

AvMA's response to the Professional Standards Authority's Consultation 'Standards of Good Regulation and Standards for Accredited Registers'

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Section 1: Questions 1-8 were for administrative purposes.

Section 2: Are our Standards looking for the right things?

Issue

The Standards of Good Regulation and Standards for Accredited Registers are the benchmarks we use to assess an organisation's performance. We use a risk-based approach to assess performance. Through this review we want to ensure we are looking for the right things to assess performance and drive improvement (such as encouraging preventative regulation) for the public benefit.

Complaints about practitioners (known as fitness to practise for the regulators) has historically been, and remains, an area of high-risk. As such, we have always had more Standards in that area to address those risks. However, we are aware that focus on complaints could result in presenting an unbalanced picture of overall performance or not identifying regulatory risks and issues in other areas, such as education and training. We want to know if we have the balance of the Standards right so that our attention during each assessment is focused where it needs to be.

Similarly, because we use a risk-based approach to assess performance, we are interested in hearing your views as to whether those Standards that are routinely met remain important areas that we should test regularly, or whether these are areas that do not require as much attention because they are at lower risk of not being met.

Proposal

To seek your views on whether we are looking for the right things to assess a regulator or register's performance and drive improvement for the benefit of the public. We also want to hear your views on whether we have the right approach in assessing a regulator or register's performance in a way that protects the public.

Question 9. Do you agree that the Standards are an effective way of assessing and reporting the performance of the regulators and registers?

Yes

Please explain

The Standards are an effective way of assessing and reporting the performance of the regulators and registers. We make comments later in this response about the need to strengthen the Standards in relation to culture, governance and leadership following the high-profile issues faced by the NMC. AvMA advocates for harmed patients and their families, and our focus is on patient safety; we are pleased to note the stress placed by the Standards on prioritising patient and service user centred care and safety as we consider this to be of crucial importance.

Question 10. To assess the performance of regulators and drive improvement in regulation for the benefit of the public what should we **keep** in the **Standards of Good Regulation**?

All the current Standards should be maintained.

Question 11. To assess the performance of regulators and drive improvement in regulation for the benefit of the public what should we **change** in the **Standards of Good Regulation**?

Standards 14-18 relate to Fitness to Practice. In AvMA's experience of working with patients and their loved ones after medical harm has occurred, it is important that processes such as Fitness to Practice are designed to meaningfully engage with patients and their families. Too often the patient voice can be sidelined or ignored. potentially missing important information as well as negatively impacting a patient's recovery and healing. Every effort should be made to reiterate the importance of effective engagement, including training for relevant staff within regulatory bodies. Standard 14 could be expanded to include a direct reference to making the process of raising a concern simple, understandable and transparent for non-medical individuals. Standard 15 could be expanded to include a reference to informing participants / interested parties of the outcome of Fitness to Practice hearings. Standard 18 - "all parties to a complaint are supported to participate effectively in the process" - is particularly important. Harmed patients and their families must be kept up to date on developments by the regulator in a way which is appropriate for individuals without a medial or legal background. This could be explicitly referenced in the Standard.

Question 12. To assess the performance of regulators and drive improvement in regulation for the benefit of the public what should we **add** to the **Standards of Good Regulation**?

To prioritise improvements in patient safety, an additional standard could be added around Fitness to Practice: information or learnings acquired through a Fitness to Practice processes are shared with related bodies where they may impact or influence other safety processes. Similarly, the Standards around education and training could include an expectation that patient safety learnings from Fitness to Practice hearings are acknowledged and education and training standards are responsive to these so, where possible, mistakes and errors are not repeated.

Question 13. To assess the performance of regulators and drive improvement in regulation for the benefit of the public what should we **remove** from the **Standards of Good Regulation**?

All the current standards should be maintained.

Question 14. To accredit registers and drive improvement in registration for the benefit of the public what should we **keep** in the **Standards for Accredited Registers**?

All the current standards should be maintained.

Question 15. To accredit registers and drive improvement in registration for the benefit of the public what should we **change** in the **Standards for Accredited Registers**?

Standard 4a on Education and Training could include a direct reference to including any learnings from complaints and concerns to help prevent repetition of identified errors. Standard 5 could be expanded to include a direct emphasis on service-user safety. It could also state that the organisation has robust processes in place to ensure that other bodies / organisations are informed and aware of any complaints and related issues of patient safety where it is appropriate to do so. This would ensure that registers and registrants have a duty to acknowledge the importance of patient safety and act upon concerns, contributing towards driving improvement.

Question 16. To accredit registers and drive improvement in registration for the benefit of the public what should we add to the Standards for Accredited Registers?

See comments above. Additionally, Standard 7 could be expanded so that in addition to actions taken to mitigate risk, that information on mitigations regarding patient safety are shared with partners and other interested parties to build on a shared culture of learning and improvement.

Standard 8 highlights the organisation's role in providing 'clear and accessible' information regarding itself, the role it registers and the Accredited Registers programme. This could be expanded to ensure that registrants also provide this information in a clear and accessible format, so that service users have adequate opportunity to understand what the Accredited registration means.

Question 17. To accredit registers and drive improvement in registration for the benefit of the public what should we **remove** from the **Standards for Accredited Registers**?

There isn't anything AvMA suggests removing.

Question 18. Do you have any suggestions on how we can make our Standards fit for the future?

Given the recent announcement of the abolition of NHS England it would be good to reflect how registers and regulated bodies work in more centralised system.

Health and social care is increasingly technologically advanced, and it would be useful to think about how the Standards reflect the increasing impact and role of technology and AI, with a view to prioritising the quality and outcomes of service users.

Question 19. Do you have any other comments or suggestions to further strengthen the Standards? (Please avoid repeating comments already detailed earlier in your answers)

In addition to our comments above, registration raises an expectation among employers and the public that the registrant is qualified across the full Standards of Proficiency for their profession. The PSA should consider what verification is undertaken to assess the accuracy of what they are being told by a regulator, especially in the face of concerns raised with them.

Section 3: Alignment of Standards of Good Regulation and Standards for Accredited Registers

Issue

For patients and service users, the differences between a regulator and an Accredited Register are likely to be not well understood. In our view, this points to a need for greater alignment between the expectations we have of an Accredited Register and those we have of a regulator.

Proposal

We believe the two sets of Standards should be the same wherever possible and in line with the principles of Right-touch regulation. If there is variation between the two sets of Standards, it should be explained.

Question 20. Do you think that the Standards should be aligned as much as possible?

Yes

Please explain

As an advocate for patient rights, we see firsthand how little understanding many patients have of the health service. The complaints system is not well understood and it is unlikely that many patients are aware of the regulatory framework and the work of the Professional Standards Authority unless they have need to, such as pursuing a Fitness to Practice process. We are therefore unconvinced that there is considerable recognition from the public of the difference between regulators and accredited registers. This issue of recognition could also be is exacerbated when considering other socio-economic factors such as deprivation, language barriers, or cultural mistrust of the NHS. In so far as it is possible, and not reductive, more alignment is helpful, so the public can be sure that whoever they receive care from is of a high standard, and if things go wrong, appropriate processes are in place and followed to prevent reoccurrence.

Question 21. Do you agree/disagree with our proposals on alignment?

Outcome focused standards:

Agree

Flexibility in how the standards are met:

Agree

Professional standards and guidance are kept up to date and informed by evidence:

Agree

Please explain

As outlined above, we believe alignment is a sensible move to assure service users that the providers of their care are held to certain levels of accountability, regardless of whether they are in a regulated profession or on an accredited register.

AvMA recognises the diversity of roles covered by regulation and accredited registers across the health and social care sector and thus there needs to be an appropriate degree of flexibility in how those standards are assessed. It is right that standards should focus on outcomes which are measurable and transparent. It is important that guidance and standards are kept update and informed by evidence, and AvMA would like to see patient safety incidents and outcomes forming part of that evidence so that examples of avoidable harm are not repeated.

Section 4: Clarity, accessibility and transparency

Issue

The PSA protects the public and upholds public confidence by overseeing the regulation and registration of health and care practitioners. It is important that everyone understands how we carry out our regulatory role.

In our pre-consultation engagement with patients and service users we heard that our Standards can be hard to understand. In addition, feedback from regulators and Accredited Registers highlighted the need for greater clarity and transparency on the evidence framework that we use to judge whether a standard has been met.

We have also identified some areas of unhelpful overlap in each set of Standards and associated guidance which we would like to remove as part of this review as well as areas that need to be simplified:

- In the Standards for Accredited Registers we propose to merge the two Standards which deal with identifying and managing risk (Standards 1 and 7).
 In addition, there is significant overlap in the minimum requirements supporting the Standards which we think can be made easier to understand and use.
- In the Standards of Good Regulation there is overlap in the Standards which
 relate to raising concerns and being supported through fitness to practise
 complaints (Standard 14 and 18) so we are proposing combining these
 Standards. In addition, we would split Standard 15 which focuses on the
 fairness and proportionality of the fitness to practise process as well as

timeliness of the process. As fitness to practise timeliness is a current issue for many of the regulators, we consider it would be more transparent, fairer and appropriate for this to be a standalone Standard.

Proposal

The Standards of Good Regulation and Standards for Accredited Registers and associated guidance should be:

- Accessible to all audiences and introduce alternative versions if required
- Simple and concise and contain minimal duplication
- Clear and transparent about how decisions are made on whether a regulator or Accredited Register has met the Standards

Question 22. Are there any **Standards of Good Regulation** you find difficult to understand?

No

Question 23. Are there any **Standards for Accredited Registers** you find difficult to understand?

Yes

Please explain

Standard One states that 'any harm' should be 'justifiable and mitigated'. What does this mean for service users? Justifiable harm could be a confusing concept for most service users and should be clarified.

Question 24. Could you tell us where you think there is unhelpful overlap in our Standards?

N/A

Question 25. Is it clear how we assess whether a regulator or Accredited Register has met the Standards?

Yes

Question 26. Do you agree/disagree with our proposals to remove unhelpful overlap in the **Standards of Good Regulation**?

Merging our standards around raising concerns and being supported through raising complaints about practitioners

Not sure

Separating out the two parts of our standard about complaints about practitioners being 1) fair and proportionate and 2) timely

Agree

Please explain

Please see our response to Section 2. AvMA feels that the standards around Fitness to Practice require strengthening to ensure that service users are properly supported to be included and kept updated if they take part in these processes.

Regarding the separation of 1) fair and proportionate and 2) timely, AvMA understands and agrees with the suggested change.

Question 27. Do you agree/disagree with our proposals to remove unhelpful overlap in the **Standards for Accredited Registers**?

Merging our standards around processes for the considering risks from practice

Not sure

Reducing overlap between the minimum requirements

Agree

Please explain

See our answer above. Standard One could be clarified around the definition of justifiable and mitigated harm. Similarly, more clarity should be provided around the responsibility of the Accredited Register itself and how much falls to the registrant. Standard Seven is clearer in this respect although could be expanded to ensure there is responsibility that mitigating actions are shared with partners as best practice.

Section 5: New standards on culture and/or governance and/or leadership

Issue

For a long time we, and others, have been considering the repeated instances where the organisational leadership, governance or culture of important institutions serving the public can have negative impacts on staff and members of the public. In health and care we can look to the major inquiries at Mid-Staffordshire NHS Foundation Trust, Gosport War Memorial Hospital or Telford Hospital NHS Trust. In each of these instances, the culture within organisations contributed to unacceptable outcomes for patients and service users.

We think it is important to ensure that all our Standards drive improvement in the health and care regulatory environment and the introduction of a Standard focused on internal culture, governance and leadership will assist us in doing so.

Proposal

To bring the Standards of Good Regulation in line with the Standards for Accredited Registers in assessing whether the governance of an organisation supports public protection and promotes transparency, integrity and accountability.

To consider introducing a new standard to assess the organisational culture of a regulator and an Accredited Register and to gather views on how to measure the

culture of an organisation.

In addition, we would like to place a greater emphasis in our Standards on regulators and registers doing more to collaborate and share good practice.

Question 28. Do you agree/disagree that organisational governance, leadership and culture are important components of ensuring regulation and registration works in the public interest?

Agree

Please explain

In over 40 years of dealing with incidents of avoidable harm we see only too clearly how impactful organisational governance, leadership and culture are in the health and social care sector, and the real impact they have on patient experience when things go wrong. We support all activity which acknowledges the importance of leadership and culture and applies appropriate scrutiny.

Question 29. Do you think the **Standards of Good Regulation** should consider the **governance of an organisation**?

Yes

Please explain

Good governance structures are essential to managing a well-run organisation, providing the frameworks which ensure ethical conduct, transparency, accountability and sustainability. Given the real and lasting impact that a regulator can have on an individual's ability to practise professionally, for example through a Fitness to Practise process, it is sensible that governance structures are assessed as appropriate, rigorous and fit for purpose. Furthermore, poor governance, at its worst, can lead to organisation and regulatory failure which brings regulation into disrepute and undermining public confidence in healthcare and professionals.

Question 30. Do you think the **Standards of Good Regulation** should consider the **leadership of an organisation**?

Yes

Please explain

Leadership is a crucial factor in shaping an organisation, its role and impact. With over 40 years of experience working with patients and their families, AvMA understands how impactful the leadership of an organisation can be, as exemplified by recent evidence given to the Thirlwall Inquiry. As the Department of Health and Social Care considers the case for regulation of NHS managers, it seems there is a groundswell of awareness of the importance and impact of leadership within health and social care, and thus the need for commensurate oversight. As such, it would be appropriate to extend that oversight to the regulator themselves. Regulators should be held to the same standards and accountability as those that they regulate.

Question 31. Do you think the **Standards of Good Regulation** and **Standards for Accredited Registers** should consider the **culture of an organisation**?

Yes

Please explain

The culture of an organisation is inextricably linked with its leadership. As we have said above, regulators should be held to the same standards as those that they regulate. To build an effective patient safety culture, accountability and a shared set of expected behaviours are key, and everyone across the landscape needs to be part of that ethos. For accredited registers, the oversight of culture is perhaps even more important, working as they will be with smaller numbers of organisations and smaller patient bodies, perhaps more siloed.

Question 32. How do you think that the PSA could assess the:

- culture of an organisation?
- governance of an organisation?
- leadership of an organisation?

Assessing the overall effectiveness of an organisation's culture, governance and leadership is far from straightforward and will require careful consideration. However, there are several indicators which can suggest a culture and leadership that are working well or otherwise. This can be gleaned through evidence from staff surveys, staff turnover, sickness absence as just some examples that indicate issues as can the number of on-going staff grievances and industrial tribunal claims. Governance of an organisation can be assessed by review of appropriate policies and procedures as well as looking at how in practice decisions are made and interviews with senior leaders and board members about such processes may be revealing as to the quality of such decision-making.

Question 33. Should we include in the Standards an expectation that the **regulators and Accredited Registers** collaborate and share learning with fellow regulators or registers and other interested stakeholders?

Yes

Please explain

Part of developing an open and transparent culture is a commitment to sharing and learning, to ensure errors aren't repeated but also to build an ethos of continual improvement. This is particularly important within the context of patient safety, because although regulators and registers focus on specific professions or job roles, it is rare for health and care professionals to work in isolation. Generally, healthcare is an ecosystem, and where it is appropriate and helpful to do so, collaboration and shared learning can only be beneficial.

Question 34. Which areas of collaboration do you think we should focus on?

There is so much scope for meaningful collaboration around patient safety, including identifying common errors and their mitigation, sharing innovation and best practice. Where appropriate it may also be possible to share learning around professional misconduct cases.

In our work with patients we know that there are issues of diversity across the healthcare sector, and this can translate into misunderstanding, mistrust and miscommunication. Therefore, any collaborative efforts could also focus on diversity initiatives, so the regulator and workforce better represent the patient population served, resulting in better outcomes.

Section 6: Supporting public expectations for criminal records checks

Issue

For the majority of health and social care practitioners, criminal record checks are carried out by their employers, though this may not always happen consistently. But for self-employed practitioners there might not be a regular check or any check at all.

The law around who can access criminal convictions information is also different in each country of the UK so we cannot take one approach for the whole of the UK.

We want to improve assurance on criminal convictions checks for self-employed practitioners and those that are employed but not checked without forcing unnecessary repeated checks for employed practitioners or conflicting with the law in each country of the UK. We also don't want to create expectations for regulators and registers that are unnecessarily burdensome or not fit for purpose.

Proposal

To set a proportionate expectation that criminal convictions checks are assured by regulators and Accredited Registers for people who are self-employed or employed but not checked and not covered by another form of check of their criminal records.

Question 35. Do you think **regulators and Accredited Registers** should collect appropriate assurances around criminal convictions checks when registrants do not routinely have checks?

Regulators:

Yes

Accredited Registers:

Yes

Please Explain

Throughout responding to this consultation AvMA has been clear that we speak for patients and their safety. It is appropriate that individuals providing healthcare to

patients or service users have the necessary criminal conviction checks. Where this information is not routinely collected the regulator and Accredited Register should collect appropriate assurances. As set out above, we question how much understanding there is of regulation among the public, especially the difference between accredited registers and regulators. Where this lack of awareness may exist it is of even greater importance that appropriate rigour is in place so that service users are assured that they are accessing safe care.

Question 36. What factors do you think the PSA should consider in making a decision on whether to introduce an expectation for assurances around criminal convictions checks?

The PSA should consider the nature of the relationship with service users and patients that different groups have. They should also assess the level of potential harm which could be inflicted.

It is right that the PSA should also consider proportionality and how to ensure information is used effectively and appropriately.

Section 7: New criteria for registers applying for accreditation

Issue

We make decisions about accreditation in two stages. In the first stage we consider if the register is eligible for accreditation and if it is in the public interest to accredit the register based on the risks and benefits of the practice in question. In the second stage we consider all the Standards for Accredited Registers, including reassessing the public interest. We have two stages because some organisations are not able to be accredited based on eligibility and the public interest alone and we do not want to force them to be assessed, and pay for assessment, against all standards if these tests cannot be met.

The two-stage process means we are unable to fully consider accreditation as part of the first stage and must wait for a full assessment to be completed at a later date. Not being able to consider accreditation broadly in the first stage could undermine confidence in our process. This is because we might publish a report that says that we think one of our Standards is met and appear to endorse an organisation that cannot meet our Standards or is acting in a way that will affect the reputation of the programme.

Proposal

To introduce changes that mean we can consider more factors in the first stage of the assessment process. We could either make changes to the Standards so that we can undertake compliance checks to make sure that a register is operating lawfully, or we could be more flexible in our process so that we can stop progressing an application if it is apparent that our Standards could not be met after the first stage of assessment.

Question 37. Do you think we should amend the Standard we use in the first stage of assessment to include compliance checks for relevant legislation, such as equality, diversity and inclusion, preventing modern slavery, or data protection?

Yes

Please explain

AvMA speaks for patients and champions their safety. Processes around regulation and registration should be as simple to understand as possible and suitably efficient. If basic compliance checks cannot be met it is much better for assessment to pick this up as early in the process as possible.

Question 38. Do you think we should have a more flexible process to be able to stop progressing an application at the first stage of assessment if there is good reason to think that any of our Standards cannot be met?

Yes

Please explain

Please see answer above. The primary duty of regulation is to protect the public. The focus of the PSA should be to focus on the quality of the work of regulators and registers as effectively and efficiently as possible. It seems that flexibility in ceasing an assessment where Standards cannot be met seems entirely reasonable, ensuring resources are used where they can make most impact.

Section 8 - Additional questions: Implementation, equalities, Welsh Language impact

Question 39. Which factors should we be considering in planning for implementation of any revisions to the **Standards of Good Regulation**?

The health and care system is currently in a state of flux and will undergo considerable change in the coming months and years. The abolition of NHS England will undoubtedly alter how the system works, as will the Ten Year plan for Health when published. The DHSC is currently considering the regulation of NHS Managers which will change the regulatory landscape. All of these factors should be considered by the PSA when planning implementation for any revisions of the Standards.

Question 40. Which factors should we be considering in planning for implementation of any revisions to the **Standards for Accredited Registers**?

The factors outlined above for the Standards of Good Regulation should also be considered for the Standards of Accredited Registers.

Question 41. Do you think any of the proposals in this consultation could impact (positively or negatively) on any persons with protected characteristics covered by the public sector equality duty that is set out in the Equality Act 2010 or by Section 75 of the Northern Ireland Act 1998 or on family formation, family life and relationships?

No

We are required by law to uphold the Welsh Language Standards (No.8) Regulations 2022 so that people who speak, read, and write in Welsh can have the same opportunity to use the Welsh language as anyone using the English language. We are also required to consider the impacts of changes to the Standards on opportunities to use the Welsh Language and treating the Welsh language no less favourably than the English Language.

There may be impacts caused by the influence our Standards have on regulators and Accredited Registers and the resulting effects on:

Members of the public interacting with regulators and Accredited Registers to:

- use online registers,
- find information about practitioners and their roles,
- engage with policy development and research,
- raise concerns about a practitioner, or
- make complaints about a regulator or Accredited Register

Registrants who are expected to meet professional standards or other requirements to be able to register as a practitioner.

Staff who work at regulators, Accredited Registers and organisations responsible for health and social care.

Therefore, we want to seek and consider views on whether there are any positive or adverse impacts caused by our proposals for the Standards, and if there are ways that we can enhance the positive impacts and reduce the negative impacts.

Question 42. Thinking about the groups described above or anyone else you think might be impacted; do you think our proposals have any impacts on:

Opportunities to use the Welsh Language?

None or Neutral impact

Treating the Welsh Language no less favourably than the English language?

None or Neutral impact

Question 43. Do you think there are ways to enhance the positive impacts or reduce the negative impacts of our proposals on:

Opportunities to use the Welsh Language

Not sure

Treating the Welsh Language no less favourably than the English language?

Not Sure

If you said there were ways to enhance positive impacts or reduce negative impacts, please explain: N/A