Response to the consultation: Providing a 'safe space' in healthcare safety investigations

December 2016

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 voluntary 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 nine health and care professional regulators, and report annually to Parliament on their performance
- Conduct research and advise the four UK governments on improvements in regulation
- Promote right-touch regulation and publish papers on regulatory policy and practice.

1.3 We welcome the opportunity to respond to this Department of Health consultation about providing a 'safe space' in healthcare safety investigations. We offer some general comments, detailed analysis and have responded some of the individual questions in the consultation document.

2. General comments

2.1 The Authority supports the goal of creating a learning culture and an environment where professionals can openly discuss issues to improve performance and patient care. We agree with Don Berwick's conclusion in *A promise to learn – a commitment to act* that patient safety depends upon a learning culture, where near misses and errors are openly discussed and learnt from. However, an open culture to share information confidentially between professionals must be consistent with the rights and needs of patients and their relatives and with the proper requirements of professional standards of conduct and effective regulation. Openness in secret is not openness.

2.2 We consider there is a fundamental contradiction between the Government's commitment to transparency and accountability, as expressed though the duty of candour, and the proposals in this paper for anonymous and confidential reporting.

2.3 We find the term 'safe spaces' unattractive. The language of safe spaces has long been used in the protection of vulnerable children and adults. For this language to be applied to health professionals as though they were the victims

of patient safety errors is distinctly unappealing. However, if professionals are to be viewed as 'victims' then it should be noted that they are 'second victims' to the 'first and obvious victims': patients.[1] Moreover the term 'safe spaces' has recently been adopted by various pressure groups claiming 'safe spaces' where they can be free from any public debate or challenge. We see no reason why 'confidential enquiry' or investigation cannot be used as it is after all what is being proposed. We use 'confidential enquiry' instead of 'safe space' in this response.

2.4 We welcome lessons that can be learned from other sectors to improve safety in healthcare. The consultation document pays particular attention to the airline industry and we note the useful lessons which Carl Macrae has drawn from that sector. He discussed the need for the UK healthcare system to develop a 'shared accountability' culture whereby all staff see patient safety as part of their role and responsibility.[2]

2.5 We note the contradiction between confidential investigations and professional regulatory operations. The consultation document makes clear that if there was an 'immediate risk to patient safety' of any information found in a confidential investigation then the information would be referred to professional regulators or other relevant authorities. The Department of Health and the Healthcare Safety Investigation Branch (HSIB) will need to work closely with all eight professional regulators operating in England to determine reliably what constitutes a 'public risk'.

2.6 We note also that as the powers of the HSIB apply to England only this will create operational variations for the regulators which are UK or GB wide.

Learning culture

2.7 The Authority is supportive of the Department of Health's policy aim of a culture of learning. In *Rethinking Regulation*, we noted Gerry McGivern's proposal for 'reflective spaces' where away from regulators, professionals can 'discuss professional issues and problems freely with each other without fear of recrimination, and enquire freely of each other'.[3] Professor McGivern's proposal differs significantly from a safe space as suggested in the consultation in that it is 'within regulatory systems', yet professionals still 'feel safe to openly discuss and address problems they might be facing in their practice' which could be an important means of 'assuring patient safety and quality of care' by addressing problems at an early stage.[4] 'Safe spaces' in confidential investigations on the

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[1] *Candour, disclosure and openness Learning from academic research to support advice to the Secretary of State*, Professional Standards Authority, pg. 11. Available at: http://www.professionalstandards.org.uk/docs/default-source/publications/research-paper/candour-research-paper-2013.pdf

[2] *Learning from patient safety incidents: Creating participative risk regulation in healthcare*, Carl Macrae. Available at: http://www.tandfonline.com/doi/abs/10.1080/13698570701782452

[3] *Rethinking Regulation*, Professional Standards Authority, pg. 18. Available at: http://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/rethinking-regulation-2015.pdf

[4] *Exploring and explaining the dynamics of osteopathic regulation, professionalism and compliance with standards in practice*, General Osteopathic Council, Pg. 15. Available at:

other hand would take professionals out of regulatory systems and lead to potential issues we outline later in this consultation response. However, the impetus for a learning culture is consistent with our recent paper, *Regulation Rethought*, where we recommend a move needs to be made from an adversarial to inquisitorial approach in fitness to practise proceedings.[5] In the same paper, we also acknowledge that many issues in the health and care workplace are best resolved locally.

2.8 On page nine, the consultation document mentions that a 'a culture of fear' prevented professionals from reporting concerns at the Mid Staffordshire NHS Foundation Trust. There is no evidence that this would be addressed by confidential investigations. Organisational cultures are determined by the people who lead and work in them.

2.9 The Authority welcomes the lessons that can be learnt from other sectors, and we have previously promoted the idea of 'shared accountability' in previous policy documents for possible models of improving the learning culture in healthcare.[6] The idea of 'shared accountability' has been developed within the aviation sector in response to avoidable aviation disasters. Pilots, air traffic control, mechanics and so on all give each other permission to constructively challenge and check each other's decisions. However, the two industries are not completely analogous as broadly outlined by Kapur, Parand, Soukup, Reader and Sevdalis.[7] The limits to which comparisons can be drawn between the two sectors on the issue of 'safe spaces' is most pronounced with regard to professional regulation. Airline professional regulation is not as complex and thorough as health and care professional regulation. Health and care regulators have public facing registers which provide to the public details of a registrant's impairment, sanctions and detailed reasons for sanctions.[8] It should also be noted that the drivers for revealing information to regulators are markedly different between the airline and health industries. In the former, as pilots share the risks (death) of passengers and their crew, they are incentivised for different reasons to health professionals.

2.10 In response to question 12, we prefer the phrase 'confidential enquiry' to 'safe space'. Safe space implies areas outside of it are not safe and potentially dangerous. This does not help foster better organisational trust locally or promote a just culture in organisations, indeed it implies that the working environment is essentially unjust.

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http://www.osteopathy.org.uk/news-and-resources/document-library/research-and-surveys/dynamics-of-effective-regulation-final-report/

[5] *Regulation Rethought*, Professional Standards Authority, pg. 10. Available at: http://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/regulation-rethought.pdf?sfvrsn=10

[6] Based on Carl Macrae's analysis of the interaction between air traffic controllers and pilots.

[7] *Aviation and healthcare: a comparative review with implications for patient safety*, Narinder Kapur, Anam Parand, Tayana Soukup, Tom Reader and Nick Sevdali, pp 1-2. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4710114/table/table1-2054270415616548/

[8] For example the Nursing and Midwifery Council's: https://www.nmc.org.uk/concerns-nurses-midwives/hearings-and-outcomes/hearings-sanctions/hearings-november-2016/

Patients, families and the public

2.11 Duty of candour has been a critical focus of the NHS over the last few years. The introduction of the statutory duty of candour was to 'ensure that providers ae open and transparent with people who use services'.[9] The goals of this regulation were echoed in a joint statement by eight of the UK professional regulators.[10,11] Confidential enquiries will be perceived by patients and their families to be contrary to the expectation of greater honesty and openness by professionals.

2.12 It is proposed that information found through safe spaces investigations would not be disclosable under the Freedom of Information Act 2000 and the Data Protection Act 1998. We believe FOI requests make organisations accountable to the public and foster greater public trust in an organisation's operations. The anonymity provided by confidential enquiries and the limitations on publishing of findings contradict the responsibility of health and care providers to share as much information as possible with patients. The Department of Health would need to reconcile the two philosophies for the public clearly. There is a reasonable expectation of transparency on the part of patients, families and the public. Confidential enquiries are likely to reduce public confidence rather than increase it.

2.13 The independence of the HSIB may be questioned due to its ties with the Department of Health. The fact that 'safe space' information will not be published, alongside the perceived lack of independence may damage public confidence.

Professional regulation

2.14 A professional regulator's purpose is to protect the public from harm, declare and uphold professional standards, and maintain public confidence in the profession. These three purposes may clash with confidential enquiries as information found in a confidential investigation may be of use to trigger a regulator to investigate a concern in line with its regulatory objectives. However, we note the consultation document says the confidential enquiry approach is intended as a learning forum to solve long term patient safety problems. The consultation further notes that 'more immediate, clear patient safety risks' still need to be acted upon. Regulators currently act on immediate risk to patient safety by the imposition of interim orders for serious allegations. An interim order prevents the registrant from practising (interim suspension order), or places limits on their practice (interim conditions of practice order) until their case is heard at a final panel hearing.[12] This means that regulators are critical in

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[9] *Regulation 20: Duty of candour*, Care Quality Commission. Pg. 8. Available at: http://www.cqc.org.uk/sites/default/files/20150327_duty_of_candour_guidance_final.pdf

[10] *Progress on strengthening professional regulation's approach to candour and error reporting*, Professional Standards Authority, pg. 5. Available at: http://www.professionalstandards.org.uk/docs/default-source/publications/advice-to-ministers/progress-on-strengthening-approach-to-candour-november-2014.pdf

[11] The ninth regulator agreed with all the 'sentiments and principles' of the joint statement but disagreed with two aspects of working.

[12] Interim Orders, Health and Care Professions Council. Available at: http://www.hpc-uk.org/complaints/registrants/interimorders/

defining what constitutes an immediate risk to the public and in acting to protect the public from immediate risk. It is difficult to see how this can be reconciled with any promises given by the confidential enquiry process that health professionals can give evidence anonymously and in confidence.

2.15 The consultation document offers little detail on how the threshold for when information gleaned in a safe space needs to be handed over to a regulator will be decided. All regulators will need to be involved at every stage of the process in creating a threshold. Particular care will need to be taken in judging thresholds as a professional may optionally choose to refer themselves to either a regulator or a confidential enquiry depending on incentives which could have unintended consequences of professionals avoiding proportionate regulatory actions and decreasing patient safety.

2.16 Regulators will be dependent on the judgement of those running safe spaces to identify issues which should be brought to their attention. Information which might not be deemed important by confidential enquiry organisers could be important for regulators and patient safety. The document does not clarify how a regulator would know if information provided to a safe space (but not brought to the attention of regulators) warranted an appeal to the high court for the release of information.

2.17 It is mentioned on page 14 that the Expert Advisory Group says: 'these protections must not interfere with the proper administration of justice, and would not prevent any legal or professional regulatory proceedings in response to intentional wrongdoing or gross negligence'. The 'protections' refers to the boundaries which secure confidential enquiry information from being disseminated to the wider world. We disagree with the assessment that only 'intentional wrongdoing or gross negligence' should be passed over to the regulator. This is an extremely high threshold. Regulators' standards encompass a much wider range of aspects of a professional's conduct and performance. It is a misunderstanding of professional regulation to limit its role to intentional wrongdoing or gross negligence both of which are uncommon.

2.18 On page six of the consultation a report from the Public Administration Select Committee (PASC) is cited: 'in order to truly create a system where investigations drive learning and improvement, any investigation carried out by the new healthcare investigation body it must offer a safe space: strong protections to patients, their families, clinicians and staff, so they can talk freely about what has gone wrong without fear of punitive reprisals.' This again misrepresents professional regulation. Regulation is not punitive. It identifies misconduct and impairment and acts to protect the public and uphold standards. It does not punish.

2.19 Professional regulation already offers opportunities for learning as regulators act proportionately, not punitively, in fitness to practise investigations in order to ensure safety and better practice.[13] Professionals who are statutorily regulated have a responsibility to be accountable and honest in order to ensure productive regulatory investigations. There is no indication as to how a

[13] Regulators also have other tools such as CPD and revalidation in order to ensure registrants keep learning and attain proper standards.

confidential investigation would compel professionals to act any differently than in a regulatory investigation. The proposals in this paper seem to be inviting health professionals to act against the standards of transparency and accountability towards patients and colleagues which have been set by their regulators and promoted by the government and which are recognised by health professionals themselves.

2.20 The consultation document mentions the General Medical Council (GMC) and Nursing Midwifery Council (NMC), however it is worth mentioning there are also six other professional regulators in England regulating 32 occupations[14]. There are also 23 accredited registers covering 54 occupations. Multi-disciplinary teams and greater integration means there is more contact than ever before between different health and care professionals. This may mean a confidential investigation could require evidence from hospital pharmacists, physiotherapists, paramedics, counsellors, healthcare scientists or other regulated or registered professions much beyond the remit of the GMC and the NMC.

2.21 Clarification is required about who will pay costs if a regulator appeals to the high court to obtain confidential investigation information. Will the regulator or HSIB pay costs in the case of an appeal, and will the designation of costs be dependent on the success or otherwise of an appeal?

Four country working

2.22 The confidential investigation proposal is to be implemented in England. This will increase inconsistency of working between the four countries of the UK. This will mean professional regulators will need to adapt to a different legislative regime. Where possible, regulators try to be consistent in how they deal with registrants across the four countries. This is displayed in criminal disclosure at registration, where the GMC adopted the policy that all applicants are required to comply with the England and Wales scheme regardless of country.[15]The GMC and other regulators deemed it necessary to implement this to ensure parity to all registrants and for reasons of operational effectiveness. If confidential enquiries were to come into force in England, the Department of Health would need to consider potential ramifications of increasing variation of professional standards between the four countries.

Overlap with current infrastructure

2.23 The interaction between professional regulators, NHS organisations, the justice system and other stakeholders is a complex one. Adding in the arrangements for confidential investigations will complicate current arrangements in the health and care system and result in other unintended effects. Simplicity of arrangements will help build public confidence and understanding, and enable staff to build a learning culture. The range of expertise offered by existing

[14] *Regulation Rethought*, Professional Standards Authority, pg. 17. Available at: http://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/regulation-rethought.pdf?sfvrsn=10

[15] *Criminal disclosure at the point of registration*, General Medical Council. Available at: http://www.gmc-uk.org/12___Criminal_disclosure_at_the_point_of_registration.pdf_66326325.pdf

organisations can create the required conditions for a learning culture coupled with robust investigation. The creation of a learning culture does not need to come at the expense of transparency. Transparency is a positive value which can help professionals to openly discuss issues and affirm public trust in healthcare organisations.

3. Consultation questions

3.1 Question 1 - Do you consider that the proposed prohibition on disclosure of investigatory material should apply both to investigations carried out by HSIB, and to investigations conducted by or on behalf of NHS Trusts, NHS Foundation Trusts and other providers of NHS-funded health care?

No

3.2 Question 2 - for those investigations undertaken by or on behalf of providers and commissioners of NHS-funded care, should the proposed prohibition on disclosure apply only in relation to investigations into maternity services in the first instance or should it apply to all investigations undertaken by or on behalf of such bodies?

No

3.3 Question 3 - Do you have any comments about the type of information that it is proposed will be protected from disclosure during healthcare investigations?

See above for our comments, but in summary we are against the protection of disclosure of information.

3.4 Question 4 - Do you agree that the statutory requirement to preserve the confidentiality of investigatory material should be subject to such disclosure as may be required by High Court order?

See our response to question 3.

3.5 Question 5 - Do you agree with the proposed elements of the test to be applied by the High Court in considering an application for disclosure?

See our response to question 3.

3.6 Question 6 - Do you have any views on the proposed exceptions that would apply to the prohibition on disclosure of material obtained during investigations by the HSIB and by or on behalf of providers and commissioners of NHS service?

See our response to question 3.

3.7 Question 7 - Do you have any views on where the bar should be set on passing on concerns to other organisations whose functions involve or have a direct impact on patient safety?

We are against any bar being set, but if a bar is set then it should be done with the agreement of all eight professional regulators in England. **See further detail in our comments above.**

3.8 Question 8 - Do you consider that the exceptions proposed could undermine the principle of 'safe space' from the point of view of those giving evidence to investigations?

See our response to question 3.

3.9 Question 9 - Do you support the principle of a 'Just Culture' (that would make a distinction between human error and more serious failures) in order that healthcare professionals might come forward more readily to report and learn from their mistakes without fear of punitive action in circumstances that fall short of gross negligence or recklessness?

Yes, but we do not agree that 'safe spaces' are necessary for a just culture.

3.10 Question 10 - If you consider that the prohibition on disclosure should be subject to an exception allowing for the disclosure of certain information to patients and their families, what kind of information do you consider should be able to be disclosed in that context? And when would be a sensible, workable point for patients/families to have access to information - eg. should they see a pre-publication draft report for comment?

In the spirit of duty of candour, openness and accountability, patients and families should have access all information.

3.11 Question 11 - Do you see any problems in a requirement that investigatory bodies (such as professional regulators, coroners and the police) must apply to the High Court if they wish to gain access to information obtained during investigations by the HSIB or by or on behalf of providers or commissioners of NHS-funded care?

Yes, many problems. See our above comments in page five for explanation.

3.12 Question 12 - Do you have any concerns about the use of the phrase "safe space" in relation to this policy; and, if so, do you have an alternative preference?

Yes. We consider it an unhelpful term and prefer 'confidential enquiry'. See above for explanation.

3.13 Question 13 - Do you see any problems in exempting information obtained during healthcare investigations from access under the Freedom of Information and Data Protection regimes?

Yes.

3.14 Question 14 - Do you agree that guidance, or an alternative source of support, should be developed?

Yes. We have mentioned the reflective spaces of Professor Gerry McGivern, we also think better use of current health and care infrastructure can create better support. Other valuable learning methodologies include 'Schwartz' rounds ('a structured forum where all

staff, clinical and non-clinical, come together regularly to discuss the emotional and social aspects of working in healthcare').[16]

3.15 Question 15 - Do you think it would be helpful for NHS staff to be supported by a set of agreed national principles around how they would be treated if involved in a local safety incident investigation; and, if so, do you have any suggestions for the areas that such a set of principles should cover?

No answer.

3.16 Question 16 - Do you have any concerns about the impact of any of the proposals on people sharing protected characteristics as listed in the Equality Act 2010?

No answer.

3.17 Question 17 - Do you have any concerns about the impact of any of the proposals on families? If you envisage negative impacts, please explain.

Yes. We explain in the above comments in more detail how duty of candour and accountability towards patients will be eroded with a detrimental impact on public trust.

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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[16] About Schwartz Rounds, Point of Care Foundation. Available at: https://www.pointofcarefoundation.org.uk/our-work/schwartz-rounds/about-schwartz-rounds/