Royal College of Anaesthetists' response to the Department of Health consultation, '*Promoting professionalism, reforming regulation*'

About the Royal College of Anaesthetists

- 16% of all hospital consultants are anaesthetists, making anaesthesia the single largest hospital specialty in the UK[1,2,3]
- Anaesthetists play a critical role in the care of two-thirds of all hospital patients[4] and 99% of patients would recommend their hospital's anaesthesia service to family and friends[5]
- With a combined membership of 22,000 fellows and members, representing the three specialties of anaesthesia, intensive care and pain medicine, the Royal College of Anaesthetists (RCoA) is the third largest Medical Royal College by UK membership.

Summary of our response:

- We agree with the proposals to reduce the number of regulators, as long as decisions are based on comprehensive analyses of the cost and workload created by regulating new groups of healthcare professions. The 'right' number of regulators should, not only result in more streamlined and efficient processes, but also allow the regulatory system enough breadth to avoid conflicts of interest and incorporate a broad range of expert and independent views, especially if small regulators are incorporated into larger ones.
- While we accept that the PSA will play an important role in the reform of regulators, as proposed by the Department of Health, we recommend that the Authority increases public awareness of its work and remit and engages better with healthcare professionals, not just their regulators, in order to gain their trust and confidence that it will apply a balanced and transparent approach in the way it works with regulators.
- We are encouraged by the range of policy factors that the PSA proposals take into account, specifically consideration of the scale of the risk and the proposals to create a 'risk profile' for each professional group, including those that are not currently regulated. We call on the PSA and the DH to establish full statutory regulation of all Medical Associate Professions, in particular Physicians' Assistants (Anaesthesia) who currently perform high risk anaesthetic procedures with only local clinical governance safeguards in place and resulting in inconsistency of standards and supervision.
- We oppose prohibition orders as an appropriate alternative for those healthcare professions not subject to statutory regulation and we call instead for full statutory regulation of all healthcare professions who carry out procedures with a significant element of risk of harm to patients (i.e. Physicians' Assistants (Anaesthesia)).
- We support the proposals to review fitness to practise investigations and relevant changes in legislation towards a more proportionate and less adversarial system, which allows for the identification of the causes of malpractice and encourages learning from mistakes. We strongly believe that regulators have an important role in supporting the professionalism of healthcare professions which goes beyond their regulatory remit.
- Any changes to regulation and the way regulators operate will need to be unequivocally supported and adopted by the PSA, so that the right balance is struck between protecting the public and unnecessarily removing doctors from practice.

If you have any questions regarding our submission, please contact Elena Fabbrani, Policy & Patient Information Co-ordinator, at efabbrani@rcoa.ac.uk or on 020 7092 1694.

Royal College of Anaesthetists

General comments

We welcome the opportunity to respond to this consultation and fully endorse the principal that 'professional regulation is central to the systems of assurance' which safeguard people when they access healthcare services.

However, we believe that the consultation's focus on the *number* and *structure* of individual regulatory bodies is to define the pertinent issues in too narrow a way.

The *approach* to regulation is the vital component to achieving the principle outlined above, and questions about the overall effectiveness of regulation at achieving the aim of improving practice and protecting patients are at the heart of this.

Statutory measures should be introduced within a culture that facilitates their objective of 'promoting professionalism'; not put in place to castigate individuals for behaviours that may have developed as a result of system failures and poor culture that are ultimately the responsibility of organisational leaders.

Professor Don Berwick, in his 2013 review into patient safety in the NHS in England, stated: 'In the end, culture will trump rules, standards and control strategies every single time, and achieving a vastly safer NHS will depend far more on major cultural change than on a new regulatory regime'.[6]

We believe that Professor Berwick's statement gets to the central issue that needs to be addressed and echoes themes interrogated in the *Francis Report* following the Mid-Staffordshire NHS Foundation Trust Public Inquiry in 2013.[7]

Responses to consultations questions

Q1. Do you agree that the PSA should take on the role of advising the UK governments on which groups of healthcare professionals should be regulated?

Based on the criteria outlined in the consultation document and the PSA's own very detailed policy documents on reforming regulation[8], we believe the PSA would be the appropriate body to advise the UK governments, in an independent and proportionate way, on which groups of healthcare professionals should be regulated.

We are concerned, however, that the PSA and its remit are not widely known to healthcare professionals and we feel that the PSA should do more to increase awareness of its aims and its work with regulators, especially around the PSA's role in challenging fitness to practise decisions. While the overall aim of the PSA of 'protecting the public' is laudable, we feel that the Authority also needs to gain the trust of health care professionals and this can only be achieved through a transparent, accessible and balanced approach in its work with regulators.

Q2. What are your views on the criteria suggested by the PSA to assess the appropriate level of regulatory oversight required of various professional groups?

We are encouraged by the range of policy factors that the PSA proposals take into account, specifically consideration of the scale of the risk and the proposals to create a 'risk profile' for each professional group, including those that are not currently regulated.

The RCoA believes that Medical Associate Professions – including Physicians' Assistants (Anaesthesia) (PA(A)s) and Advanced Critical Care Practitioners (ACCPs) – can make a valuable contribution towards a sustainable anaesthetic workforce, but only if these roles are properly regulated. Therefore, we strongly support the introduction of statutory regulation of PA(A)s, ACCPs and other MAPs, as per our response to the DH consultation *Regulating Medical Associate Professions in the UK*[9].

In July 2016 the RCoA established a voluntary register for PA(A)s in order to better understand the PA(A) scope of practice across the UK and to develop a comprehensive record of all PA(A)s as a prelude to statutory regulation. The register was always intended as a stepping stone in the professionalisation and expansion of the role, but this has now reached its limit in the absence of a framework for statutory regulation.

Despite publication of guidance on the scope of practice of PA(A)s by both the RCoA and the Association of Anaesthetists of Great Britain and Northern Ireland, we are aware that extension of the PA(A) role beyond the training received at the point of qualification has occurred sporadically across the UK to include higher risk procedures and, in limited cases, induction and emergence from anaesthesia without direct supervision.

Q3: Do you agree that the current statutorily regulated professions should be subject to a reassessment to determine the most appropriate level of statutory oversight? Which groups should be reassessed as a priority? Why?

We support this approach and we believe that, in order to protect patient safety, healthcare professions, operating in an often complex and dynamic environment, need to undergo regular assessments of regulatory structures, especially if the scope of practice has expanded beyond the one originally intended for them.

Further to our response to question two, any reassessment should be considered alongside the outcomes of the Department of Health's consultation on the regulation of MAPs.[a]

In *Right-touch reform* the PSA lists 'inappropriate anaesthesia' in its categories of misconduct that the Authority uses for final fitness to practise hearing determinations. The document goes on to state that 'these categories, while not to be confused with the harm they cause, illustrate the different kinds of event and behaviour to which patients and those close to them can be subject, and of which any of the types of harm listed above can be the consequence.'

Some of the examples of harm listed by the PSA that could result from inappropriate anaesthesia are:

- Harm to the physical and/or mental health of patients and those close to them, their career, financial status and family life, sometimes irrevocable
- Harm to the physical and/or mental health of the registrant, their career, financial status and family life, sometimes irrevocable

With reference to table 1 of the consultation document, we believe that the current arrangements that see professions such as arts therapists and speech therapists enjoy full regulatory oversight, while PA(A)s and ACCPs – dealing with complex anaesthetic

[a] The consultation period runs from 12 October to 22 December 2017
https://www.gov.uk/government/consultations/regulating-medical-associate-professions-in-the-uk

procedures and the administration of anaesthetic drugs – remain unregulated, are inconsistent.

Q4. What are your views on the use of prohibition orders as an alternative to statutory regulation for some groups of professionals?

We do not believe that prohibition orders are an appropriate alternative for those healthcare professions not subject to statutory regulation. The recommendation by the Law Commission, noted in paragraph 2.9 of the consultation document, also recommends that 'the relevant regulatory body' should issue prohibition orders. However, where there is no regulatory body for groups – such as MAPS – it is unclear who would then have the powers to issue such orders. We would reiterate the point made in response to question three that many elements of this consultation need to be considered alongside the feedback to the Department of Health's MAPs consultation.

As stated in the consultation document, an evaluation by the PSA has found insufficient evidence to demonstrate that prohibition orders are effective schemes in health and social care[10] and we recommend instead that all healthcare professions be subject to statutory regulation, especially those whose scope of practice carries a significant element of risk of harm to patients. The proposed creation of a 'risk profile' for each profession will facilitate the PSA to make an adjudication of risk.

Q5. Do you agree that there should be fewer regulatory bodies?

We agree that a reduced number of regulators would lead to a more streamlined and flexible system which simplifies the regulatory landscape.

As is noted in paragraph 2.2 of the consultation document, it is important that the regulatory landscape is wide enough so as to avoid potential conflicts of interest and the example of the HCPC's legislative power to recommend that a group should be statutorily regulated highlights this point well. Consideration should also be given as to how a smaller number of regulators could lead to a more concentrated regulatory framework, which is then more vulnerable to both 'groupthink' and 'cognitive dissonance' that has a detrimental impact on the decision-making process.

We would support a reduction in the number of regulators, however we feel that it may be premature to propose 'three or four' regulators, as suggested in the consultation document, until an analysis has been carried out to assess the cost and workload created by regulating new groups of healthcare professions. We call for a reduction to the 'right' number of regulators that, not only results in a more streamlined and efficient processes, but also allows the regulatory system enough breadth to avoid conflicts of interest and incorporate a broad range of expert and independent views.

Q6. What do you think would be the advantages and disadvantages of having fewer professional regulators?

A system with a reduced number of regulators could achieve a number of advantages:

- Processes could be standardised and made more consistent across regulators, for example around patient complaints, giving more clarity where members of the public need to go when they have concerns about a profession, but also around developing standards and discharging powers.
- Economies of scale could be made by combining regulators and the sharing of back office functions, leading to savings.

- The sharing of ideas and best practice across professions falling under one regulator is another advantage, as well as sharing of best practice between fewer regulators. Care should be taken, however, when integrating smaller regulators into larger ones, to ensure that each profession is not prioritised over another and that regulators 'taken in' by a larger one can still play a role in the development of standards and regulatory frameworks on an equal basis.

As is noted in response to question five, potential disadvantages can be mitigated by ensuring that the number of regulators which are retained/maintained allows the regulatory system enough breadth to avoid conflicts of interest and incorporate a broad range of expert and independent views.

Q7. Do you have views on how the regulators could be configured if they are reduced in number?

The PSA's proposals for assessing whether professional groups should be regulated could be a good starting point to draw up how regulators could be configured in the future, in particular the proposal to gather evidence of risk of harm in the three key areas, identified as:

- The complexity of the activities/intervention undertaken
- Where the intervention occurs
- The vulnerability/autonomy of the patient and their ability to make an informed choice about their care

Based on the above principles an initial grouping could be attempted - for example: health care professions who have a customer service/retail element, such as opticians and pharmacists, could be incorporated under a single regulator; health care professions who operate in direct delivery of clinical care settings, such as hospitals, health centres, dentists and GP surgeries could form another regulator; care homes and community services could form another one and so on.

An alternative could be to group the professions by setting in which the majority of public or patient engagement occurs i.e. primary care regulator, secondary care regulator and a social/tertiary care regulator.

Q8. Do you agree that all regulatory bodies should be given a full range of powers for resolving fitness to practise cases?

We agree that regulatory bodies should be given a more comprehensive range of powers in handling cases and we welcome the proposals that seek to embed a more proportionate and less adversarial system of regulation, which allows for the identification of the causes of malpractice and encourages learning from mistakes.

Moreover, the RCoA is concerned about the level of pressure experienced by doctors undergoing GMC investigations. An internal review by the GMC highlighted that doctors undergoing fitness to practice investigations are at a higher risk of suicide.[11] Such investigations can be extremely stressful, isolating and avoidably prolonged.

We welcome in particular the proposals for an increased use of warnings as punitive actions, which would distinguish between the actual fitness to practice of a doctor from issues to do with conduct and behaviour. A more flexible approach to punitive action should also take into consideration any remediation that a doctor may undergo during investigations, which

may result in doctors remaining 'fit to practise' at the time of panel judgement while at the same time being issued with a fairer and more balanced type of punishment.

Importantly, this more flexible approach to fitness to practise and new range of powers for regulators will need to be supported and adopted by the PSA, if it is to work in practice, so that the right balance is struck between protecting the public and unnecessarily removing doctors from practice.

Q9. **What are your views on the role of mediation in the fitness to practise process?**

Every year the RCoA receives a considerable number of enquiries from patients who have not been able to get any resolution with the doctor or hospital about complaints they have raised. We know that many of these patients, possibly out of frustration, then decide to refer their case, regardless of gravity, to the regulators leading to costly and stressful investigations.

We welcome the proposals for a mediation service, which would allow for open conversations between doctors/service providers and patients to help resolve disputes before they are escalated to the regulators.

A mediation process may also advise on the need for escalating cases to regulators and could help foster a culture of learning in the medical professions.

In addition to the consultation proposals we would encourage consideration of what role the National Guardian's Office[b] might have in the mediation procedures, to ensure that any implications about organisational culture which may have had an implication on – or for –an individual case, can be appropriately addressed.

Q10. Do you agree that the PSA's standards should place less emphasis on the fitness to practise performance?

Yes. Legal measures and fitness to practice procedures are only one element of regulating healthcare professions. For many years the RCoA has called for steps to facilitate a 'no-blame' learning environment where staff and organisations can learn from mistakes when they do happen. We believe that regulators have an important role to play in this.

Q11. Do you agree that the PSA should retain its powers to appeal regulators' fitness to practise decisions to the relevant court, where it is considered the original decision is not adequate to protect the public?

We believe that the PSA should retain these powers, but under governance arrangements which have the support of the regulators, especially in light of the proposals to review fitness to practise procedures and have a less adversarial approach to investigations.
As stated in our answer to question 8, both the PSA and the regulators need to work together to strike the right balance between protecting the public and judging healthcare professionals fairly, so that those who are judged fit to practise, can continue to practise.

Q12. Do you think the regulators have a role in supporting professionalism and if so how can regulators better support registrants to meet and retain professional standards?

We strongly believe that regulators have a central role in supporting professionalism. We welcome the positive inroads that the GMC has made through its Regional Liaison Service,

[b] *National Guardian's Office.* http://www.cqc.org.uk/national-guardians-office/content/national-guardians-office

but also in working with the NHS Practitioner Health Programme (NHS PHP) in supporting doctors who are experiencing personal and career difficulties. The RCoA has called for the expansion of the NHS PHP across the UK[12] which can facilitate the continuation of the GMC's work in engaging with the programme.

Furthermore, as stated above, the importance of a change in the healthcare sector from a blame culture to one that encourages honesty and learning when things go wrong should go hand in hand with the development of new regulatory frameworks.

As Don Berwick stated in his review into patient safety in 2013[13]:
'In the end, culture will trump rules, standards and control strategies every single time, and achieving a vastly safer NHS will depend far more on major cultural change than on a new regulatory regime.'

Q13. Do you agree that the regulators should work more closely together? Why?

Yes. Please refer to our response to question six.

Q14. Do you think the areas suggested above are the right ones to encourage joint working? How would those contribute to improve patient protection? Are there any other areas where joint working would be beneficial?

The four potential areas identified for joint working seem sensible, however it is unclear whether the suggested 'three or four' regulators in a new structure would be expected to work jointly on these areas or if this is also applicable to existing regulators in the current structure.

While it would make sense for all regulators to share a single set of generic standards, (underpinned by sector-specific standards), a single register could be confusing for patients. We suggest that each regulator maintains its own, clearly identifiable register, to aid direct and therefore faster resolution of any issues.

Q15. Do you agree that data sharing between healthcare regulators including systems regulators could help identify potential harm earlier?

We agree that data should be shared and used by regulators to identify problems and improve care so long as robust processes for protecting sensitive and personal data are in-place.

Q16. Do you agree that the regulatory bodies should be given greater flexibility to set their own operating procedures?

We support the principle that regulatory bodies should enjoy greater autonomy and freedom to amend their operating practices, especially in circumstances where this can mitigate potential risk to patients that might have emerged.

However, the importance of consistency across regulatory processes cannot be underestimated, if the system is to be reformed effectively, and variation in procedures should only take place when it can be demonstrated that different procedures are necessary for specific groups of healthcare professionals.

We welcome the proposal for the PSA to continue to report to Parliament, which retains overall accountability.

Q17. Do you agree that the regulatory bodies should be more accountable to the Scottish Parliament, the National Assembly for Wales and the Northern Irish Assembly, in addition to the UK Parliament?

In addition to the accountability to the UK Parliament, we would support an alignment between the powers which are devolved to the respective national Parliament or Assembly and the accountability of the respective regulatory bodies.

Q18. Do you agree that the councils of the regulatory bodies should be changed so that they comprise of both non-executive and executive members?

We have no comments in response to this question.

Q19. Do you think that the views of employers should be better reflected on the councils of the regulatory bodies, and how might this be achieved?

This seems a sensible proposal, but will require clear (formal) channels for employers to communicate with regulators about concerns and views they might have.

Q20. Should each regulatory body be asked to set out proposals about how they will ensure they produce and sustain fit to practise and fit for purpose professionals?

As per our answer to question nine, we believe that regulators have an important role to play in setting standards and to foster a culture of learning in the healthcare professions.

Q21. Should potential savings generated through the reforms be passed back as fee reductions, be invested upstream to support professionalism, or both? Are there other areas where potential savings should be reinvested?

Any savings generated through reforms should be reinvested to support research initiatives, educational grants and other activities, which underpin quality improvements in patient care. Any surplus from such activities should be passed back as fee reductions to healthcare professionals.

Q22. How will the proposed changes affect the costs or benefits for your organisation or those you represent?
- an increase
- a decrease
- stay the same

Please explain your answer and provide an estimate of impact if possible.

If the new regulatory framework results in savings from economies of scale and sharing of back office functions, then it is right that these are passed onto registrants in the form of reduced fees.

Q23. How will the proposed changes contribute to improved public protection and patient safety (health benefits) and how could this be measured?

As stated in the above responses, we envisage that the proposals would make it easier for patients to report concerns about healthcare professionals; they would standardise the way regulators operate; they would make it easier for regulators to share best practice and

improve own processes; they would lead to a reduction in operating costs; in addition a mediation service would help patients and healthcare providers to resolve disputes without the need to escalate to regulators, leading to considerable financial and manpower savings and reduced stress for healthcare professionals.

Q24. Do you think that any of the proposals would help achieve any of the following aims:

- Eliminating discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010 and Section 75(1) and (2) of the Northern Ireland Act 1998?
- Advancing equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it?
- Fostering good relations between persons who share a relevant protected characteristic and persons who do not share it?

If yes, could the proposals be changed so that they are more effective? If not, please explain what effect you think the proposals will have and whether you think the proposals should be changed so that they would help achieve those aims?

We have no comments in response to this question.

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[1] NHS Digital. *NHS Hospital & Community Health Service (HCHS) monthly workforce statistics - Provisional Statistics*. July 2017.
[2] Stats Wales. *Medical and dental staff by specialty and year.* March 2017.
[3] Information Services Division Scotland. *HSHS Medical and Dental Staff by Specialty*. December 2016.
[4] Audit Commission. *Anaesthesia under examination: The efficiency and effectiveness of anaesthesia and pain relief services in England and Wales*, National report, 1998.
[5] EMK Walker, M Bell, TM Cook, MPW Grocott, and SR Moonesinghe for the SNAP-1 investigators. Patient reported outcome of adult perioperative anaesthesia in the United Kingdom: a cross-sectional observational study. British Journal of Anaesthesia 2016
[6] Berwick, D. A promise to learn – a commitment to act. Improving the safety of patients in England. National Advisory Group on the Safety of Patients in England. 2013
[7] Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry. www.midstaffspublicinquiry.com/report . February 2013
[8] Professional Standards Authority. *Right-touch reform - a new framework for assurance of professions.* November 2017
[9] Royal College of Anaesthetists. *Response to the Department of Health's consultation on the Regulation of Medical Associate Professions in the UK.* December 2017
[10] Professional Standards Authority. *Initial evaluation of the feasibility of prohibition order schemes for unregulated health and care workers in the United Kingdom.* December 2016. https://professionalstandards.org.uk/docs/default-source/publications/feasibility-of-prohibition-order-schemes---initial-evaluation-dec-16.pdf
[11] General Medical Council. *Doctors who commit suicide while under GMC fitness to practice investigations.* GMC internal review, 2014
[12] Royal College of Anaesthetists. A report on the welfare, morale and experiences of anaesthetists in training: the need to listen. December 2017
[13] National Advisory Group on the Safety of Patients in England. *A promise to learn, a commitment to act – improving the safety of patients in England*. August 2013