Regulating Healthcare Professionals, Protecting the Public

June 2021

Introduction

Action against Medical Accidents (AvMA) is the national patients' charity for patient safety and justice. AvMA provides free independent specialist advice and support to patients and families who have been affected by avoidable harm in any healthcare setting. This provides us with a unique and extensive insight into the experience of patients and families following such patient safety incidents. We use this experience and our knowledge of the healthcare system to work with others to develop policies, systems and practice to improve patient safety and the way that patients and families are treated following avoidable harm.

AvMA welcomes the Government's intention to modernise health professional regulation. However in the consultation document this has largely been framed in terms of modernising legislation and making the system more flexible for the regulators. There is very little if any focus on the needs of patients and those reporting concerns. We believe that more radical changes are needed that better take on board patient safety and introduce more transparency, accountability and safeguards.

Based on the experience of AvMA's beneficiaries, AvMA has been calling for:

- The right for people who raise concerns about a health professional but where an investigation is refused or no regulatory action is taken to:
    a) appeal to the registrar of the regulatory body and have the decision reviewed; and
    b) if the registrar's decision is considered unreasonable, request the Professional Standards Authority (PSA) to review and for the PSA to have the power to challenge the decision.
- For the Professional Standards Authority to be empowered to review and challenge decisions including initial refusals to investigate up to and including accepted outcome decisions and findings of fitness to practise panels. This is an essential safeguard for protecting the public.
- Abolition of the 'Five Year Rule' operated by the GMC, or any other time-based rule making it more difficult for potentially unfit professionals to be investigated.
- Independent, specialist advice to be available to anyone who is raising a serious concern about a health professional with a regulator or considering doing so to allow them to be fully engaged and empowered in the process.
- Measures to prevent bullying of witnesses/people who raise concerns in fitness to practise hearings.

- Safeguards to ensure that cases dealt with without a formal hearing are fully transparent and can not result in 'plea bargaining'.
- Implementation of Baroness Cumberlege's recommendation in her review of medicines and devices for the GMC to maintain a register of doctors' commercial interests.
- Inclusion of a registrants indemnity arrangements on the professional register.

Response to Consultation Questions

1. Do you agree or disagree that regulators should be under a duty to co-operate with the organisations set out above? Please give a reason for your answer.

Agree.

There is a need for considerably more detail in terms of what this cooperation will look like in practice for it to be meaningful. There needs to be further discussion and consultation to establish templates for engagement and cooperation with specific duties set out within that. This cooperation and joint working will be essential to ensure there is sharing of learning and consistency across regulators. The risk otherwise is that instead of creating greater consistency, we will end up with a far more complex and fragmented system of regulation.

2. Do you agree or disagree that regulators should have an objective to be transparent when carrying out their functions and these related duties? Please give a reason for your answer.

Agree with an important caveat.

There is insufficient information to determine whether the suggested approach would go anywhere near far enough to prevent the type of problems seen with respect to regulation in the past or to avoid transparency being little more than 'window-dressing'. There is also the risk that organisations will see this as 'ticking the box' for transparency whereas there is an equal if not greater need for transparency when it comes to key areas such as fitness to practise and the decision-making process.

3. Do you agree or disagree that regulators should be required to assess the impact of proposed changes to their rules, processes and systems before they are introduced?

Please give a reason for your answer

Agree.

The changes proposed in the consultation will represent a significant change in approach for many of the regulators. That level of change will inevitably bring with it very significant risks of things going wrong, particularly with respect to fitness to practise, the proposals representing a fundamentally different approach. That type of wholesale change represents a considerable risk as well as the expenditure of enormous

resources and time to potentially reinvent the wheel many times over with varying degrees of success and failure by the individual regulators. This is also likely to place a considerable burden on patients' groups if they are to have a meaningful voice in the process, particularly if they find they are having to respond in a concentrated period of time to multiple regulators. This needs to be factored in.

The other key concern is that whilst the consultation suggests that one of the key aims is to create greater consistency across the regulators, the proposed changes around freeing up regulators to create and adopt their own rules is at the same time likely to create far greater inconsistencies.

We are in support of regulators having the flexibility to allow them to adapt to a changing external world but there have to be safeguards to ensure the end result does not create a fragmented and inconsistent approach to professional regulation.
If regulators are going to be able to amend their own rules, there should be limits set on that with a requirement to consult publicly. The PSA should be empowered to challenge any change considered inappropriate or if it would cause too much inconsistency.

4. Do you agree or disagree with the proposal for the constitution on appointment arrangements to the Board of the regulators? Please give a reason for your answer.

Agree.

5. Do you agree or disagree that regulators should be able to set their own fees in rules without Privy Council approval? Please give a reason for your answer

Agree but there should be appropriate safeguards in place to protect the interests of individual registrants and the professions and that it should not act as an artificial barrier to registration.

6. Do you agree or disagree that regulators should be able to set a longer-term approach to fees? Please give a reason for your answer.

Agree but see response to Qu.5.

7. Do you agree or disagree that regulators should be able to establish their own committees rather than this being set out in legislation? Please give a reason for your answer.

Agree but with the caveat that as with some of the other proposals, this is yet another area where we are likely to see greater inconsistencies between the various regulators. AvMA recognises that a 'one size fits all' approach is not necessarily appropriate given the varying needs of the different regulators but there is also a need for some core consistencies to avoid increasing divergence in operation.

8. Do you agree or disagree that regulators should be able to charge for services undertaken on a cost recovery basis, and that this should extend to services undertaken outside of the geographical region in which they normally operate? Please give a reason for your answers.

Agree but with a caveat. This is primarily a question for the organisations concerned but it would be important to ensure that this does not place an undue burden on those organisations and in so doing impact on their continuing viability or create unfair competition.

9. Do you agree or disagree that regulators should have the power to delegate the performance of a function to a third party including another regulator? Please give a reason for your answer.

Agree but with a caveat. There are potential risks in terms of quality but also in terms of accountability. Accountability must always remain entirely with the regulator. There needs to be some additional controls, safeguards and external oversight built in.

10. Do you agree or disagree that regulators should be able to require data from and share data with those groups listed above? Please give a reason for your answer.

Agree. In addition, a body such as the Professional Standards Authority should in its position of being responsible for oversight of professional regulation, be able to require disclosure of information in order to fulfil its duties.

11. Do you agree or disagree that regulators should produce an annual report to the Parliament of each UK country in which it operates? Please give a reason for your answer.

Agree.

12. Do you agree or disagree that the Privy Council's default powers should apply to the GDC and GPhC? Please give a reason for your answer.

Agree. This will ensure greater consistency across regulators but in the context of the very significant changes to professional regulation proposed in the consultation, is a relatively minor change in terms of creating greater consistency given the proposed freedom that regulators will have in other areas.

13. Do you agree or disagree that all regulators should have the power to set:

- *standards for the outcomes of education and training which leads to registration or annotation of the register for individual learners;*

  Agree.

- *standards for providers who deliver courses or programmes of training which lead to registration;*

  Agree.

- *standards for specific courses or programmes of training which lead to registration;*

  Agree.

- *additional standards for providers who deliver post-registration courses of programmes of training which lead to annotation of the register; and*
- *additional standards for specific courses or programmes of training which lead to annotation of the register?*

  Agree.

Please give a reason for your answer.

It is essential that the public can be assured that all registrants have met consistent core standards of education and training and that the information on the relevant register is accurate, clear, and transparent and provides the public with sufficient information to make an informed choice where relevant.

There are some significant gaps in relation to professional regulation as it stands currently. With the development of new healthcare roles, there is an increasing issue with respect to patients not always being able to identify who is treating them and what qualifications and training that individual might possess. This can be important for example in the context of decisions about whether the patient might need or want to escalate concerns if they are unsure about the advice or treatment given by the healthcare worker. This has become more of an issue over recent decades with a multitude of new roles having been developed and as a result it is often very difficult for patients to know whether they can be assured that the person treating them has the appropriate knowledge and skills required. From the evidence that AvMA sees from cases, the blurring of professional roles can sometimes present a real and significant risk to patient safety if there are not clear professional boundaries in place and a recognition of the significant gaps in terms of knowledge and skills this might represent.

One example is that of advanced nurse practitioners as well as a multitude of other enhanced roles where there currently appears to be a lack of consistent benchmark standards for education and training. It is also the case that these roles are sometimes allowed to fall outside of normal management structures within healthcare organisations. This means that whilst in practice they are often performing roles that might normally be the preserve of a doctor and come under consultant control, doctors can sometimes be reluctant to interfere with the management of nurses resulting in inadequate supervision and potentially unsafe practice. This can often relate to the culture of the individual organisation. The NMC should be strongly encouraged to work

with the GMC to set benchmark standards for education and training as well as the boundaries for those roles and for these enhanced roles to be included on the NMC register. We have already witnessed the slippage with respect to the role of healthcare assistants and tasks and roles being delegated for which they do not have adequate education or training. As indicated, this can be a significant risk to patient safety, particularly if the patient and their family is unaware of who is treating them. This is also in the context that there are often pressures on employing organisations to replace professionals with 'cheaper' alternatives. This is not to say that these enhanced roles should not exist but that they should be subject to appropriate and transparent regulation. This is why AvMA welcomes the regulation of Medical Assistants and Anaesthetic Assistants by the GMC.

14. Do you agree or disagree that all regulators should have the power to approve, refuse, re-approve and withdraw approval of education and training providers, qualifications, courses or programmes of training which lead to registration or annotation of the register? Please give a reason for your answer.

Agree. It is essential that education and training programmes are quality controlled and fit for purpose.

15. Do you agree that all regulators should have the power to issue warnings and impose conditions? Please give a reason for your answer.

Agree.

16. Do you agree or disagree with the proposal that education and training providers have a right to submit observations and that this should be taken into account in the decision-making process? Please provide a reason for your answer.

Agree.

17. Do you agree that:

- *education and training providers should have the right to appeal approval decisions;*
- *that this appeal right should not apply when conditions are attached to an approval;*
- *that regulators should be required to set out the grounds for appeals and appeals processes in rules? Please provide a reason for your answer.*

Agree.

Education and training providers should have a right of appeal and the regulators should set out the grounds for appeal. However there needs to be some protections to prevent appeals becoming all-consuming for the regulators, particularly for the smaller less well-resourced ones. It is not clear why the right of appeal should not apply to conditions but this is primarily a matter for education and training providers to address.

18. Do you agree or disagree that regulators should retain all existing approval and standard setting powers? Please provide a reason for your answer.

Agree. Regulators should retain existing powers.

19. Do you agree or disagree that all regulators should have the power to set and administer exams or other assessments for applications to join the register or to have annotations on the register? Please provide a reason for your answer.

Agree. All regulators should have the powers to set and administer exams and assessments where this is deemed necessary for public protection and maintaining standards.

In most situations, you would expect that the exams and assessments set by the education and training providers would negate the need for additional assessments. However allowing regulators to set their own assessments would provide an additional safeguard in circumstances where there were concerns with respect to the external assessment process. The imposition of additional assessments needs to be proportionate but with patient safety as a core principle. It is about ensuring that all registrants can demonstrate that they have the education and training that will allow them to practise safely and competently within their chosen profession and that patients and the public can be assured that the individual treating them meets those requirements.

20. Do you agree or disagree that this power to set and administer exams or other assessments should not apply to approved courses or programmes of training which lead to registration or annotation of the register? Please provide a reason for your answer.

Neither agree nor disagree. See response to Qu.19. It may not always be possible to predict when the need for this power might arise but if a regulator identifies that an additional assessment or exam is necessary in order to protect patients and the public, then that power should be available to them but exercised judiciously.

21. Do you agree or disagree that regulators should be able to assess education and training providers, courses or programmes of training conducted in a range of ways? Please provide a reason for your answer.

Agree with some caveats. We can see both benefits and potential drawbacks to allowing more flexibility in the assessment process for education and training providers and courses. This is one of the essential roles of a regulator and as with any assessment process caution needs to be exercised to ensure it does not become a 'tick-box' exercise that fails to assure standards. For both the regulators and the organisations subject to assessment, there is room for joint working to ease the burden of regulation whilst assuring standards.

22. Do you agree or disagree that the GMC's duty to award CCTs should be replaced with a power to make rules setting out the procedure in relation to, and evidence required in support of, CCTs? Please give a reason for your answer.

Neither agree or disagree. It was not clear exactly what the question was asking or the intended outcome of the proposal.

23. Do you agree or disagree that regulators should be able to set out in rules and guidance their CPD and revalidation requirements? Please give a reason for your answer.

Agree. However evidence including arising from fitness to practise cases would indicate that there are problems with the current systems of revalidation and CPD in terms of their effectiveness in assuring standards of professional practice. There is room for greater oversight of the revalidation process as well as sharing of best practice across regulators. Where a practitioner is removed from the register following FTP proceedings, it would be helpful to examine whether there might have been opportunities to identify concerns at an earlier stage and whether a different approach to revalidation might have captured those concerns before they became a FTP issue. This should be one of the core aims of revalidation.

24. Do you agree or disagree that the regulators should hold a single register which can be divided into parts for each profession they regulate? Please give a reason for your answer.

Neither agree nor disagree. It is unclear what the implications of this change would be but if it would provide greater consistency as well as more flexibility to be able to add additional professional groups to the register, then it appears to provide a pragmatic solution. From a patients' perspective it is about clarity and the ability to easily find and confirm the qualifications and training that an individual healthcare professional holds.

25. Do you agree or disagree that all regulators should be required to publish the following information about their registrants:

- *Name*
- *Profession*
- *Qualification (this will only be published if the regulator holds this information. For historical reasons not all regulators hold this information about all of their registrants)*
- *Registration number or personal identification number (PIN)*
- *Registration status (any measures in relation to fitness to practise on a registrant's registration should be published in accordance with the rules/policy made by a regulator)*
- *Registration history*

Please provide a reason for your answer.

Agree.

There is some additional information that we believe should be included.
The first includes details of a registrant's indemnity arrangements. AvMA continues to see examples where harmed patients have been unable to obtain redress because it has not been possible to identify the practitioner's professional indemnity provider. Unless this information is held centrally on the register, the professional requirement to have indemnity cover can prove to be meaningless.

The second is to include details of commercial interests. In Baroness Cumberlege's report on the Independent Medicines and Medical Devices Safety Review, the following recommendation was made:

'We believe that the GMC should expand the List of Registered Medical Practitioners to include financial and non-pecuniary interests. The Department of Health and Social Care (DHSC) should address any legislative barriers to these changes. (Chapter 1, Recommendation 8)'. The report of the IMMDS Review

26. Do you agree or disagree that all regulators, in line with their statutory objectives, should be given a power allowing them to collect, hold and process data? Please give a reason for your answer.

Agree.

27. Should they be given a discretionary power allowing them to publish specific data about their registrants? Please give a reason for your answer.

Agree. As indicated above, where held, indemnity arrangements and commercial interests should be included as a matter of course for all registrants.

28. Do you agree or disagree that all regulators should be able to annotate their register and that annotations should only be made where they are necessary for the purpose of public protection? Please give a reason for your answer.

Agree that regulators should be able to annotate their register. It is important that the annotations are accurate, verified and easily understood by the public.

There can be an issue around a registrant's specialist status if they have not worked in that field for many years and may therefore not in fact be currently fit or equipped to practise in that particular field.

It is unclear what is intended with respect to the phrase that annotations 'should only be made where they are necessary for the purpose of public protection'. That does depend on how 'public protection' is interpreted in practice and how the benchmark is set.

29. Do you agree or disagree that all of the regulators should be given a permanent emergency registration power as set out above? Please give a reason for your answer.
Neither agree or disagree. Generally we would agree but before any decision is made on this, it would be essential to examine the evidence arising from the emergency powers utilised under Covid so that any lessons can be learnt. This includes any harm that may have arisen, how best to implement emergency powers in the future and how to establish and set exclusions from temporary re-registration. There should also be independent oversight whenever a regulator is looking to use these powers.

30. Do you agree or disagree that all regulators should have the same offences in relation to protection of title and registration within their governing legislation?

Agree. As indicated above, there is a separate but related issue about transparency more generally and patients knowing who is treating them, the type of professional qualifications that the healthcare professional holds, and the training that they will have undertaken. For example, a patient might believe they are being treated by a doctor, but it is in fact a healthcare assistant, or they may seek advice at a pharmacy and not be aware that they are talking to a pharmacy assistant. There is always a risk that some individuals will overstep the boundaries of their role and patients and the public need to be protected. All healthcare workers and healthcare professionals should be required to be absolutely clear with patients about their role to avoid patients being misled.

31. Do you agree or disagree that the protection of title offences should be intent offences or do you think some offences should be non-intent offences (these are offences where an intent to commit the offence does not have to be proven or demonstrated)? Please give a reason for your answer.

Neither agree or disagree. In most instances, intent should be the benchmark but it is possible to envisage situations where someone has prepared the ground sufficiently to avoid intent being established in order to evade prosecution.

32. Do you agree or disagree with our proposal that regulators should be able to appoint a deputy registrar and/or assistant registrar, where this power does not already exist? Please give a reason for your answer.

Agree. This would allow regulators to be more pro-active and avoid unnecessary delays but there needs to be clear lines of accountability.

33. Do you agree or disagree with our proposal that regulators should be able to set out their registration processes in rules and guidance? Please give a reason for your answer.

Neither agree or disagree. Whilst in principle we agree with the proposal, there is the underlying concern that allowing regulators more freedom to set their own rules could well result in far greater inconsistencies between regulators as opposed to the intended purpose as out in the consultation to create more consistency. The risk is that it will become far more complex for patients and the public to navigate the system of

professional regulation as well as for employers. These stakeholders have an essential role to play in helping to assure standards by bringing poor practice to the attention of the regulator. Sometimes it is more complicated to navigate a system which is similar to other systems but is also subtly different in the detail.

34. Should all registrars be given a discretion to turn down an applicant for registration or should applicants be only turned down because they have failed to meet the new criteria for registration? Please give a reason for your answer.

We believe that all registrars should be given the discretion to turn down an applicant for registration. It is possible to envisage situations where an applicant appears on paper to meet the requirements for registration but there are specific factors that make them unfit to be entered onto the register. There needs to be an adequate appeals system in place to ensure fairness in the application of this power.

35. Do you agree or disagree that the GMC's provisions relating to the licence to practise should be removed from primary legislation and that any requirements to hold a licence to practise and the procedure for granting or refusing a licence to practise should instead be set out in rules and guidance? Please give a reason for your answer.

Neither agree or disagree. We are unclear as to the meaning of this question or the intended outcomes.

36. Do you agree or disagree that in specific circumstances regulators should be able to suspend registrants from their registers rather than remove them? Please give a reason for your answer.

Agree. A lack of cooperation could in itself act as a warning sign but there may also be mitigating factors as to why a registrant has failed to cooperate or respond. Removal may sometimes present too high a bar for a regulator to take swift action and the power to suspend would provide a timely interim safeguard until such time as the matter can be more fully investigated. Registrants have a right to be treated fairly and equitably but the safety of patients and the public is paramount.

37. Do you agree or disagree that the regulators should be able to set out their removal and readmittance processes to the register for administrative reasons in rules, rather than having these set out in primary legislation? Please give a reason for your answer.

Neither agree or disagree. This is an important issue and one where there does need to be consistency across the regulators. Given that there are some fairly fundamental changes being proposed to regulation, the regulators are going to be facing a very considerable workload over the coming years. There is a real risk that if regulators are left to develop their own rules on some of these important issues, they may fail to recognise and address the potential pitfalls.

For some of these key areas, we would lean more towards legislation and making sure that we are incorporating learning from regulators who have already experienced and

dealt with some of the pitfalls that can arise. For example, registrants who might try to avoid FTP proceedings by removing themselves from a register only to seek re-registration at a later date.

38. Do you think any additional appealable decisions should be included within legislation? Please give a reason for your answer.

Neither agree or disagree. This is really a matter for the regulators and professional bodies based on the issues that may have been identified or experienced under current arrangements.

39. Do you agree or disagree that regulators should set out their registration appeals procedures in rules or should these be set out in their governing legislation? Please give a reason for your answer.

Neither agree or disagree. The need for consistency across regulators would suggest the need for a legislative framework with some limited flexibility for regulators to adapt as required.

40. Do you agree or disagree with our proposal that the regulators should not have discretionary powers to establish student registers? Please give a reason for your answer.

Agree. However, this is on the basis that there are and will continue to be effective processes in place to prevent those identified as unfit to practise from entering the profession. Students who have patient contact should always be bound by equivalent professional standards whether or not they are on a 'register' and the educational institutions should adjudge them on that basis. There need to be robust systems in place and that should form part of a regulator's assessment of providers of education and training.

41. Do you agree or disagree with our proposal that the regulators should not have discretionary powers to establish non-practising registers? Please give a reason for your answer.

Neither agree or disagree. We would generally agree but it is unclear what effect this proposal would have in relation to the GMC and its dual system of licenced and unlicensed practitioners.

42. Do you agree or disagree that the prescriptive detail on international registration requirements should be removed from legislation? Please give a reason for your answer.

Agree with the caveat that there are adequate safeguards in place and that there is oversight of those safeguards. The primary concern is ensuring that international registrants are safe to practise and that their training and experience will equip them to

work safely in the UK to an equivalent standard. Regulation in the context of membership of the EU highlighted significant issues around a lack of equivalence across the EU in relation to the standards of education and training required for entry to professional registers. It is therefore important that we maintain a robust system for vetting entry to the UK registers.

43. Do you agree or disagree with our proposal that regulators should be given powers to operate a three-step fitness to practise process, covering:

- *1: initial assessment*
- *2: case examiner stage*
- *3: fitness to practise panel stage?*
  Please give a reason for your answer.

Agree but with some significant caveats.

There is very little detail attached to the proposals, particularly with respect to the initial assessment stage. The detail of how these various stages will work is critical including the initial assessment because this is where failings in FTP procedures so often arise.

Whilst the document makes frequent references to reducing the burden on patients and the public with respect to FTP, what is of far more importance to patients and their families is the quality of the investigations undertaken and the cogency of the outcome. There needs to be far more detailed consideration around the initial assessment stage including what would be required in order to constitute a robust investigation, how it will be conducted, how decisions will be made, and how patients and families will be engaged and supported in that process. This is critical to creating an effective FTP process. There has been repeated evidence from the various enquiries into healthcare scandals of significant failures during the screening and initial assessment stages of FTP cases.

With respect to the case examiner stage, whilst AvMA welcomes the ability for cases to be dealt with more swiftly, this should not be at the expense of excluding patients and families from the process. AvMA has expressed concerns around the FTP procedures operated by the GMC and the need for greater transparency with repect to the decision making process. There have been continued assurances that 'plea bargaining' will not take place but in reality, there will be pressures on case examiners to identify outcomes that are more likely to be accepted and which will bring a case to a conclusion, creating in effect an 'internalised' form of plea bargaining.

AvMA has seen an example of a letter to a family from the GMC closing a FTP investigation which could easily have been misinterpreted as having been written by the registrant's medical defence organisation. The clinician who advised the patient to complain was equally concerned about the outcome. This example highlighted the risk that case examiners can be overly mindful of potential legal arguments in defence of a FTP allegation such that cases are either not pursued or the outcome is insufficent to protect patients. This is why it is essential that there is independent oversight of FTP decisions at both the initial assessment and case examiner stages.

44. Do you agree or disagree that:

- *All regulators should be provided with two grounds for action – lack of competence, and misconduct?*
- *Lack of competence and misconduct are the most appropriate terminology for these grounds for action?*
- *Any separate grounds for action relating to health and English language should be removed from the legislation, and concerns of this kind investigated under the ground of lack of competence?*
- *This proposal provides sufficient scope for regulators to investigate concerns about registrants and ensure public protection?*

Please give a reason for your answers.

Disagree. With respect to restricting regulators to two grounds for action, lack of competence and misconduct, we would be concerned that this could potentially limit a regulator's powers to take action in cases which might otherwise fall short of FTP and therefore leave a gap in public protection.

With respect to English language which was identified as a significant problem whilst the UK was a member of the EU and the inability of UK regulators to gatekeep entry to the register, removing this ground from legislation would appear to limit the powers of regulators to intervene in a proactive way and potentially allow remedial action to be taken.

As presently proposed we do not believe the proposal provides sufficient scope for regulators to investigate concerns about registrants.

45. Do you agree or disagree that:

- *all measures (warnings, conditions, suspension orders and removal orders) should be made available to both Case Examiners and Fitness to Practise panels; and*
- *automatic removal orders should be made available to a regulator following conviction for a listed offence?*

Please give a reason for your answers.

We agree that all measures should be available to case examiners and FTP panels. Further consideration and consultation is required with respect to the nature of the outcomes available to regulators to ensure the bar for imposing measures is not set too high such that the regulator is unable to protect patients and the public.

Further consideration should be given as to whether additional measures should be made available to case examiners and FTP panels. This would be to allow for situations where the actions of the registrant may not meet the threshold for action based on the current suite of measures but taking no action at all may not fully protect the public. This might for example include recommendations with respect to further training,

additional supervision, a subsequent review or other such remedial action as to ensure the registrant remains fit to practise. In all cases, the registrant would need to demonstrate insight into any failings. However, alternative measures should never replace formal action where this is the appropriate outcome.

46. Do you agree or disagree with the proposed powers for reviewing measures? Please give a reason for your answer.

Agree but this does require more detailed consideration. There is a risk of registrants being able to 'game' the system. That will need to be addressed not least because any attempts to circumvent the outcome of a FTP investigation could well suggest a lack of insight on the part of the registrant.

47. Do you agree or disagree with our proposal on notification provisions, including the duty to keep the person(s) who raised the concern informed at key points during the fitness to practise process? Please give a reason for your answer.

Agree with a significant caveat.

Other than the potential to reduce delays and the perceived burden of public hearings, the consultation is noticeably silent with respect to the potential drawbacks of the proposals for patients and the public and provides little in the way of other benefits.
The duty to keep person(s) who raised the concern informed is welcome but this does not go anywhere near far enough. Those reporting concerns should have the right to be fully engaged in the process. This is particularly important where an individual patient or their family is central to the matter giving rise to the FTP investigation. This includes having the right and opportunity to respond to evidence, for example, if the registrant produces information that may counteract the evidence of the patient or their family. It is wholly insufficient to inform the patient or their family after key decisions have already been made. The proposals as currently drafted would potentially further marginalise patients and the public within the FTP process.

48. Do you agree or disagree with our proposal that regulators should have discretion to decide whether to investigate, and if so, how best to investigate a fitness to practise concern? Please give a reason for your answer.

Agree in principle assuming this will give regulators greater powers to exercise discretion in order to investigate as opposed to a wider discretion not to investigate.
As indicated previously, the detail of how cases will be triaged and investigated at that initial stage is critical. This is where failures in FTP procedures so often arise. That initial assessment process requires the application of both knowledge and forensic skills.

A particular area where we would like to see regulators exercise their discretion to investigate is in situations where a formal complaint has not been made but information comes to the attention of the regulator which indicates concerns with respect to FTP. We have encountered situations in the past where a regulator has had access to adverse

information about a registrant but has refused to act in the absence of a formal complaint.

49. Do you agree or disagree that the current restrictions on regulators being able to consider concerns more than five years after they came to light should be removed? Please give a reason for your answer.

Strongly Agree. AvMA has long campaigned for the removal of the five-year rule. There has been a whole raft of healthcare enquiries over recent years demonstrating how it can sometimes take a decade or more before concerns come to light and where regulatory action would still be warranted for public protection. Public protection should be the paramount concern of regulators and arbitrary time limits or bureaucratic obstacles such as this are neither helpful or necessary. Our understanding is that the regulators themselves agree with this.

50. Do you think that regulators should be provided with a separate power to address non-compliance, or should non-compliance be managed using existing powers such as "adverse inferences"? Please give a reason for your answer.

We believe that regulators should be provided with separate powers enabling them to address non-compliance. This would allow regulators to act more quickly to protect the public, particularly in situations where non-compliance might be indicative of underlying FTP concerns.

51. Do you agree or disagree with our proposed approach for onward referral of a case at the end of the initial assessment stage? Please give a reason for your answer.

Neither agree or disagree. There is insufficient detail in relation to how the process would work in practice in order to respond in a meaningful way.

It is noted that the registrant can provide written submissions, but the consultation is silent with respect to the original complainant being able to submit further evidence in response or to supplement their original complaint. Those reporting concerns should be given far more rights within the process including seeing and being able to respond to information provided by the registrant concerning the concerns / allegations that were made. This is an important safeguard.

52. Do you agree or disagree with our proposal that regulators should be given a new power to automatically remove a registrant from the Register, if they have been convicted of a listed offence, in line with the powers set out in the Social Workers Regulations? Please give a reason for your answer.

Agree. The nature of these offences is such that regulators need to be able to act swiftly. It also sends a clear message to registrants and the public.

53. **Do you agree or disagree with our proposals that case examiners should:**

- *have the full suite of measures available to them, including removal from the register?*

Agree

- *make final decisions on impairment if they have sufficient written evidence and the registrant has had the opportunity to make representations?*

Agree but as set out above, AvMA is concerned that the document is silent with respect to engagement with the complainant at this and other stages in the FTP process other than informing them after decisions have already been taken.

We strongly believe that those reporting concerns should be given more rights within the process including the right and opportunity to challenge information which may run contrary to the evidence they have provided. This would apply to anyone reporting concerns to a regulator.

- *be able to conclude such a case through an accepted outcome, where the registrant must accept both the finding of impairment and the proposed measure?*

Agree but the document is silent with respect to engagement with the complainant at this and other stages in the FTP process other than a duty to inform them after decisions have already been taken.

In all cases, the proposed measure and any outcome or sanction should be decided by the regulator (case examiner) before it is presented to the registrant. There should be no room for negotiation. If the registrant disagrees with the outcome, the case should be referred to a FTP panel.

Case examiners always need to be aware of the risks of pre-judging how a registrant and their representative might respond to any proposed outcome measure and not allow this to in any way influence their decision making. There are going to be pressures on case examiners to recommend outcomes that are more likely to avoid a case going forward to a FTP panel. This is why it is important that these decisions are subject to independent scrutiny.

It is important that those reporting concerns should have the ability to challenge decisions made both at the initial assessment stage as well as the case examiner stage. This is an important part of the checks and balances that the various reports on professional regulation have highlighted and are so often missing resulting in concerns being dismissed or the FTP outcome being inadequate to protect the public.

- *be able to impose a decision if a registrant does not respond to an accepted outcomes proposal within 28 days?*

Agree.

54. Do you agree or disagree with our proposed powers for Interim Measures, set out above? Please give a reason for your answer.

Agree.

55. Do you agree or disagree that regulators should be able to determine in rules the details of how the Fitness to Practise panel stage operates? Please give a reason for your answer.

Agree but with the caveat that as indicated elsewhere there is a real risk that allowing regulators too much flexibility to determine their own rules could lead to far more inconsistencies overall and make it even more difficult for patients, families and others reporting concerns, to navigate FTP procedures.

There should be a duty on regulators to consult publicly on any proposed rule changes and for the PSA to be able to challenge the regulator where those changes are considered inappropriate or would cause too much inconsistency.

The move to resolving the majority of cases at the case examiner stage will mean that individual regulators will have far less experience of dealing with cases at the FTP panel stage. This is an area where it would be important for regulators to cooperate and share learning.

56. Do you agree or disagree that a registrant should have a right of appeal against a decision by a case examiner, Fitness to Practise panel or Interim Measures panel? Please give a reason for your answer.

Agree. But this must be accompanied by the ability of patients and anyone reporting concerns, to also be able to challenge decisions.

The current proposal that a request can be made to the registrar is on its own wholly inadequate for ensuring FTP cases do not slip through the net and unsafe practitioners allowed to continue practising. The example of Morecambe Bay demonstrates how important it is to have an effective and robust system to allow patients and others reporting concerns to challenge key decisions during Stage 1 and Stage 2 of the FTP process. An effective appeals system is an essential safeguard.

The current proposal for the basis on which a registrar may review a decision is far too narrow and does not provide adequate protections. The ability to challenge decisions is a very important quality control tool both in terms of testing the operation of the procedures as well as the quality of decision making. It is also an important way of encouraging best practice by regulators. A request for a review by a patient should be weighted in favour of a review being undertaken. The current proposals as drafted appear to suggest that reviews will be the exception.

Subject to the outcome of the registrar's review, there should be the right to appeal to an independent body. The Professional Standards Authority (or a body adjacent to the

PSA) would be the most obvious choice to undertake reviews of decisions by a registrar including a refusal to review a FTP decision whether at the initial screening stage or subsequently. There should be an option for the PSA to refer a matter back to the regulator without the need for recourse to the courts where this can be avoided. The PSA should be able to ask the regulator to change its decision and if the regulator disagrees, to then challenge it in court. Over time, it would be anticipated that the learning from reviews and challenges by the PSA would result in fewer cases needing to be subject to review once that learning has been incorporated into the operation of the FTP procedures.

57. Should this be a right of appeal to the High Court in England and Wales, the Court of Session in Scotland, or the High Court in Northern Ireland? Please give a reason for your answer.

Agree but the cost of appeals to the courts could potentially act as an inhibitive factor both for registrants as well as regulators. There is a question of whether there could be an alternative option prior to having to resort to the courts but retaining the right of appeal to the courts.

58. Do you agree or disagree that regulators should be able to set out in Rules their own restoration to the register processes in relation to fitness to practise cases? Please give a reason for your answer.

Neither agree or disagree.

Erasure from the register is a serious matter and so restoration should be treated with equal gravity. There has been evidence in the past of registrants 'gaming' the system and removing themselves from a professional register to avoid a FTP finding only to reapply for restoration at a later date. It is essential that we learn from past FTP cases to ensure that the same mistakes are not repeated and the same loopholes not exploited. Given the importance of this issue, this is a matter that requires consistency across the regulators and should not be left to individual regulators to determine. The risk is that it could create an open door for abuse by registrants, particularly in the context that these are practitioners who have already been removed from the register. It is important that there is the possibility of redemption for registrants but any process has to be exercised with great caution and independent oversight.

59. Do you agree or disagree that a registrant should have a further onward right of appeal against a decision not to permit restoration to the register? Please give a reason for your answer.

The most straightforward approach would be for all requests for restoration to the register to be considered by a FTP panel. The registrant would then have recourse to the courts if appropriate.

60. Should this be a right of appeal to the High Court in England and Wales, the Court of Session in Scotland, or the High Court in Northern Ireland? Please give a reason for your answer.

Yes.

61. Do you agree or disagree that the proposed Registrar Review power provides sufficient oversight of decisions made by case examiners (including accepted outcome decisions) to protect the public? Please provide any reasons for your answer.

Strongly disagree. As set out above, we do not believe the Registrar Review power provides sufficient oversight of decisions by case examiners to protect patients and the public. Firstly, this should not just be a power but a duty for registrars to review decisions when they are challenged, for example by the person who has raised a concern. An effective system of independent review of FTP decisions at each stage is an essential method of both ensuring the robustness of FTP procedures as well as overall accountability of the regulators.

In addition to having a registrar review duty, AvMA has consistently advocated for an independent appeals process for anyone raising concerns with a regulator's decision, following a registrar review. An effective appeals system is not just important in terms of the individual case but is also an important method for checking the robustness of a regulators FTP procedures and their operation. This is particularly important at the stage of decisions to investigate or not, and at the stage of accepted outcomes decisions, as this is where the greatest risks exist for the public of the regulator getting the decision wrong and a dangerous health professional being allowed to practise when they are unfit to. There have been numerous examples where regulators have failed to take appropriate action to protect the public as a result of failures in the operation of their FTP procedures. Having a robust system for challenging decisions would provide an important safeguard.

This is also in the context that the proposals would represent a very significant change in approach to FTP for many of the regulators with all the inherent risks of operating a new system. There are already significant concerns around the transparency of decision making with existing procedures operated by some regulators and the inclusion or more often exclusion of patients in that process. In the absence of a public hearing, access to an independent review / appeals process would help to ensure more robust investigations and decision-making processes at all stages.

There was a long history of concerns that ultimately led to the recommendation that FTP decisions should be made by independent panels. The proposals would represent a complete reversal, with the majority of decisions being made internally by the regulator. This is another reason why independent oversight of those decisions is essential. The risk otherwise is that the operation of FTP procedures will revert and reintroduce all the problems seen in the past.

In summary, we believe that the Professional Standards Authority, should be empowered to review and challenge decisions including initial refusals to investigate up

to and including accepted outcome decisions and findings of fitness to practise panels. This is an essential safeguard for protecting the public. The reporter of a concern should be able to request a review by the PSA. The form that this power should take will need to be considered in some detail, but it should be noted that the PSA's regulations already allow for such a role, but this has not yet been enacted. Where a patient believes a regulator has failed to take appropriate action and the registrar has refused a review or has not overturned the decision, the PSA should be empowered to review and challenge those decisions. There needs to be a number of options open to the PSA short of having to resort to the courts in all cases. If the registrar has used its power (duty) to review decisions and provided the rationale for their final decision, relatively few people would have to recourse to the PSA. The PSA would screen such requests and have discretion as to when they challenge a decision and how, so this need not be a resource intensive or expensive function, but would provide important safeguards and improve public confidence in the system.

62. Under our proposals, the PSA will not have a right to refer decisions made by case examiners (including accepted outcome decisions) to court, but they will have the right to request a registrar review as detailed above. Do you agree or disagree with this proposed mechanism? Please provide any reasons for your answer.

Strongly Disagree. As set out in response to Qu.61, we believe the Professional Standards Authority should be empowered to review and challenge decisions made by the regulators at all stages of the FTP process. Simply recommending a registrar to review decisions is woefully inadequate.

63. Do you have any further comments on our proposed model for fitness to practise?

1. Patients and families are a vitally important source of intelligence about health professionals who may be unfit or pose a risk. They are not given anywhere near as much attention in the current system or in the proposed changes so far. The FTP system is bewildering and daunting to most members of the public. It is important that patients and families have access to specialist independent advice to enable them to be active participants in the process, to help them present their evidence in the most cogent way, and to challenge decisions made by regulators. This need was clearly identified and was the subject of a specific recommendation to provide funding for such independent specialist advice stemming from the last major review of health professional regulation in 2009 but has never been acted upon. Nor has an explanation been given for the failure to address this gap. We strongly recommend that the opportunity to address this is taken now. See below for details:

   "Recommendation 2: We recommend that the Department should take forward with the national regulators and with NHS bodies, and in consultation with patient and professional groups, the further steps needed to support patients and colleagues in raising concerns about a healthcare professional as identified by the clinical governance subgroup. This will include confidential advice and clearer signposting for those considering raising a concern; support in articulating the concern, including advocacy support for vulnerable people; and support as the concern is progressed,

for instance for people invited to give evidence at disciplinary hearings [para 3.11, para 8.12]. In the particular case of concerns relating to doctors which have been referred to the GMC for consideration, the GMC affiliates might have a particular role in liaising with the patient or carer raising the concern and ensuring that they have access to appropriate support."

['Tackling Concerns Locally': Report of the Working Group re: Trust Assurance and Safety: the Regulation of Health Professionals in the 21st century", Department of Health, 2007].

For full report see:
https://webarchive.nationalarchives.gov.uk/20130103005754/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_096492

2. The final proposals should include safeguards for people who raise concerns to prevent inappropriate and bullying attacks on their integrity, which sometimes happens when they appear as a witness at FTP hearings. This is a major disincentive for people who would otherwise report concerns. Hearings should restrict themselves to the facts of the allegations/concerns.

Regulation of PAs and AAs

64. Do you agree or disagree with the proposed approach to the regulation of PAs and AAs? Please give a reason for your answer.

Agree with some caveats. Overall, AvMA welcomes bringing the roles of Physician Assistant and Anaesthetic Assistant under the umbrella of statutory professional regulation.

As indicated previously, it remains important that there is a clear demarcation between these roles and that of qualified doctors in recognition of the very different education and training that they will have received. Registrants themselves must remain vigilant and aware of those professional boundaries notwithstanding their registration with the GMC. AvMA has seen increasing examples of patient harm where boundaries have not been respected and individuals have provided care which goes beyond that which their education and training equips them for.

65. In relation to PAs and AAs, do you agree or disagree that the GMC should be given a power to approve high level curricula and set and administer exams? Please give a reason for your answer.

Agree. PAs and AAs will in many circumstances be undertaking tasks and fulfilling roles traditionally undertaken by qualified doctors. It is therefore important that the GMC is empowered and able to set the benchmarks and assessments for PAs and AAs.

66. Do you agree or disagree with the transitional arrangements for PAs and AAs set out above? Please give a reason for your answer

Neither agree nor disagree. There is always some concern if there is an apparent lacuna in regulation but it is unclear to what extent that would represent a risk in this case. Two years might from a patients' perspective appear a relatively long period subject to the safeguards that would be in place.

67. Do you agree or disagree that PAs and AAs should be required to demonstrate that they remain fit to practise to maintain their registration? Please give a reason for your answer.

Agree. These are roles involving potentially high-risk patient contact and it is therefore essential that registrants are subject to revalidation.

68. Do you agree or disagree with the benefits identified in the table above? Please set out why you've selected your answer and any alternative benefits you consider to be relevant and any evidence to support your views.

As set out above, it is unclear to what extent the current proposals will directly benefit patients, particularly with respect to patients reporting concerns to professional regulators.

Whilst the ability to investigate and resolve FTP concerns more efficiently and speedily would clearly be a significant benefit, the proposals are largely silent on the potential drawbacks for patients reporting concerns. It is essential that the needs of patients are given far more prominence and consideration within any reforms. This includes the extent to which the proposals will assist or act as a barrier to patients bringing concerns to a regulator and the trust that they will ultimately have in how their concerns have been dealt with.

69. Do you agree or disagree with the costs identified in the table above? Please set out why you've chosen your answer and any alternative impacts you consider to be relevant and any evidence to support your views.

It is clear that if regulators are afforded more freedoms, there will be a far greater need for external oversight by bodies such as the Professional Standards Authority. Without this oversight, there is a real risk of the system of professional regulation being undermined.

The move towards the majority of FTP cases being resolved by case examiners will necessitate greater external oversight. This should be factored into the costs of the proposals. Without that independent oversight, AvMA would have significant concerns with respect to the proposals as set out. The PSA (or alternative body) will need to be resourced accordingly in order to meet those demands.

Additionally, resources will be required for independent specialist advice for members of the public. The funding for this could come from the regulators themselves (there would be cost savings for them in terms of helping prevent cases being inappropriately/prematurely referred to them, and in making reported concerns easier to assess), or centrally from the Department of Health and Social Care, or a mixture. There are opportunities to minimise the cost of this by combining it with addressing unmet needs for specialist independent advice already identified for patients/families involved in patient safety investigations, inquests, complaints, and potential litigation. For example, a national Helpline could cover all of these issues and more intensive advice/advocacy be provided where needed. Ideally, the needs of patients/families considering or involved in FTP and these other processes should be thought about holistically rather than each part of the system address this completely separately.

70. Do you think any of the proposals in this consultation could impact (positively or negatively) on any persons with protected characteristics covered by the general equality duty that is set out in the Equality Act 2010, or by Section 75 of the Northern Ireland Act 199

There is the potential for negative impacts for patients reporting concerns as set out in our response to the consultation.

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Contact details:
Liz Thomas
Action against Medical Accidents (AvMA)
Freedman House
Christopher Wren Yard
117 High Street
Croydon CR0 1QG
Email: policy@avma.org.uk