Response to consultation on the regulation of medical associate professions in the UK

December 2017

1. Introduction

1.1 The Professional Standards Authority for Health and Social Care promotes the health, safety and wellbeing of patients, service users and the public by raising standards of regulation and registration of people working in health and care. We are an independent body, accountable to the UK Parliament. More information about our work and the approach we take is available at www.professionalstandards.org.uk

1.2 As part of our work we:

- Oversee the nine health and care professional regulators and report annually to Parliament on their performance
- Set standards for and accredit registers of practitioners working in health and care occupations not regulated by law
- Conduct research and advise the four UK governments on improvements in regulation
- Promote right-touch regulation and publish papers on regulatory policy and practice.

1.3 Right-touch regulation describes the approach we adopt in the work we do. We encourage others to adopt it too[1]. It means understanding the problem before deciding on the solution. It makes sure that the level of regulation is proportionate to the level of risk to the public and that the consequences of regulation are properly considered. It builds upon the principles of good regulation, identified by the Better Regulation Executive to which we added 'agility'. This means looking forward to anticipate change.

2. General comments

2.1 We welcome the opportunity to respond to this consultation on the regulation of the medical associates professions (MAPs) in the UK. As our *Right-touch assurance* methodology has been used as the basis for the assessment of the four medical associate professions carried out by Health Education England (HEE), we feel it is important to clarify from the outset that our methodology was used without our knowledge or involvement.

[1] Professional Standards Authority 2015, *Right-touch regulation*. [Online] Available at: http://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/right-touch-regulation-2015.pdf?sfvrsn=16 [Accessed: 21/12/2017]

2.2 We have described *Right-touch assurance* as a work in progress and it was only partially tested in the work commissioned from us by the Department of Health in 2016 to assess the role of nursing associate. We consider that the model that we have developed is robust and has the potential to provide objective advice to those making decisions about appropriate levels of assurance for different occupations. However, until a full analysis has been completed, only limited conclusions can be drawn from it.

2.3 We have several concerns about the way the model has been applied by HEE (outlined in detail below) which affects the validity of the results they report and we cannot endorse the conclusions that have been reached. We ask the Government to take this into account when assessing the stakeholder responses gathered through the consultation.

2.4 The information provided on the assessment of the medical associate professions provides little compelling evidence of risk of actual harm which cannot be mitigated through existing means of assurance. It should be noted that whilst there may be a desire to enhance the professional credibility of the professions or to grow and develop medical associates as a group within the workforce, this is not the role of statutory regulation. There are many other associate and assistant roles which are developing with the health and care workforce and any attempts to use statutory regulation in this way could lead to widespread calls for regulation of many of these occupations.

2.5 In addition, the roles grouped together as MAPs vary widely both in scope, the type and risk of harm to the public as well as the level of assurance they are already subject to. For example, Surgical Care Practitioners (SCPs) and Advanced Critical Care Practitioners (ACCPs) are already required to be registered healthcare professionals in order to carry out the role. There is also variation over whether those within the MAPs group operate as autonomous professionals. There appears to be a tension between calls to regulate a profession due to the stated need for individuals to exercise autonomy in decision making and the desire to require regulated individuals to continue to be accountable.

2.6 We suggest that further analysis is required to establish the most appropriate way forward for the MAP roles and we would be able to advise the Department of Health on this issue.

3. Purpose of regulation

3.1 The purpose of regulation is to minimise harm to the public and reduce the likelihood of harm occurring. Decisions on the use of regulation, including which health and care occupations need to be statutorily regulated, should be based on a thorough assessment of risk of harm rather than for other reasons such as to enhance professional status or as a result of lobbying by particular occupations or organisations.

3.2 As the purpose of health and care professional regulation is to control risk of harm, the role of the regulator should not be confused with the remit of other

organisations who may also influence and interact with health and care professionals:

- **Regulators** are responsible for protecting the public by setting and upholding standards of conduct and competence, controlling entry to the profession and taking action in response to concerns about conduct or competence
- **Professional bodies**, such as Colleges, are generally responsible for quality improvements to education, training, professional practice and continuing professional development
- **Representative bodies** such as trade unions are responsible for protecting and advancing the interests of the members they represent.

4. Use of the Right-touch assurance model

4.1 The Authority developed *Right-touch assurance*[2] as a tool for assessing the risk of harm presented by different health and care occupations. This tool is intended to be used to advise Government on what form of assurance is needed to manage the risk of harm to patients and service users arising from the practice of an occupation.

4.2 One of the primary reasons that we developed the model is to ensure that regulation is proportionate to the likelihood of actual harm occurring, rather than as an assessment of theoretical harm or a basic assessment of activities which might have the potential for harm.

4.3 It is important to be clear on the difference between actual and potential harm. As we outlined in *Right-touch regulation*: 'Hazards are the conditions or events that can lead to or contribute to harm. Risk is the likelihood of a harm materialising. In health and social care, harm is physical injury or psychological distress experienced by people through interaction with health or social care practitioners and services.'[3]

4.4 We also want to ensure that regulation is not used for the wrong reasons, for example to enhance the professional status of a particular group or as a reaction to public or media pressure to regulate. This is because statutory regulation, whilst it is an important tool in protecting the public, can be inflexible, restrictive, expensive or even counterproductive if used inappropriately.

4.5 We have previously described a 'continuum of assurance'[4] which shows how, as the risk of harm increases, the regulatory force required to manage that risk also increases. Different levels of regulatory oversight include:

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[2] Professional Standards Authority 2016, *Right touch assurance*. [Online] Available at: https://www.professionalstandards.org.uk/publications/detail/right-touch-assurance-a-methodology-for-assessing-and-assuring-occupational-risk-of-harm [Accessed:21/12/2017]

[3] Professional Standards Authority 2015, *Right-touch regulation*. [Online] Available at: http://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/right-touch-regulation-2015.pdf?sfvrsn=16 [Accessed: 21/12/2017]

[4] Professional Standards Authority 2015, *Rethinking regulation*. [Online] Available at: https://www.professionalstandards.org.uk/publications/detail/rethinking-regulation [Accessed: 21/12/2017]

- Employer controls - refers to any requirements that employers might put in place to provide assurance of minimum standards of practitioners such as training, qualifications, codes of conduct, supervision and appraisal
- Credentialing - refers to developing a consistent method of validating the identity and legitimacy of external employees with access to healthcare settings. (This is distinct from the General Medical Council (GMC) use of the term credentialing for specific areas of medical practice for doctors who are already on a register)
- Assured registration - refers to the Accredited Registers programme operated by the Professional Standards Authority. The Authority accredits organisations that hold registers of health and social care practitioners who are not regulated by law, against 11 standards
- Statutory registration and licensing - refers to the legal requirement for registration of health and care professionals who are currently covered by the nine statutory regulators.

4.6 It should be noted that Government policy remains that statutory regulation for unregulated groups will only be considered when there is a clear case based on risk of harm to the public and where assured registration is not considered sufficient to manage this risk[5]. As noted, departure from this position without compelling evidence of risk of harm may lead to calls for unnecessary regulation for many other groups within the health and care workforce.

4.7 We were previously commissioned by Government to test our model on the emerging role of nursing associate[6], however we were unable to complete our assessment as the role was insufficiently developed to be able to determine an accurate picture of the risk of harm associated with practice. We recommended registration rather than regulation as an interim measure to allow additional evidence to be gathered about how nursing associates would work once the role was more fully defined. A decision was subsequently made by the Secretary of State for Health to proceed with statutory regulation of the role. As a result, we have yet to complete a full test of the model which we envisage would need to include expert input on risk modelling.

4.8 Our concerns about the way that the model has appears to have been misunderstood are detailed below:

Changes to categories of hazards

4.9 In our Right-touch assurance model we identified groups of hazards relating to the practise of an occupation from which harm might arise. These were:

[5] Department of Health 2011, *Enabling Excellence*, p.18. [Online] Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216580/dh_124374.pdf [Accessed: 21/12/2017]

[6] Professional Standards Authority 2016, *Interim report: Oversight of Nursing Associates*. [Online] Available at: https://www.professionalstandards.org.uk/latest-news/latest-news/detail/2016/11/18/oversight-of-nursing-associates-the-professional-standards-authority-publishes-its-interim-report [Accessed: 21/12/2017]

- Intervention/complexity: potential for harm caused by features of practice from prescribing, surgical and psychological interventions to other kinds of physical therapies such as massage or invasive diagnostic techniques
- Context: including environments with varying levels of oversight (hospitals, community pharmacies and hospices amongst others), as well as patients' and service users' homes or high street premises
- Agency/vulnerability: contact with patients and service users who may have less or more ability to exercise control over their care and circumstances, potentially including children, people with disabilities, those with literacy and communication problems or competent adults purchasing services.

4.10 In the Medical Associates consultation document, in certain places 'Agency/vulnerability' of patients and service users has been replaced with 'Accountability' relating to the practitioner's level of autonomy. This has a fundamentally different meaning and means that the need we identified to take into account the vulnerability of the patients and service users when considering the most appropriate form of oversight for a role is excluded. It is however unclear which term was used in the assessment as our original categories are used in the completed evidence template published alongside the consultation document. The consultation document does not explain this change nor the inconsistency.

Type of evidence

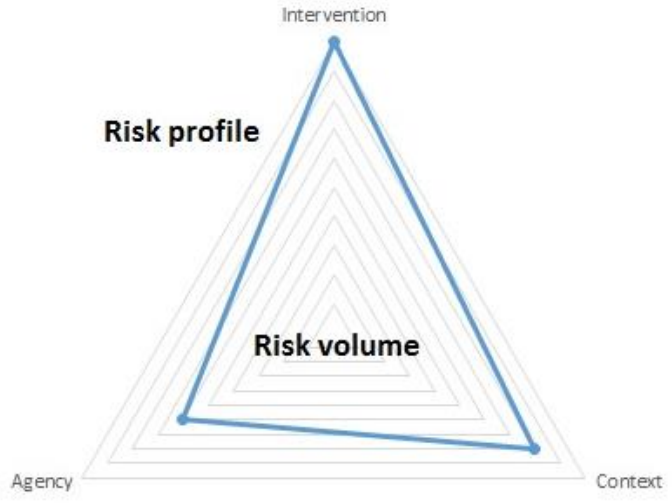
4.11 In our publication outlining the principles behind the model we were clear that evidence of risk of harm relating to the hazards under the three categories identified (particularly intervention based hazards) must relate to the actual likelihood of harm occurring. For example, if a practitioner is likely to be prescribing medication, evidence could be based on the incidence and impact of prescribing errors by professionals working in the same or a similar role. It is not sufficient merely to say that prescribing is risky.

4.12 In the MAPs consultation, evidence of likelihood of harm is generally not provided. Instead the completed evidence templates which are provided for each of the medical associate roles alongside the consultation primarily list the skills required or the interventions that the practitioner will be carrying out. Evidence consists of a mixture of stakeholder views on the potential for the expansion of the PA role across the four countries, information on demands on the health service and stakeholder views on the need for regulation. For example, one piece of evidence provided is a petition to Parliament signed by 10,000 people calling for regulation. This is not evidence of risk of harm.

4.13 This is precisely the kind of unscientific assessment that we were attempting to avoid when developing our model. Most health professions can present a case that the tasks it carries out are potentially risky and can identify stakeholders who believe that the role should be regulated for public confidence or professional self-interest. However, a genuine assessment of the likelihood of harm occurring and the most appropriate mechanism to control the risk should go beyond this and statutory regulation should be used only when the likelihood of harm is sufficiently high.

Risk scoring and profiling

4.14 As outlined in *Right-touch assurance*, the model principally involves assessing the evidence of actual harm relating to the hazards in the categories outlined (intervention, context and vulnerability/agency), scoring based on the likelihood and severity of harm occurring in the different areas and profiling the risk (the risk triangle, see below).



4.15 It is unclear in the consultation whether this has been done for the medical associate roles. If it has then the working has not been included in the documentation. Instead in the consultation document there is a summary table highlighting whether there is a 'high, low or medium' risk of harm under the three categories for each of the medical associate roles. This table also uses the incorrect label of 'Accountability' for the third category of hazards. As noted we have not had a chance to pilot the risk scoring element of the model fully.

Impartiality of process

4.16 We were clear when developing the model that there should be independent decision makers assessing the evidence provided and reaching a decision, with input from clinical experts, on the scale and profile of the risk of harm and the most appropriate form of assurance for the occupation. This is because those collating the evidence and information may have specific views on the most appropriate form of oversight or an interest in a particular outcome. It also mirrors good practice in many contexts including science to separate data collection or investigation from adjudication or decision making on an issue.

4.17 It is unclear how the assessment was carried out for these roles and whether there was any separation between those collating and providing the evidence of risk of harm and those making decisions on risk level and means of assurance.

Means of assurance

4.18 Whilst we recognise that there is demand from some stakeholders for statutory regulation for some or all of the medical associate professions, we urge

Government to consider carefully the most appropriate methods of assurance based on a clear assessment of actual risk of harm and the most proportionate way to manage the risk. In our view, the assessment of the MAPs provided in this consultation does not clearly identify a risk of harm that cannot be managed by any other mechanisms and implementing statutory regulation of any of the medical associate professions without further analysis may set an unhelpful precedent.

4.19 As we have highlighted statutory regulation may not be an appropriate form of assurance as it tends to inflexibility and may have a range of unintended consequences both for the profession and the workforce more broadly. As noted, the Government's current position remains that statutory regulation should only be considered if other means of assurance, such as assured registration, are not sufficient.

4.20 We would be happy to advise the Department of Health on how the methodology should have been applied. We would suggest that in the absence of compelling evidence of risk of harm the most appropriate response would be to look at strengthening and developing the existing schemes of voluntary registration. This would be in line with current Government policy and would allow a more thorough assessment of risk and consideration of whether there is the need for any additional assurance for any of the roles within this group.

5. Questions

Question 1: 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.

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

5.1 The first test of right-touch regulation is to identify the problem before the solution. As highlighted in our general comments, we do not believe that the assessment carried out of this role is sufficient to establish the risk of harm inherent in the practise of the occupation and to determine the most appropriate way to manage it.

5.2 The assessment of this role highlights a range of skills that physician associates will need to have and a range of tasks that they carry out. However, there is little evidence to demonstrate the seriousness or likelihood of harm arising from these interventions as carried out by these practitioners in the context in which

they work. Therefore, any risk identified is purely theoretical and may well already be adequately managed by existing mechanisms.

5.3 In the absence of compelling evidence of risk of harm, the most appropriate response would be to look at strengthening and developing the existing scheme of voluntary registration which is operated by the Faculty of Physician Associates which sits within the Royal College of Physicians.

Question 2: 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.

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

5.4 We agree that the assessment carried out of this role is insufficient to establish the level of risk inherent in the practise of the occupation and to determine the most appropriate way to manage it. As with the physician associate role, in the absence of compelling evidence of risk of harm the most appropriate response would be to look at strengthening and developing the existing scheme of voluntary registration operated by the Association of Physicians' Assistants (Anaesthesia).

Question 3: 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.

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

5.5 We agree that the assessment carried out on this role is insufficient to establish the level of risk inherent in the practise of the occupation and to determine the most appropriate way to manage it. As with the physician associate and physician assistant (anaesthesia) roles, in the absence of compelling evidence of risk of harm the most appropriate response may be to look at strengthening and developing the existing schemes of assurance. Alternatively, there may be scope to look at other mechanisms to strengthen recognition within the existing regulatory mechanism for this role, for example annotation on the register with whichever regulatory they are already registered with. However, models do exist within the Accredited Registers programme for specialist registers of practitioners who are statutorily regulated such as registers of cosmetic practitioners.

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

5.6 We believe that the assessment carried out on this role is insufficient to establish the level of risk inherent in the practise of the occupation and to determine the most appropriate way to manage it. As with the physician associate and physician assistant (anaesthesia) roles, in the absence of compelling evidence of risk of harm the most appropriate response may be to look at strengthening and developing the existing schemes of assurance. Alternatively, there may be scope to look at other mechanisms to strengthen oversight within the existing regulatory mechanism for this role, for example annotation on the register with whichever regulatory body they are already registered with.

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)

5.7 We do not have a view on whether medicines supply, administration or prescribing responsibilities should be extended to any of the MAP roles.

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

5.8 We do not believe that there is sufficient evidence of risk of harm to suggest that statutory regulation is required for any of the MAP roles at this stage and therefore we do not have a view on which regulator should have responsibility for regulating any of the roles.

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

5.9 We note that not all of the benefits outlined are excusive to statutory regulation and similar benefits may be gained from a strengthened or expanded system of assured registration.

5.10 Additionally, some of the costs and benefits of statutory regulation will be dependent on the fees ultimately charged for registration. For example, the level the registration fee is ultimately set at may influence the number seeking to join the profession. By creating barriers to entry and additional cost to work, statutory regulation may reduce supply rather than increase it amongst lower paid occupations.

5.11 Statutory regulation is likely to increase the pay of the professional group in question which will be more costly for employers who as a result may seek to employ unregulated staff when they face pressure on resources. More generally, statutory regulation, whilst an important tool in protecting the public in certain circumstances tends to be inflexible in its ability to adapt to changing employment and workforce needs.

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

5.12 No.

6. Further information

6.1 Please get in touch if you would like to discuss any aspect of this response in further detail. You can contact us at:

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