

**AvMA response to the
Department of Health Consultation
'Promoting professionalism, reforming regulation'**

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Action against Medical Accidents

- 1.1 Action against Medical Accidents (AvMA) is the UK charity for patient safety and justice. Established in 1982, AvMA provides specialist support and advice to around 3,000 people each year who have been affected by lapses in patient safety. We have staff and trustees with extensive knowledge of and experience in patient safety and medico-legal matters including clinical negligence. AvMA works with government departments, health professionals, the NHS, regulatory bodies, lawyers and other patients' organisations to improve patient safety and the way injured patients and their families are treated following lapses in patient safety.
- 1.2 AvMA offers specialist services to the public, free of charge. AvMA's specialist services are its helpline, pro bono inquest service and advice and information services. Included as part of these services, is supporting patients and their families in bringing concerns to the attention of the professional regulators.

Summary

- 1.3 Whilst we consider that there are improvements that could be made to the current fragmented and inconsistent systems of professional regulation, we would be concerned if any professional group involved in the provision of a medical, clinical or other therapeutic service were not to be subject to a form of regulation, and believe that statutory regulation provides the greatest protection to patients. That is the basis on which we have responded to the specific questions below.
- 1.4 In establishing a more flexible legislative framework, it is important that this does not lead to even greater inconsistency between regulators and a lowering of professional standards overall. Any system of professional regulation should have patient protection at its core which means creating a more pro-active model which is aimed at pre-empting problems before it becomes a disciplinary issue or harm is caused. This includes the standards that are applied for entry to the register, to supporting professionals in keeping their practice up to date and in line with current best standards, as well as the early detection of professionals who are at risk of causing avoidable harm.
- 1.5 The responsibility for safe professional practice falls not just to the professional regulators, but is also the responsibility of their employing organisations in ensuring the work environment supports life-long learning and professional development, provides an environment which supports safe practice, particularly when health services are under pressure, and has a range of mechanisms in place to identify professionals who are in need of support or whose practice is potentially unsafe.
- 1.6 We were disappointed that the consultation made no reference to key elements of reform that patients, patients' organisations and others have been calling for for years. These include scrapping the 'five year rule'; introducing a right of appeal about decisions not to investigate concerns reported; availability of independent advice for members of the public in raising concerns to regulators; and clearer rules over consensual proposal. Nonetheless we have incorporated these points in our response below.

Response to the consultation 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?

The PSA has a key role at present and is well placed to advise the UK government. However, before such considerations take place, we believe serious thought needs to be given to the concept that some groups may not be subject to regulation and the risk this poses for patient safety.

Whilst the PSA is well placed to advise on professional regulation, it should not be the sole arbiter. It should be a core requirement that the PSA consults with patients and the public as well as other stakeholders in formulating any policy advice.

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?

The staged approach proposed by the PSA (paras 2.5 and 2.6) seems to us to be simplistic and problematic:

- i. The approach appears quite straight forward but we suspect the opposite is true: for example, how will 'complexity' be measured to ensure that the level of regulatory oversight given to each group is proportionate and equitable?
- ii. Regulation can bring benefits and consideration of what these might be to each group should be a factor (see if below).
- iii. There will be different levels of complexity within a specific group. For example, the outcomes from the first stage assessment would surely be different across medical specialties. Is the intention to build this into the model and does that mean that there will be different levels of regulation within a profession?
- iv. There are currently moves to develop the roles of 'medical associate professionals' such as those involved in surgical services. These are not currently regulated notwithstanding they may be undertaking tasks otherwise performed by highly regulated doctors. AvMA is strongly in support of regulation for these and other similar groups; it is not unreasonable to suggest that most patients would be both surprised and concerned to learn that this is not already the case. We raise this for two reasons: (a) risk perception should perhaps be a first-stage consideration; and (b) regulation might help achieve acceptance of and confidence in these new roles.
- v. Quite rightly, the assessment criteria focus on risk of harm. However, evidence of efficacy is also important. Protection of the public might be considered to go beyond physical harm and, when making an informed choice, patients should be able to be confident that the proposed intervention will have some therapeutic benefit.
- vi. The two-stage assessment is based on some worrying assumptions, e.g. that there may be less risk associated with activities carried out in a patient's home. We are not convinced this is the case (e.g. wound care).

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 cannot imagine a situation when doctors, nurses, midwives and dentists are not statutorily regulated, regulation being a key factor in ensuring patient safety, upholding standards and maintaining confidence in the profession. Also, as mentioned above, we are concerned about any professional group falling outside a system of statutory regulation. Therefore, any reassessment must be based on this principle.

Clarification on levels of regulation within a profession, depending on risk, would be helpful.

We note that in Scotland, social care workers (care assistants) and domiciliary care workers are also now being regulated so the Government there is increasing rather than decreasing regulation – why is their approach different? These individuals are required to uphold the same standards as qualified social workers.

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 understand how a prohibition order could work effectively if not based on a regulatory system.

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

Possibly, for the reasons set out in the paper but the arguments are not compelling. There is a real risk of valuable expertise being lost in the drive for efficiency gains and we feel strongly that any proposed reduction in the number of bodies should take this into account and militate against it. Any loss of expertise risks undermining effective regulation.

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

Advantages might be a centralised register of professionals, a common approach to the development and application of core standards, unified complaints processes, greater consistency in considering sanctions and more effective information sharing. Disadvantages might be the loss of expertise and the difficulties associated with merging regulators with different processes, for example in relation to revalidation, which presumably would have to be rationalised.

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

Possibly move some of the smaller ones into the HCPC, which will soon lose oversight of social workers in England.

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

Provided this does not in any way detract from patient safety. We are not clear about the links between the various actions/sanctions that can be taken against an individual and the assessment criteria set out earlier in the document e.g. how would the complexity of the intervention be a factor in determining the outcome in each case? Perhaps this should be a consideration.

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

In general, mediation is more applicable to trying to resolve differences between parties, e.g. complaints, rather than to assessing a fitness to practise case, where failure to meet fundamental standards is alleged and must be proven or not. In respect of an adversarial v inquisitorial approach to regulation, we were encouraged by Dame Janet Smith (Shipman report) to become more inquisitorial. Following her recommendation, conduct panels are able to ask questions at hearings, which is an important part of independent evidence gathering, but whilst some regulators regard and describe their process as inquisitorial, other regulators and legal advisers insist that it is adversarial. Greater consistency here would be helpful.

Mediation would have a place following the conclusion of fitness to practise cases, in allowing complainants to better understand the outcome, and providing an opportunity for the practitioner to explain and apologise as a measure of the practitioner's insight into their actions which will be particularly important with respect to cases disposed of by way of consensual disposal.

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

No, fitness to practise seems to us to be paramount in ensuring patient safety and upholding standards. Arguably, a robust approach to fitness to practise underpins and supports the professionalism of registrants as it demonstrates what is expected of them and the potential consequences of non-compliance. As set out in response to Qu.12, this does not mean that the PSA should not also be looking at the performance of regulators in reducing the number of cases that necessitate action under the FTP procedures through earlier intervention.

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?

Yes, PSA was set up to ensure standards and consistency, so it should retain these powers; in any event, there must be an appeal system.

With the move towards consensual disposal, there is a need to embed transparency of process and outcomes. Meetings with professionals to explore consensual disposal should be based on a pre-determined decision about what the sanction should be to avoid any form of plea bargaining. The professional will already have had every opportunity (and indeed a professional obligation) to contribute to the investigation and explain any mitigating circumstances beforehand. The result of

the meeting should either be to accept the sanction(s) consensually or progress to a formal fitness to practise hearing.

There also needs to be a right for patients and others who report concerns to appeal decisions at each stage of the process with particular reference to decisions at both the screening stage and consensual disposal. This could be in the form of an appeal to the PSA to review the decision and would act as a failsafe to ensure the rigour of investigative as well as the decision making processes. The PSA's would not have to fully investigate every appeal but would need to assess them and have the power to refer cases back for investigation. It is a major gap in the current system that there is no independent appeal mechanism at the point that a decision is made not to investigate. In terms of risk to patient safety, the risk of a potentially dangerous professional going uninvestigated with serious consequences is far greater than at the adjudication stage.

Dealing with the fitness to practise process is a very daunting process for patients or members of the public. In spite of recommendations for independent advice services to be made available to people concerning potential and actual fitness to practise cases they bring to the attention of regulators (*Trust, Assurance and Safety –the Regulation of Health Professionals in the 21st Century, 2007*), this has not been actioned. This is another important component that could help the whole system. It is ironic that NHS patients are guaranteed independent advocacy services for any complaint whether or not it concerns a risk to patient safety, but someone helping bring attention to a dangerous health professional and navigating the regulators' system does not have any funded service available to them.

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?

A fundamental tenet of the role of a regulator is to set professional standards, oversee education and training to meet those standards and then to take action where those standards are not met. So, the focus should be on ensuring that regulated professionals understand the requirements of regulation and the standards they are expected to uphold. Other areas of activity in relation to supporting professionalism might be the publication of information (e.g. codes of practice, guidance, etc.) and working with those who publish outcomes data from which others can learn and against which they can compare themselves.

Regulators should also be prepared to highlight where factors in the work environment is at danger of undermining professional standards whether it be insufficient protected time for training or the impact of resources on safe practice.

All regulators should be working towards a model of early intervention and being able to identify and support practitioners who are at risk of not meeting professional standards. By the time a practitioner appears before a FTP hearing, the damage will already have been done and patients will not have been protected.

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

Yes, so that there is appropriate standardisation (for example, of core standards and how standards are developed), sharing of good practice and collaboration where this would benefit

patients. That said there will still need to be profession or specialty-specific standards and efficiency gains/cost savings must not be at the expense of expertise built up by individual regulators. As mentioned in the consultation, the HCPC does this currently, issuing standards common to all the professions it regulates, and then individual profession-specific standards on top.

Collaboration is also important to help achieve improved joined-up care, for example from hospital to home.

A key area where collaboration is essential is at the boundary of professional groups, where individuals from one profession or workforce are taking on roles normally the preserve of another e.g. nurse practitioners and medical associate professions. AvMA has seen an increasing number of examples where the delegation of roles across professional boundaries as well as to unqualified and unregulated healthcare workers has been a key contributing factor in significant patient harm. Collaboration should extend not just between professional regulators but also with those bodies tasked with monitoring standards at the front line, with employers, and with patients whose contribution to patient safety is still not fully recognised or utilised.

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?

With respect to moving towards a model comprising a single adjudicator, it would be important to be clear about the benefits but perhaps more importantly, the potential drawbacks and risks. It is recognised that there is a need for greater consistency over process which the PSA could be tasked with overseeing. It would also be important to look at how independence and separation could be achieved. We already have separation of investigation and adjudication functions in a number of regulators e.g. MPTS, and HCPTS, and it is important to maintain the mix of lay and profession-specific panel members in hearings and other stages of the process.

An important area that should be included in the list is revalidation and extending this to all professional groups.

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

Yes, and we support the development of systems that improve or facilitate the sharing of data, particularly to help identify system problems within an organisation that pose a risk to patients.

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

Yes but only within a clearly defined framework. There is otherwise a risk of creating even greater inconsistencies between regulators, and ultimately, the professional standards that apply. There are areas of activity that would particularly benefit from being consistent across regulators e.g. the management of complaints and the support provided to patients and families.

Existing serious discrepancies between how different regulators manage fitness to practise must be addressed. In particular, the so called "five year rule" currently used by the GMC and favoured by the Department of Health in its last consultation should be scrapped. There is agreement between regulators and patients' groups that such a rule has no place in modern regulation. It runs the risk of an unfit professional wrongly escaping action by a regulator simply because of the length of time it has taken for the regulator to become aware of the problem.

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?

Yes, this makes sense.

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?

Yes.

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?

Yes. This is on the basis that employers will have a particular insight into the effectiveness or otherwise of professional regulation in terms of education and standards and to what extent this adequately equips healthcare professionals to practise safely and effectively in the workplace, as well as the effectiveness of different forms of intervention in supporting practitioners to maintain professional standards. However, it would be important that employers did not hold undue influence that might lead to a lowering of standards as a matter of expediency to meet workforce shortages.

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?

Yes. This would be a helpful exercise before any major reform of professional regulation is considered but should be done in conjunction with core input from patients and the public in order to identify priority areas.

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?

Both. Ensuring standards at the point of registration and maintaining standards through early intervention.

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.

N/A

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

The desired outcome of any reform would be a more efficient, effective, and responsive system of professional regulation but maintaining the same rigour with respect to maintaining and raising professional standards. Whether this is achieved in practice will be down in part to embedding a commitment to a rigorous application of professional standards, something that has been at risk of being eroded with the increasing use of unregulated healthcare workers within our health services. It is also having a system of professional regulation that is open and transparent with patient protection at its core which will in turn determine the main priorities within professional regulation.

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?

A robust and transparent system of professional regulation with common core standards and processes would help underpin a more equitable application of regulation across all professional groups.

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