs work in GP surgeries, accident and emergency departments, and inpatient medical and surgical wards throughout the UK. 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.

4.3 A direct entry route on to PA training courses is available. PA training usually consists of a two-year course at diploma or Masters level. Courses are open to graduates with a degree in a relevant subject - including, but not limited to, biomedical science, biochemistry, anatomy, physiology and healthcare science. Registered healthcare professionals can also apply to train as a PA.

4.4 The Faculty of Physician Associates at the Royal College of Physicians is the professional body for PAs and they administer a voluntary register for professionals to join. To join the register, applicants must be a graduate of a nationally recognised PA programme and have passed the PA National Certifying Examination (PANCE). To remain on the register, PAs have to sit recertification examinations every six years.
Analysis of consultation responses

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

<table>
<thead>
<tr>
<th>Response</th>
<th>Individuals</th>
<th>Organisations</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of respondents</td>
<td>Percentage</td>
<td>Number of respondents</td>
</tr>
<tr>
<td>Statutory regulation</td>
<td>2,756</td>
<td>95%</td>
<td>153</td>
</tr>
<tr>
<td>Voluntary registration</td>
<td>25</td>
<td>1%</td>
<td>3</td>
</tr>
<tr>
<td>Accredited voluntary registration</td>
<td>67</td>
<td>2%</td>
<td>2</td>
</tr>
<tr>
<td>Other</td>
<td>24</td>
<td>1%</td>
<td>0</td>
</tr>
<tr>
<td>Not answered</td>
<td>28</td>
<td>1%</td>
<td>5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>2,900</td>
<td>100%</td>
<td>163</td>
</tr>
</tbody>
</table>

Note: Percentage figures have been rounded and therefore may not total 100%.

4.5 The vast majority of respondents (95%) who answered this question favoured the introduction of statutory regulation for PAs. This equated to 95% of individuals and 94% of organisations who responded to the question.

4.6 The main arguments put forward by those that advocated statutory regulation centred on patient safety, accountability and quality assurance. A significant number of respondents also highlighted workforce pressures and facilitating the pursuit of prescribing responsibilities as being arguments for the introduction of statutory regulation.

4.7 A summary of some of the arguments made by respondents is set out below:

- Even though PAs are a dependent role, they often see and treat patients on their own, in particular in primary care settings, and make decisions independently.
• Regulation will facilitate the pursuit of prescribing responsibilities which would enhance the role and improve the efficiency of patient care.

• Education and training will be standardised and subject to mandatory quality assurance checks.

• Regulation will protect the PA title and reassure the public that professionals are qualified, insured and of a sufficient level of competence and that they will be subject to formal fitness to practise processes should they breach their Code of Conduct.

4.8 The 4% of respondents that advocated other forms of regulation (such as accredited registration or voluntary registration) as appropriate levels of assurance cited reasons which included:

• PAs are dependent practitioners therefore their activities are supervised.

• Registration checks can readily be undertaken through employer governance processes.

• A PA’s training and clinical experience is insufficient in extent, depth and quality to allow them to work autonomously, which statutory regulation would enable them to do.

• Pathways already exist for healthcare professionals, such as nurses and pharmacists, to train as advanced practitioners who could carry out the functions of a PA. There is no need for a separate, regulated profession.

Quote from respondent in favour of statutory regulation of PAs:

“Physician Associates form part of the medical team. They are able to perform invasive procedures and make patient management plans. As a part of the medical team, they need to be accountable for their decisions. Statutory regulation is the only way to ensure that PAs are (legally) accountable for their actions.”

Quote from respondent against statutory regulation of PAs:

“PAs are dependent practitioners who require supervision from a named healthcare professional. This precludes them operating in private practice, and hence the clinical governance of their employer can easily ensure they are on a voluntary assured register. A move to statutory registration would facilitate PAs operating as autonomous practitioners outside the supervision of a healthcare professional, which is inappropriate and would expose the public to risk.”
Government response

The Government plans to introduce statutory regulation for PAs.

4.9 The view we set out in our initial consultation document that statutory regulation for PAs is necessary and proportionate has been supported by the vast majority of responses we have received.

4.10 The value of PAs lies in their increasing ability to operate with an independent caseload, releasing doctors to be able to handle more complex cases.

4.11 Whilst we acknowledge that supervision support for PAs in secondary care is, in most cases, adequate and readily accessible, the ‘closed door’ environment of the primary care setting means that PAs are increasingly likely to find themselves seeing patients without direct supervision and making autonomous decisions about treatment. The commitment to expand the number of PAs working in primary care in England therefore strengthens the argument for bringing this role into statutory regulation as the growth of the PA workforce will increase the scale of the risk.

4.12 A direct entry route to PA training exists which means that, along with regulated healthcare professionals, individuals who are new to healthcare can train to become a PA. The existence of a direct entry route to training will increase workforce numbers and bring new talent into the NHS. However, the direct entry route increases the need for appropriate regulatory oversight as there is currently no statutory assurance in place.

4.13 Regulating PAs will also be essential to facilitating the longer-term aspiration of achieving prescribing responsibilities. Prescribing responsibilities are only considered for roles that are statutorily regulated and the current inability of PAs to prescribe is, employers argue, limiting the usefulness of the role, particularly in primary care settings.

4.14 These circumstances, alongside the direct entry route to training and the planned increase in PA numbers in the primary care workforce, create a compelling case for statutory regulation being the appropriate level of regulatory oversight for this group.
5. Physicians’ assistants (anaesthesia) (PA(A)s)

Background

5.1 PA(A)s were introduced to the UK in 2004. 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. 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).

5.2 PA(A)s will also deputise for anaesthetists in a variety of situations to assist in patient care and where medically qualified anaesthetists are not available. A number of PA(A)s work to an extended scope of practice managed within the local governance structures of organisations which can include performing sedation and regional anaesthesia for acute pain.

5.3 A direct entry route onto PA(A) training courses is available (with a biomedical science degree or similar usually being required) although registered healthcare professionals, such as nurses and operating department practitioners can also apply to train as a PA(A).

5.4 The Royal College of Anaesthetists only approve one PA(A) training course in the UK at present. This is run by the University of Birmingham. The Association of Physicians’ Assistants (Anaesthesia) is the representative body for PA(A)s in the UK and hold a voluntary register of qualified PA(A)s and a list of those currently in training.

5.5 We used the consultation process as a way of seeking further evidence of the need for regulation of this group of professionals. In particular we sought further information in relation to the level of clinical autonomy and delegated responsibility in the PA(A) role.
Analysis of consultation responses

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

Table 4: Summary of responses to Q2

<table>
<thead>
<tr>
<th>Response</th>
<th>Individuals</th>
<th></th>
<th>Organisations</th>
<th></th>
<th>Overall</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of</td>
<td>%</td>
<td>Number of</td>
<td>%</td>
<td>Number</td>
<td>%</td>
</tr>
<tr>
<td></td>
<td>respondents</td>
<td></td>
<td>respondents</td>
<td></td>
<td>respondents</td>
<td></td>
</tr>
<tr>
<td>Statutory regulation</td>
<td>2,428</td>
<td>84%</td>
<td>116</td>
<td>71%</td>
<td>2,544</td>
<td>83%</td>
</tr>
<tr>
<td>Voluntary registration</td>
<td>66</td>
<td>2%</td>
<td>3</td>
<td>2%</td>
<td>69</td>
<td>2%</td>
</tr>
<tr>
<td>Accredited voluntary registration</td>
<td>222</td>
<td>8%</td>
<td>10</td>
<td>6%</td>
<td>232</td>
<td>8%</td>
</tr>
<tr>
<td>Other</td>
<td>73</td>
<td>3%</td>
<td>10</td>
<td>6%</td>
<td>83</td>
<td>3%</td>
</tr>
<tr>
<td>Not answered</td>
<td>111</td>
<td>4%</td>
<td>24</td>
<td>15%</td>
<td>135</td>
<td>4%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>2,900</strong></td>
<td><strong>100%</strong></td>
<td><strong>163</strong></td>
<td><strong>100%</strong></td>
<td><strong>3,063</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

Note: Percentage figures have been rounded and therefore may not total 100%

5.6 The majority of respondents (83%) who answered this question favoured the introduction of statutory regulation for PA(A)s. This equated to 84% of individuals and 71% of organisations who responded to the question.

5.7 Where further comments were made in favour of statutory regulation, accountability was a key argument put forward. Patient safety was also highlighted linking to the level of autonomy and the nature of the tasks carried out by PA(A)s. A summary of the arguments presented is set out below:

- PA(A)s make critical decisions without the supervision of a consultant anaesthetist, including the decision to delay elective surgery to investigate additionally detected clinical problems.
- PA(A)s perform complex, time-critical tasks and, in extending their role and working to locally defined procedures, some are operating at the boundaries of the PA(A) scope of practice. This includes performing high-risk, invasive procedures such as spinal anaesthesia and regional anaesthetic blocks.
• Regulation will facilitate the pursuit of prescribing responsibilities which would enhance the role and improve the efficiency of service provided.

• Regulation will increase employer confidence to recruit to the role.

5.8 13% of respondents suggested that other forms of regulation (such as accredited registration or voluntary registration) may be more appropriate. Comments included:

• The majority of PA(A)s are already regulated healthcare professionals.

• The PA(A) works alongside a consultant anaesthetist therefore there is not the same level of autonomy and their scope of practice is limited.

• Low numbers of professionals and the cost of regulation would be prohibitive and provide little benefit.

• The role should be regarded as advanced practice for other professions (such as nurses) rather than as a distinct profession requiring separate regulation.

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**Quote from respondent in favour of statutory regulation of PA(A)s:**

“PA(A)s work under supervision but are performing skills as an anaesthetist (cannulation, regional anaesthesia, giving complex groups of drugs for anaesthesia). They should have the same regulatory standards as other medical professionals, and AHPs. ODPs are statutory regulated and PA(A)s have a more demanding, more independent, more invasive role, with only voluntary registration.”

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**Quote from respondent against statutory regulation of PA(A)s:**

“Based on the lack of increasing demand, perhaps the costs associated with regulation may be better met by an accredited voluntary register. This allows some form of regulation as anaesthesia is an important area of medicine that could carry great risk. Autonomy should be limited.”

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**Government response**

The Government plans to introduce statutory regulation for PA(A)s.

5.9 The Government is satisfied that the consultation process has provided the additional clarity on the practices and the level of clinical autonomy afforded to PA(A)s. Although the curriculum framework for PA(A)s sets out that typically PA(A)s work in a 2:1 model under a consultant anaesthetist, we have received
further evidence through this consultation that PA(A)s are commonly working at a local level with a higher level of autonomy.

5.10 We have considered the consultation responses alongside a number of extrinsic factors, including entry routes and the existing level of assurance in place for the PA(A) role.

5.11 We are aware that there are PA(A)s who were registered healthcare professionals (such as nurses) before they completed their PA(A) training and therefore, for these professionals, a level of assurance already exists. However, there is a direct entry route to PA(A) training meaning that regulatory assurances are not always in place for those undertaking this role.

5.12 It is evident that PA(A)s are performing high-risk interventions and potentially exercising a high level of autonomy at critical times. These factors, when considered in conjunction with the existence of a direct entry route to training, means that the Government considers that statutory regulation is proportionate for the role.
6. Surgical care practitioners (SCPs)

Background

6.1 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.

6.2 Under the direction of a consultant surgeon, the SCP may participate in tasks including:

- Pre-operative assessment, including clinical history taking and physical examination;
- 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;
- Arranging appropriate pre- and post-operative investigations;
- Post-operative care – including wound assessment and management; and
- Evaluation of care, including the discharge process, follow-up care and outpatient activities.

6.3 Entrants into training for this role must already be an established regulated healthcare professional, such as a registered nurse, with at least 18 months post-registration experience.
Analysis of consultation responses

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

Table 5: Summary of responses to Q3

<table>
<thead>
<tr>
<th>Response</th>
<th>Individuals</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of</td>
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<td>Number of</td>
<td>%</td>
<td>Number of</td>
<td>%</td>
</tr>
<tr>
<td></td>
<td>respondents</td>
<td></td>
<td>respondents</td>
<td></td>
<td>respondents</td>
<td></td>
</tr>
<tr>
<td>Statutory regulation</td>
<td>2,071</td>
<td>71%</td>
<td>93</td>
<td>57%</td>
<td>2,164</td>
<td>71%</td>
</tr>
<tr>
<td>Voluntary registration</td>
<td>127</td>
<td>4%</td>
<td>5</td>
<td>3%</td>
<td>132</td>
<td>4%</td>
</tr>
<tr>
<td>Accredited voluntary registration</td>
<td>379</td>
<td>13%</td>
<td>22</td>
<td>14%</td>
<td>401</td>
<td>13%</td>
</tr>
<tr>
<td>Other</td>
<td>141</td>
<td>5%</td>
<td>20</td>
<td>12%</td>
<td>161</td>
<td>5%</td>
</tr>
<tr>
<td>Not answered</td>
<td>182</td>
<td>6%</td>
<td>23</td>
<td>14%</td>
<td>205</td>
<td>7%</td>
</tr>
<tr>
<td>Total</td>
<td>2,900</td>
<td>100%</td>
<td>163</td>
<td>100%</td>
<td>3,063</td>
<td>100%</td>
</tr>
</tbody>
</table>

Note: Percentage figures have been rounded and therefore may not total 100%

6.4 As shown in Table 5, the majority of respondents (71%) who answered this question favoured the introduction of statutory regulation for SCPs. This equated to 71% of individuals and 57% of organisations who responded to the question. The main arguments put forward centred on patient safety, quality assurance and credibility. The main arguments presented by respondents are summarised below:

- Statutory regulation will enhance the credibility of the role amongst peers and patients.
- The current regulatory framework does not reflect the role they undertake and, if there are issues or concerns within the expanded role, the original registration body may struggle to act.
- Individuals working in this role are not all regulated by the same regulator (for example they could be regulated by the Nursing and Midwifery Council (NMC)
or the HCPC) so there could be inconsistencies in the accountability and quality assurance standards of professionals.

- Statutory regulation is needed to gain employer confidence in the role.
- Statutory regulation will provide recognition of the experience and skills gained and allow the role to be developed in a controlled way.

6.5 22% of respondents suggested that other forms of regulation (such as accredited registration or voluntary registration) may be more appropriate levels of assurance for this role. Of those that provided further comments, common themes were:

- The existence of a large number of nurses in very similar roles which are classed as advanced practice rather than new professions. Further statutory regulation may not be the most proportionate way to recognise extended practice.
- The current regulatory arrangements in place for SCPs are proportionate and appropriate, given they must be a regulated healthcare professional to be accepted onto the required SCP training course.
- A voluntary register would ensure additional specified skills are identified and recognised; without losing sight of the individual's primary regulated profession and could provide employers with additional reassurance.
- Statutory regulation would be a hindrance for the development of this role.
- Concerns around the potential for paying dual registration fees.

**Quote from respondent in favour of statutory regulation of SCPs:**

“The potential high-risk environments in which SCPs can find themselves, such as operative procedures, demonstrates the necessity for statutory regulation.”

**Quote from respondent against statutory regulation of SCPs:**

“Individuals are already registered on a statutory register and have extended practice roles within the context of their working environment that is within their current roles.”

**Government response**

Please see pages 29-31 for the Government response in relation to both SCPs and ACCPs.
7. Advanced critical care practitioners (ACCPs)

Background

7.1 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, intensive care unit technicians, physiotherapists and clinical pharmacists in response to increasing complexity of care pathways. ACCPs are experienced members of the care team working in intensive care units. They can 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.

7.2 ACCPs carry out a number of tasks including:

- Undertaking comprehensive clinical assessment of a patient’s condition;
- Requesting and performing diagnostic tests;
- Initiating and managing a clinical treatment plan;
- Undertaking invasive interventions within the scope of practice; and
- Providing professional leadership and support within a multi-professional team.

7.3 The Department understands that a key part of the ACCP role is the ability to prescribe, having undergone appropriate training. Therefore, entrants into training for this role must already be regulated healthcare professionals, with three years full-time, post-qualification work experience, who have or are able to acquire prescribing responsibilities. Supervision of ACCPs varies dependent upon the situation and skill of the individual and ranges from distant to direct. All trainee ACCPs are also required to register with the Faculty of Intensive Care Medicine so that they can monitor the ACCP workforce.
Analysis of consultation responses

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

Table 6: Summary of responses to Q4

<table>
<thead>
<tr>
<th>Response</th>
<th>Individuals</th>
<th></th>
<th>Organisations</th>
<th></th>
<th>Overall</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of</td>
<td>%</td>
<td>Number of</td>
<td>%</td>
<td>Number</td>
<td>%</td>
</tr>
<tr>
<td></td>
<td>respondents</td>
<td></td>
<td>respondents</td>
<td></td>
<td>respondents</td>
<td></td>
</tr>
<tr>
<td>Statutory regulation</td>
<td>2,120</td>
<td>73%</td>
<td>95</td>
<td>58%</td>
<td>2,215</td>
<td>72%</td>
</tr>
<tr>
<td>Voluntary registration</td>
<td>123</td>
<td>4%</td>
<td>5</td>
<td>3%</td>
<td>128</td>
<td>4%</td>
</tr>
<tr>
<td>Accredited voluntary</td>
<td>362</td>
<td>13%</td>
<td>20</td>
<td>12%</td>
<td>382</td>
<td>13%</td>
</tr>
<tr>
<td>registration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>129</td>
<td>4%</td>
<td>22</td>
<td>14%</td>
<td>151</td>
<td>5%</td>
</tr>
<tr>
<td>Not answered</td>
<td>166</td>
<td>6%</td>
<td>21</td>
<td>13%</td>
<td>187</td>
<td>6%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>2,900</td>
<td>100%</td>
<td>163</td>
<td>100%</td>
<td>3,063</td>
<td>100%</td>
</tr>
</tbody>
</table>

Note: Percentage figures have been rounded and therefore may not total 100%

7.4 As shown in Table 6, the majority of respondents (72%) who answered this question favoured the introduction of statutory regulation for ACCPs. This equated to 73% of individuals and 58% of organisations who responded to the question. The main arguments presented are summarised below:

- The scope of practice is different to the role that they are currently regulated under (for example, nursing).
- There needs to be standardised roles across trusts and protection of the professional title.
- Unification of regulatory and professional structures is necessary to grow the workforce, for example, training, prescribing and professional practice.
- There is a lack of clarity of the role for service users and other professionals.
22% of respondents that answered this question thought that other levels of assurance might be more appropriate for this group. A selection of additional comments supporting this view are summarised below.

- There is a requirement to be a registered healthcare professional to enter ACCP training therefore further regulation may be an unnecessary bureaucratic and financial burden.

- Low numbers in the role means that statutory regulation would be disproportionate.

- There is likely to be a great deal of variation in the roles undertaken by this group of professionals in different trusts. Each trust should be permitted to define its own training requirements, and working arrangements.

- Accredited voluntary registration would provide clarity for both ACCPs and their employers on expectations, requirements and standards involved in the role.

- The professional’s current registration could be annotated with their extended scope of practice.

**Quote from respondent in favour of statutory regulation of ACCPs:**

“[Statutory Regulation]… is vital. ACCPs are recruited from diverse backgrounds e.g. nurse, physio, ODP. This is the future of ICU staffing especially to fulfil the shortfall in the medical model. To grow this workforce we must recognise that we have to unify their regulatory and professional structure e.g. training, prescribing, professional practice.”

**Quote from respondent against statutory regulation of ACCPs:**

“ACCPs already hold registration with a regulatory body and are practicing specialist, extended or advanced skills - this does not alter the primary registration.”

**Government response**

The Government maintains the view that further statutory regulation is not proportionate for SCPs and ACCPs at this time.

The Government acknowledges that the consultation responses indicate clear support for the introduction of statutory regulation for SCPs and ACCPs and the arguments presented highlight that those practising in these roles may be
performed high-risk interventions, at times autonomously. However, we consider that the assurances already in place for these roles continue to be proportionate.

7.7 SCP and ACCP training courses are currently only open to regulated healthcare professionals, with no direct entry routes available, meaning that there is already a level of assurance in place for those practising in these roles. A number of consultation responses raised concerns over the potential inconsistencies caused from individuals in these roles being regulated by different regulators for example, a nurse working in an SCP role will be regulated by the NMC whilst an operating department practitioner working in this role would be regulated by the HCPC.

7.8 However, regardless of which regulator the individual is registered with, or their scope of practice, SCPs and ACCPs will be bound by the relevant regulator’s code of conduct. The codes of conduct set out by the healthcare regulators contain broadly similar expectations of their registrants. A breach of these codes may bring a practitioner's fitness to practise into question which could result in regulatory proceedings being undertaken against them. We understand that employers require SCPs and ACCPs to maintain their registration with their original regulator and we fully endorse this approach to ensure patient safety is maintained.

7.9 Given the pre-requisite to be a regulated healthcare professional, SCP and ACCP roles exemplify the broad range of advanced practice roles that are increasingly being deployed to meet workforce need. This is fundamental when considering the appropriate use of prescribing responsibilities. Regulated professionals cannot use their prescribing responsibilities when practising in unregulated roles but can do so if their role is an extension of their original registration. We consider that, when the points set out above are taken into account, an additional level of assurance would be disproportionate and burdensome with no real patient safety benefit.

7.10 A future change in entry requirements for these two roles could potentially have implications for patient safety. We are aware that the relevant professional bodies are exploring options for SCPs and ACCPs becoming direct entry professions. Direct entry would mean that applicants for these roles would no longer have to be regulated healthcare professionals before entering training. In this case, the Government would consider reviewing the appropriate level of regulatory oversight.

7.11 The Government will consider whether further work is needed with key stakeholders, including employers and regulatory bodies, to reiterate the importance of ensuring that healthcare professionals that move into SCP and ACCP roles maintain their professional registration with their original regulatory body. Professional bodies may also want to give further consideration to the possible benefits that can be gained from [accredited registration](#) in recognition of
the advanced nature of these roles. Accreditation from the PSA can provide an additional level of assurance to both employers and the public that a professional is maintaining specific standards of personal behaviour and technical competence.
8. Prescribing responsibilities

Background

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

- **Exemptions:** Some professions, such as orthoptists, are allowed under medicines regulations to supply specific medicines directly to patients as clinically required.

- **Patient Group Directions (PGDs):** These allow particular healthcare professionals, such as occupational therapists, to be trained to assess a patient within stated parameters. A separate direction is needed for each different medicine to be supplied.

8.2 Only "appropriate practitioners" can prescribe medicine. An appropriate practitioner can be either:

- **An independent prescriber** - someone able to prescribe medicines under their own initiative, such as doctors and dentists.

Or

- **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, such as dietitians.

8.3 “Appropriate practitioners” must complete an approved post-registration training programme to become independent or supplementary prescribers. Those professionals granted prescribing responsibilities have their entry on the professional register annotated accordingly.

8.4 Whilst there is no legal requirement for a profession to be subject to statutory regulation before it can be given prescribing responsibilities, because prescribing is a high-risk activity it is widely agreed that it should only be carried out by individuals operating in a regulated context.

8.5 The process required to extend prescribing responsibilities to a profession can take a number of years to complete and is a separate legislative process to the introduction of statutory regulation for a profession and therefore subject to consultation. It must be noted that the Government has used this consultation to seek initial views on whether prescribing responsibilities should be extended to the
MAP roles, should they become regulated, which could then be fed in to any future consultations on prescribing responsibilities.

Analysis of consultation responses

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?

Table 7: Summary of responses to Q5

<table>
<thead>
<tr>
<th>Response</th>
<th>Individuals</th>
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<th>Organisations</th>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of respondents</td>
<td>%</td>
<td>Number of respondents</td>
<td>%</td>
<td>Number of respondents</td>
<td>%</td>
</tr>
<tr>
<td>Yes</td>
<td>2,425</td>
<td>84%</td>
<td>144</td>
<td>88%</td>
<td>2,569</td>
<td>84%</td>
</tr>
<tr>
<td>No</td>
<td>300</td>
<td>10%</td>
<td>3</td>
<td>2%</td>
<td>303</td>
<td>10%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>159</td>
<td>6%</td>
<td>10</td>
<td>6%</td>
<td>169</td>
<td>5%</td>
</tr>
<tr>
<td>Not answered</td>
<td>16</td>
<td>1%</td>
<td>6</td>
<td>4%</td>
<td>22</td>
<td>1%</td>
</tr>
<tr>
<td>Total</td>
<td>2,900</td>
<td>100%</td>
<td>163</td>
<td>100%</td>
<td>3,063</td>
<td>100%</td>
</tr>
</tbody>
</table>

Note: Percentage figures have been rounded and therefore may not total 100%

8.6 The majority of respondents (84%) agreed that expansion of medicines supply, administration mechanisms and/or prescribing responsibilities should be considered for a number of or all four MAP roles. There was particular support for expansion of these responsibilities to PAs with 63% of respondents specifying that this role should be able to prescribe. The main argument put forward was that extending responsibilities to PAs would help to fully utilise their potential for employers.

Quote from respondent:

“I feel strongly that PAs should be independent prescribers. Failure to (enable this) will limit the effectiveness of PAs within the NHS. I am aware that some NHS organisations are reticent to employ PAs due to their not being able to prescribe.”
8.7 However, the point was also made that, whilst PAs do cover the principles of pharmacology within their entry programme, further training would be required to ensure that they are of sufficient competence.

**Quote from respondent:**

“Physician Associate degree programmes are designed to include prescribing safety training and relevant pharmacology. We believe that physician associates should be able to prescribe but we are aware that this may need to be introduced incrementally, including a period of supervised practice.”

8.8 In a similar vein, some respondents suggested that PAs should start off as supplementary prescribers, progressing to independent status after a period of further training and experience. Conversely, it was also argued that, due to the variety of clinical settings in which PAs work, supplementary prescribing would not be sufficiently flexible.

8.9 Further arguments in support of extending prescribing responsibilities across all of the MAP roles included:

- A reduction in the burden on doctors, GPs and other healthcare professionals who would otherwise have to sign off prescriptions or requests for ionising radiation treatments or X-rays.
- Increased efficiency of patient care.
- Improved continuity of care for patients with one healthcare professional overseeing their whole care journey.

8.10 It was also highlighted that extending prescribing responsibilities for any MAP role would need to be implemented in a managed way. Consideration would also need to be given to MAP professionals that can already prescribe by virtue of a registered parent profession.

8.11 10% of respondents did not agree with extending prescribing responsibilities to either one or more of the MAP roles. The main arguments put forward included:

- The breadth and depth of medical knowledge, skill and judgement required for safe prescribing is significant and requires time to acquire. MAPs may not possess or be capable of this, especially PAs, as their training period is relatively short and their clinical experience limited.
- Increasing the number of professionals able to prescribe would defeat efforts to reduce excessive prescribing of medicines, notably antibiotics, opioids and antidepressants.

**Government response**

The Government will ensure that the views obtained during this consultation will be fed into any future proposals around extending prescribing responsibilities.

8.12 We used the consultation to seek initial views in relation to extending prescribing responsibilities to the medical associate professions in the future.

8.13 The process to extend prescribing responsibilities to regulated professions is separate to this one and is subject to separate consideration and consultation. As set out above, we will ensure that the views put forward through this consultation will be fed into any future proposals around extending prescribing responsibilities.
9. Consideration of the appropriate professional regulator

9.1 The consultation sought views on which healthcare professional regulator would be most appropriate to regulate one, some or all of the MAP roles, setting out the principal considerations to inform this decision. These included:

- 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))

9.2 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 regulators given their current registrant bases.

Analysis of consultation responses

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

<table>
<thead>
<tr>
<th>Response</th>
<th>Individuals</th>
<th>Organisations</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of respondents</td>
<td>%</td>
<td>Number of respondents</td>
</tr>
<tr>
<td>GMC</td>
<td>1,718</td>
<td>59%</td>
<td>84</td>
</tr>
<tr>
<td>HCPC</td>
<td>574</td>
<td>20%</td>
<td>29</td>
</tr>
<tr>
<td>Don't mind</td>
<td>494</td>
<td>17%</td>
<td>30</td>
</tr>
<tr>
<td>Other</td>
<td>89</td>
<td>3%</td>
<td>12</td>
</tr>
<tr>
<td>Not answered</td>
<td>25</td>
<td>1%</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>2,900</td>
<td>100%</td>
<td>163</td>
</tr>
</tbody>
</table>

Note: Percentage figures have been rounded and therefore may not total 100%
9.3 The majority of both individual respondents and organisations (59%) favoured the GMC as the potential regulator for the MAP roles. However, analysis of additional comments\textsuperscript{v} highlighted that the GMC was mostly selected in relation to the regulation of PAs and PA(A)s, whereas for SCPs and ACCPs there was a leaning towards HCPC.

9.4 Those that favoured the GMC for PAs and PA(A)s gave the following reasons for their choice\textsuperscript{vi}:

- PAs and PA(A)s are more aligned to doctors in terms of their training, practice and supervision.
- Regulation by the GMC would bring a level of professional credibility and public confidence to the roles owing to the GMC’s standing and kudos as the regulator for doctors.

9.5 Those that were in favour of HCPC (for all the MAP roles) argued that:

- It is already well-versed in multi-professional regulation and so has the mechanisms in place to readily take on these and also any other MAP roles that may develop and require regulation in the future. The GMC has only ever regulated doctors so taking on a new profession would be unchartered territory.
- HCPC registrant fees are likely to be cheaper. There is the potential for the GMC’s annual retention fee (ARF) to be unaffordable for relatively lower-paid registrants.
- HCPC would offer the means to establish a distinct professional identity for the MAP roles as they develop.
- Regulation by the GMC, particularly of PAs, sends out the wrong message about their role suggesting they are on a par with doctors. This could potentially confuse the public.

9.6 Amongst the suggested alternatives to either the GMC or HCPC were:

- A relevant royal college
- A new, independent body established specifically to regulate MAPs
- The Nursing and Midwifery Council (NMC)
Quote from respondent in favour of the GMC:

“All of these roles will be required to work extremely closely with medical staff and will work as part of the medical team, being accountable to the senior physician responsible for the patient. Regulation through the GMC will be most effective.”

Quote from respondent in favour of HCPC:

“The HCPC are a major regulator of differing professions and therefore are effectively placed to regulate other new and evolving professions of non-medical practitioners who are complementary to the medical profession.”

Government response

The Government is currently carrying out further scoping work before reaching a decision about the most appropriate regulator.

9.7 Given the additional clarity the consultation has provided in relation to the scope of practice of PA(A)s and points raised by respondents concerning registrant fees under the costs and benefits and equalities considerations (see Chapter 10, pp 39-43), the Government identified the need to carry out further scoping work before reaching a decision about the most appropriate regulator.

9.8 We will take account of the views put forward by respondents and work with the GMC and HCPC to better understand the legislative changes that would be required to regulate PAs and PA(A)s. We will also assess the potential set-up costs to Government and ongoing fees to registrants and further consider which regulator would be the ‘best fit’ for the two professions.
10. Costs and benefits and equalities considerations

10.1 During the development of our proposals the Government considered the costs and benefits of three professional assurance options and how they might impact on the MAP roles. The professional assurance options we have considered are:

- Voluntary registration
- Accredited registration
- Statutory regulation

Analysis of consultation responses – costs and benefits

Q7. Do you agree or disagree with the costs and benefits on the different types of regulation identified? If not, please set out why you disagree. Please include any alternative costs and benefits you consider to be relevant and any evidence to support your views.

Table 9: Summary of responses to Q7

<table>
<thead>
<tr>
<th>Response</th>
<th>Individuals</th>
<th>Organisations</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of respondents</td>
<td>%</td>
<td>Number of respondents</td>
</tr>
<tr>
<td>Agree</td>
<td>1,417</td>
<td>49%</td>
<td>99</td>
</tr>
<tr>
<td>Disagree</td>
<td>115</td>
<td>4%</td>
<td>7</td>
</tr>
<tr>
<td>Don’t know</td>
<td>1,288</td>
<td>44%</td>
<td>37</td>
</tr>
<tr>
<td>Not answered</td>
<td>80</td>
<td>3%</td>
<td>20</td>
</tr>
<tr>
<td>Total</td>
<td>2,900</td>
<td>100%</td>
<td>163</td>
</tr>
</tbody>
</table>

Note: Percentage figures have been rounded and therefore may not total 100%

10.2 As the figures in the above table illustrate there was a fairly even split between those that agreed with the costs and benefits that had been identified in the consultation document and those that answered ‘don’t know’. Only 4% of respondents said they disagreed with the Government’s assessment.
10.3 Below is a summary of some of the additional comments respondents made about the costs and benefits of the different types of regulation:

- Statutory regulation is worth the financial costs involved as patient safety, quality assurance of professional standards and professional accountability are paramount.

- Statutory regulation would give employers greater confidence in employing MAPs therefore current costs associated with employing agency or locum staff would be reduced.

- Statutory regulation would benefit professionals by placing an obligation on employers to adhere to governance processes and allow time and funding for Continuing Professional Development (CPD).

- Statutory regulation is unjustifiably costly and bureaucratic with little extra benefit where the workforce is small with no plans to expand numbers.

- Accredited voluntary registers / voluntary registers are not necessarily a ‘cheaper’ alternative to statutory regulation. They require their own local governance structures and complaints management processes which can be costly to establish and administrate.

- Accredited voluntary registers / voluntary registers are insufficient measures of assurance, owing to their voluntary status, and so their use would be at a cost to patient safety.

- Accredited voluntary registers / voluntary registers allow flexibility and varied scope of teaching in sub specialties which facilitates a more responsive workforce.

10.4 A selection of other points that were made in response to this question have been summarised below:

- Annual retention fee - It was suggested that this should be set at a rate to reflect the earning potential of the MAP and not at the same level as that charged to doctors by the GMC, for example. It was argued that a high fee could put off potential entrants and curtail the supply of lower-paid MAPs. Some respondents also raised concerns about the potentially unaffordable costs of dual-registration for SCPs and ACCPs.
- Cross-subsidy - An additional point of note made was that the subsequent on-going management of the register, could (and should) be borne by the MAP registrants and not cross-subsidised by existing registrants.

- Annotation – For healthcare professionals moving into SCP and ACCP roles, the idea of annotating the existing statutory registers for nurses and those professionals registered with HCPC was suggested as a way of reducing costs both for registrants and regulators.

### Quotes from respondents:

“[The] cost of statutory regulation is outweighed by the benefits to the profession, patient safety and public trust.”

“Numbers are small and the roles are supervised. Autonomy required is insufficient to warrant the cost and bureaucracy of statutory regulation.”

“The PA(A) role is closely supervised and functions within the anaesthetic and surgical specialties only, therefore expected caseload is likely to be more defined. Given their closely supervised clinical environments, I would argue Accredited Voluntary Registration would be sufficient in ensuring high quality care and patient safety.”

“The primary purpose of regulation is to ensure clinicians practice safely and protect the public. Voluntary registration only protects the public if employing organisations require and support voluntary registration.”
Analysis of consultation responses – equalities considerations

10.5 In addition to considering the costs and benefits of the different levels of assurance, the Department of Health has considered them in relation to the Equality Act 2010, specifically the Public Sector Equality Duty (‘the Duty’), and also Section 75 of the Northern Ireland Act 1998.

10.6 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 and sexual orientation.

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?

Table 10: Summary of responses to Q8

<table>
<thead>
<tr>
<th>Response</th>
<th>Individuals</th>
<th></th>
<th></th>
<th>Organisations</th>
<th></th>
<th></th>
<th>Overall</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of respondents</td>
<td>%</td>
<td>Number of respondents</td>
<td>%</td>
<td>Number of respondents</td>
<td>%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>597</td>
<td>21%</td>
<td>23</td>
<td>14%</td>
<td>620</td>
<td>20%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>992</td>
<td>34%</td>
<td>84</td>
<td>52%</td>
<td>1,076</td>
<td>35%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Don’t know</td>
<td>1,268</td>
<td>44%</td>
<td>42</td>
<td>26%</td>
<td>1,310</td>
<td>43%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not answered</td>
<td>43</td>
<td>1%</td>
<td>14</td>
<td>9%</td>
<td>57</td>
<td>2%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>2,900</strong></td>
<td><strong>100%</strong></td>
<td><strong>163</strong></td>
<td><strong>100%</strong></td>
<td><strong>3,063</strong></td>
<td><strong>100%</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: Percentage figures have been rounded and therefore may not total 100%

10.7 A significant proportion of respondents (43%) answered “Don’t know” to this question while 35% of respondents thought that any changes to the level of professional assurance for the MAP roles would not impact upon protected equality characteristics.

10.8 Of the 20% that thought a change to the level of professional assurance would have an impact on protected equality characteristics, the majority did not provide any comments. Of those that did make additional comments the majority felt that
there would be a positive impact on protected characteristics if statutory regulation was introduced as:

- It would facilitate more robust monitoring of adherence to the duties and increase commitment to them.
- Statutory regulation would also increase the diversity of entrants to the MAP roles as it would enable professions to establish direct entry routes.

Quotes from respondents:

“Increased regulation in these professions would allow accurate assessment of (implicit or explicit) discrimination which may currently be occurring within the training and recruitment for these MAPs. Without regulation it could be impossible to accurately assess which sectors of society are being under represented in these professions.”

“Statutory regulation of all four MAPs would have a positive impact on the protected characteristics covered by the Public Sector Equality Duty as it would enable direct entry programmes into each profession across England. This would widen participation and attract a diverse range of trainees.”

10.9 A small number commented that there may be a negative impact if statutory regulation was introduced in terms of the financial burden of registrant fees, especially on lower-paid or part-time registrants. This impact would increase if either the annual retention fees were high or if dual registration was a requirement and therefore fees were payable to more than one regulator.

Government response

The information gathered through this consultation will inform our thinking as we work through the next stage of the process.

10.10 A full impact assessment will be produced during the next stage of our proposals and will be published alongside the consultation on draft legislation. Any relevant information provided through the consultation on the potential costs and benefits of different types of regulation will inform the development of the impact assessment and be considered as we develop our proposals to introduce statutory regulation for PAs and PA(A)s.

10.11 We will also ensure that any potential impacts (negative or positive) on protected characteristics that have been highlighted through this consultation process are taken into consideration throughout the next stage of the process.
11. Conclusion

11.1 The Government is grateful to those who took the time to respond to this consultation. The analysis of comments put forward as part of the consultation has enabled us to consider the issues and complexities of the regulation of the MAP roles in more detail and has informed our decision making.

11.2 In conclusion:

- The Government plans to introduce statutory regulation for PAs and PA(A)s.
- The Government maintains the view that further statutory regulation is not proportionate for SCPs and ACCPs at this time.
- Further exploratory work is needed to inform the decision on whether the GMC or the HCPC would be most appropriate to take on responsibility for the regulation of PAs and PA(A)s.

Next steps

11.3 The Government, in conjunction with relevant stakeholders, will confirm which healthcare regulator is best placed and draft the required legislation which will introduce statutory regulation for PAs and PA(A)s. As part of this process, we will look to develop a framework to which other MAP roles could be added at a later date as the case arises.

11.4 In order to bring a professional group into statutory regulation the Government uses a legislative vehicle called a Section 60 Order (which is made under Section 60 of the Health Act 1999). This Order will amend existing legislation relevant to the chosen regulator to bring the professional group under its responsibility.

11.5 A public consultation on the draft legislation will be required and the legislation will be subject to the agreement of the health ministers across the UK in advance of it going before Parliament.

11.6 The appropriate level of regulatory oversight for different professional groups remains a key issue for the Government.

11.7 The consultation on regulatory reform sets out future options in this area. These include the development of risk profile models for all professional groups (including new and emerging professions and those currently subject to statutory regulation) alongside the consideration of prohibition orders as an alternative regulatory approach.
Annex A - Detailed breakdown of healthcare role descriptions

Table 11: Categories of healthcare professionals

The table below provides a breakdown of the number of respondents who identified as healthcare professionals according to their specified profession. It should be noted that this data has been rationalised to consolidate the number of categories of professional titles.

<table>
<thead>
<tr>
<th>Category</th>
<th>Number of respondents</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MAP ROLES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician associate / physician associate student</td>
<td>556</td>
<td>25%</td>
</tr>
<tr>
<td>Physicians’ assistant (anaesthesia) / physicians’ assistant (anaesthesia) student</td>
<td>57</td>
<td>3%</td>
</tr>
<tr>
<td>Surgical care practitioner / trainee surgical care practitioner</td>
<td>19</td>
<td>1%</td>
</tr>
<tr>
<td>Advanced critical care practitioner / trainee advanced critical care practitioner</td>
<td>19</td>
<td>1%</td>
</tr>
<tr>
<td><strong>OTHER ROLES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consultant anaesthetist / anaesthetist</td>
<td>295</td>
<td>13%</td>
</tr>
<tr>
<td>Consultant - other</td>
<td>268</td>
<td>12%</td>
</tr>
<tr>
<td>Junior doctor</td>
<td>68</td>
<td>3%</td>
</tr>
<tr>
<td>General practitioner (GP) / trainee GP</td>
<td>107</td>
<td>5%</td>
</tr>
<tr>
<td>Operating department practitioner / trainee operating department practitioner</td>
<td>46</td>
<td>2%</td>
</tr>
<tr>
<td>Advanced practitioner / trainee advanced practitioner (including clinical)</td>
<td>17</td>
<td>1%</td>
</tr>
<tr>
<td>Advanced nurse practitioner / trainee advanced nurse practitioner</td>
<td>17</td>
<td>1%</td>
</tr>
<tr>
<td>Category</td>
<td>Number of respondents</td>
<td>%</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>-----------------------</td>
<td>-----</td>
</tr>
<tr>
<td>Nurse - other</td>
<td>106</td>
<td>5%</td>
</tr>
<tr>
<td>Medical or healthcare student</td>
<td>17</td>
<td>1%</td>
</tr>
<tr>
<td>Other healthcare professional</td>
<td>641</td>
<td>28%</td>
</tr>
<tr>
<td>Academic</td>
<td>14</td>
<td>1%</td>
</tr>
<tr>
<td>Other</td>
<td>7</td>
<td>0.3%</td>
</tr>
<tr>
<td>Not specified</td>
<td>2</td>
<td>0.1%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>2,256</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

Note: Some percentage figures have been rounded and therefore may not total 100%
Annex B - End notes

i It should be noted that the summary of comments represents the views of respondents and are not necessarily the view of the Government.

ii See endnote i above.

iii See endnote i above.

iv See endnote i above.

v See endnote i above.

vi See endnote i above.

vii See endnote i above.

viii See endnote i above.