Response to consultation on the appointment and operation of the Patient Safety Commissioner

August 2021

1. Introduction

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

1.2 As part of our work we:

- Oversee the ten health and care professional regulators and report annually to Parliament on their performance
- Accredit registers of healthcare practitioners working in occupations not regulated by law through the Accredited Registers programme
- Conduct research and advise the four UK governments on improvements in regulation
- Promote right-touch regulation and publish papers on regulatory policy and practice.

2. General comments

2.1 We welcome the opportunity to respond to this consultation by the Department of Health and Social Care (DHSC) on the appointment and operation of the Patient Safety Commissioner.[1] Our answers to the questions asked by the consultation are below.

3. Answers to questions

Terms of office

Question 1 - We propose that the Patient Safety Commissioner shall serve for a term of 3 years. What do you think of this length of service?

3.1 Too short.

Please explain your answer.

[1] Department of Health and Social Care, *Consultation on the appointment and operation of the Patient Safety Commissioner*. Available at: https://www.gov.uk/government/consultations/the-appointment-and-operation-of-the-patient-safety-commissioner/consultation-on-the-appointment-and-operation-of-the-patient-safety-commissioner#how-to-respond

3.2 We note that this is consistent with the length of term served by the Victims Commissioner who can also serve two three-year terms. However, the Children's Commissioner is appointed for a single six-year term.

3.3 If this has not already been done it may be worth considering the relative merits of the appointment rules that apply to these two similar roles to consider whether there are particular advantages to having a single long term or two shorter terms.

3.4 We note that in healthcare some issues may not be dealt with easily in a shorter term of office which may suggest advantages of longer term to allow more progress to be made.

Question 2 - We propose that the Patient Safety Commissioner will be eligible for one reappointment after having held office and that they may resign and be removed by the Secretary of State, if appropriate. Do you agree or disagree with this proposal?

3.5 Neither agree nor disagree

Please explain your answer.

3.6 See previous answer for suggestion to consider the approach used for length of appointment to similar roles.

3.7 We agree that the post holder should be able to resign or be removed if appropriate. However, we query whether the Secretary of State should have this power directly as this may compromise the independence of the role and make it more likely to be seen as a political appointment.

3.8 We note that other organisations have previously made recommendations for how the role of the Children's Commissioner could be made more independent from Government which may be helpful for DHSC to consider.[2]

Remuneration

Question 3 - We propose that the Patient Safety Commissioner will receive remuneration. Do you agree or disagree with this proposal?

3.9 Strongly agree

Please explain your answer.

3.10 We do not believe that it will be possible to attract a sufficiently diverse pool of applicants without providing renumeration for a potentially complex and time-consuming role.

3.11 If the role is not renumerated, then it will be more likely to attract applicants with independent income or require anyone applying for the role to maintain

[2] Joint Committee on Human Rights, *The role and independence of the Office of the Children's Commissioner for England – Written Evidence*. Available at: https://www.parliament.uk/globalassets/documents/joint-committees/human-rights/Childrens_Commissioner_Written_Evidence_5.pdf

additional employment which may not be conducive to recruiting a Commissioner who can commit sufficient time and attention to the role.

Funding

Question 4 - We propose that the Secretary of State will fund the operation of the Patient Safety Commissioner. Do you agree or disagree with this proposal?

3.12 Neither agree nor disagree

Please explain your answer.

3.13 We have some concerns that this funding model could compromise the independence of the Patient Safety Commissioner as the role would effectively be funded by Government.

3.14 With this in mind it will be all the more important to ensure that the independence of the role is guaranteed in other ways.

Business plan

Question 5 - We propose that the Patient Safety Commissioner produces an annual business plan setting out their strategic priorities for that year, and that they will have to take reasonable steps to consult before publishing each plan. Do you agree or disagree with this proposal?

3.15 Strongly agree

Please explain your answer.

3.16 We agree that it will be important for the Commissioner to lay out priorities for each year clearly and transparently. However, as it may be challenging to achieve progress on some issues in a one-year period we suggest it may make sense for there to be scope for a Commissioner in the role to lay out strategic priorities for their period in office and then to update on specific priorities for each year as part of the annual business plan.

Accounting

Question 6 - We propose that the Patient Safety Commissioner is to keep proper accounts, including a statement of accounts each financial year, a copy of which is to be provided to the Secretary of State. Do you agree or disagree with this proposal?

3.17 Strongly agree

Please explain your answer.

3.18 This is good practice for all public bodies and authorities and should help to promote transparency and confidence in the role.

Annual report

Question 7 - We propose that the Patient Safety Commissioner must publish an annual report to explain the activities they have undertaken during the year in relation to the Commissioner's core duties. Do you agree or disagree with this proposal?

3.19 Strongly agree

Please explain your answer.

3.20 It is good practice for such a role to report on activity undertaken during the year and it is important for transparency reasons. Along with the suggestions outlined for what should be included in such a report we would suggest the following additional areas:

- How the Patient Safety Commissioner has worked with any counterparts and other relevant bodies across the UK particularly in the devolved administrations. We note that this role is new, and the Scottish Government has recently consulted on introducing a similar role. The other nations of the UK are also considering how to respond to this recommendation from the Cumberlege Review. However, it would be good to embed the concept of joint working across the UK from the start
- Assessment by the Commissioner of whether the powers and scope provided to the role are sufficient to ensure effective working to support patient safety objectives. This is particularly important as a number of bodies, including ourselves, have highlighted the value of this role having a broader remit than just medicines and medical devices. It will be important to assess whether the relatively narrow remit that the role has been given requires review at a later date.

Advisory panel

Question 8 - We propose that the Patient Safety Commissioner may appoint an advisory panel, whose members will have a broad range of relevant interests, such as experience and/or knowledge of the health system, sectors and types of patient experiences. Do you agree or disagree with this proposal?

3.21 Strongly agree

Please explain your answer.

3.22 We would agree that the Commissioner should have the discretion to establish an advisory panel if s/he considers it necessary or helpful.

3.23 It will be important for the Commissioner to draw on the expertise and experiences of others in carrying out the role. As the purpose of the role is to work in the best interests of patients there may be value in drawing on the expertise of those with experience of campaigning and working on behalf of patients on a wide range of different issues.

Conferring of functions on others

Question 9 - We propose that any staff of the Patient Safety Commissioner, so far as authorised by the Commissioner, may exercise any of the Commissioner's functions. Do you agree or disagree with this proposal?

3.24 Agree

Please explain your answer.

3.25 It would be impractical for the Commissioner to be required to deliver all of the functions of this role personally therefore it will be important that he or she can be supported by staff in the exercise of the functions provided to the role.

3.26 Any delegation of functions should be carried out in accordance with principles of good governance via an agreed scheme of delegation.

Question 10 - Do you have any additional thoughts on the operation and appointment of the Patient Safety Commissioner?

3.27 We support the Government's decision to implement the recommendation in *First Do No Harm – The Independent Medicines and Medical Devices Safety Review*[3] (the Cumberlege Report) to create the role of a Patient Safety Commissioner. However, as we stated in our response to the Cumberlege review we believe that in order to fully address the problems identified, it would have been beneficial for the role have a broader remit to avoid becoming just another player in a complex landscape.[4] As it stands the Commissioner will only be able to take action on issues arising relating to the safety of medicines and medical devices.[5]

3.28 We recognise that this scope is now enshrined in law via amendment to the Medicines and Medical Devices Act and therefore this is fixed for now. We believe the Commissioner will need to manage the challenges arising from this more limited scope as part of their work, in particular the expectations of patients and families and communicate their remit as clearly as possible.

3.29 However, in our view it is also essential that Government keep the role and remit of the Commissioner under review so that if it is unable to fulfil the objectives envisaged for it or if it becomes clear that it is constrained by the scope of the role the legislation could be amended as necessary.

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[3] *First Do No Harm - The Independent Medicines and Medical Devices Safety Review*. Available at: https://www.immdsreview.org.uk/Report.html

[4] Professional Standards Authority 2020, *Authority response to First Do No Harm, the report of the Independent Medicines and Medical Devices Safety Review (the Cumberlege Report)*. Available at: https://www.professionalstandards.org.uk/docs/default-source/publications/consultation-response/others-consultations/2020/professional-standards-authority-response-to-cumberlege-review-(medicines-and-medical-devices-safety-review).pdf?sfvrsn=7aa97620_6

[5] *Part 1: The Commissioner for Patient Safety, Medicines and Medical Devices Act 2021*. Available at: https://www.legislation.gov.uk/ukpga/2021/3/part/1

3.30 We note that organisations campaigning on behalf of patients have also called for the role to have a wider remit including Action on Medical Accidents (AvMA)[6] and the Harmed Patients Alliance[7].

3.31 We further note AvMA's call for independent specialist advice to be available to patients involved in patient safety investigations, inquests, complaints, and potential litigation as well a professional regulatory proceedings, as outlined in their response to the recent consultation on reforms to health professional regulation.[8] We agree that there is a need for more support for patients involved in the regulatory processes. There is the potential for this service to sit with the role of the Patient Safety Commissioner if the role was broadened. We suggest that the Government consider this issue and whether this support could be provided via the Patient Safety Commissioner role in the future.

3.32 With regard to the justification for considering a wider remit for the role in the future: multiple reports have pointed to the complexity of the system and the lack of clarity for patients on the role of different organisations. Others have highlighted the risk of patient safety concerns falling through the gaps between organisational boundaries. As well as the Cumberlege report itself this includes the report by Sir Ian Kennedy into failures at Bristol Royal Infirmary between 1984-1995, the report by Sir Robert Francis into concerns identified at Mid-Staffordshire NHS Foundation Trust between 2005-2008 and more recently the Paterson Inquiry chaired by the Rt Revd Graham James.

3.33 In all of these examples, patients and families experienced great challenges in seeking to draw attention to failures identified and to bring about action, in part because of the complexity of the system and the difficulties of knowing who should take responsibility. We ourselves described the difficulty for members of the public trying to navigate this system in *Rethinking regulation*.[9]

3.34 With this in mind there is the potential for a Patient Safety Commissioner to act as a navigator of the system for patients and to help organisations to work in a coherent way across jurisdictional boundaries in the interest of patients. However, the current remit proposed for the role may make this more challenging as issues are likely to stretch beyond medicines and medical devices alone.

3.35 As suggested in our comments under question 7 on the annual report, this is something that the Commissioner themselves could keep under review with a view to informing any future legislative change.

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[6] *AvMA comment on Cumberlege report on Medicines and Devices*. Available at: https://www.avma.org.uk/news/avma-comment-on-cumberlege-report-on-medicines-and-devices/

[7] The bmj opinion, 4th February 2021, James Titcombe and Joanne Hughes, *A patient safety commissioner—why we need a new voice for all harmed patients*. Available at: https://blogs.bmj.com/bmj/2021/02/04/a-patient-safety-commissioner-why-we-need-a-new-voice-for-all-harmed-patients/

[8] *AvMA response: Regulating Healthcare Professionals, Protecting the Public*. Available at: https://www.avma.org.uk/wp-content/uploads/AvMA-Response-to-Regulating-Healthcare-Professionals-June-2021.pdf

[9] Professional Standards Authority (2015) Rethinking regulation: Available at: https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/rethinking-regulation-2015.pdf

4. Further information

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

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