

Department of Health
Attention: Neil Townley
Safe Space policy lead
Quality, CQC and Investigations Team

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15 December 2016

Dear Sir,

Providing a 'safe space' in healthcare safety investigations

The General Pharmaceutical Council (GPhC) is the regulator for pharmacists, pharmacy technicians and registered pharmacy premises in Great Britain. Our role is to protect, promote and maintain the health, safety and wellbeing of patients and the public who use pharmaceutical services in England, Scotland and Wales.

We have a statutory role in relation to 'system' regulation, as we regulate registered pharmacies, as well as 'professional' regulation of individual pharmacists and pharmacy technicians.

We welcome the opportunity to respond to the consultation on providing a statutory 'safe space' in healthcare safety investigations, in addition to our previous [response](#) to the Independent Patient Safety Investigation Service Expert Advisory Group call for evidence. We support the important work of the Healthcare Safety Investigation Branch (HSIB) and are keen to ensure we are working collaboratively where possible in the interests of patient safety.

Whilst the consultation document as a whole is of interest to us we have limited our response to areas where we feel our work is directly relevant to the proposals.

We know that health professionals being open and honest when things go wrong is one of the best ways to protect patients. We believe that a culture of openness and honesty is critical to improving safety and ensuring there is less emphasis on blame and more focus on transparency, speaking up and learning from mistakes.

We fully support the principles of learning and improvement, and agree that independent investigations could bring about valuable lessons by shedding light on systemic failures. However we have some concerns about the practical implications of a statutory 'safe space' on how we, as a regulator, can hold individuals and registered pharmacies to account.

We welcome any opportunity to increase transparency for patients and the public about the relationships across the wider healthcare system but we query the extent to which this will be achieved by the proposed approach.

Our approach

We are unique amongst health and social care professional regulators because of our role in regulating registered pharmacies. Our inspectors assess registered pharmacies in Great Britain against our [standards for registered pharmacies](#) which includes looking at whether there is a culture of openness, honesty and learning. Pharmacists and pharmacy technicians also have a professional responsibility, through the standards for pharmacy professionals, to raise concerns if they believe the standards are not being met.

We are interested in, and would welcome further clarity on, how the HSIB will work in parallel with the regulators and alongside other investigations, and in particular, how the HSIB will work alongside the GPhC as a regulator of both systems and professionals.

Scope of investigations

We are unclear about the scope of the investigations that would be subject to the 'safe space' principle. We would welcome further clarity on how the HSIB proposes to identify appropriate investigations to carry out and whether these will be reactive or proactive, driven by data and trends or by a particular trigger, incident or 'complainant'. We are particularly interested to understand the criteria which the HSIB proposes to apply to enable it to determine which and what investigations it intends to carry out.

Context

We note that the proposal to create a statutory prohibition about the disclosure of material obtained during certain health service investigations is modelled on the approach taken by the Air Accidents Investigation Branch (AAIB). However we believe the AAIB operates in a very different context and space to that within the healthcare sector. As you will be aware, the AAIB operates in a predominantly commercial sector and investigates post-incident. This is significant as companies operating in this area will have a particular interest in maintaining the confidentiality of commercially sensitive information. Given the AAIB have been in operation for a number of years and have a strong statutory framework, we query what lessons have been learnt by this body and how they are being applied in this sector.

The AAIB puts a strong emphasis on sharing information with families, but this does not appear to translate across to the healthcare sector context. The proposals talk at length about the need to balance the expectations and reassurance of patients and families with the need to preserve a 'safe space' so people can talk freely about what has gone wrong. The consultation does not explain how this balance can be struck in its current proposals.

As the consultation rightly points out, public sentiment surrounding healthcare investigations is sensitive and there is a concern that the conclusions of investigations will be covered up, particularly following the Mid-Staffordshire Inquiry. The consultation highlights that many patients and families "felt cut out of the process of investigations and were fearful of cover ups". A statutory 'safe space' does not appear to account for this crucial factor, and may not improve the experiences of patients and their families if they continue to feel excluded from the process. Such an approach may, in fact, contribute to a public feeling that inquiries, investigations, decisions or recommendations are taken in a non-transparent way – ie "behind closed doors".

There is a consistent theme among many of the AAIB's memoranda of understanding (MoUs) with other bodies that "The public interest requires that safety considerations are of paramount importance, the consequence of which may mean that the interests of an AAIB investigation have to take precedence over the criminal investigation." It is worth noting that GPhC regulatory investigations serve a different purpose from a criminal investigation in that they seek to protect the public and improve quality – of which safety is a critical element. In this sense, we anticipate being aligned with the interests of HSIB.

We question the proposal to extend the 'safe space' provisions to information obtained not only by the HSIB during its investigations, but across all NHS safety investigations. We often rely on referrals and material generated during the course of a 'local' investigation so that we can decide whether further action is required. Extending 'safe space' provisions as suggested may have the effect of restricting the scope of necessary regulatory interventions and investigations which the GPhC might otherwise be able to undertake in the public interest.

We are concerned that 'safe space' may contradict the progress of other government initiatives intended to promote greater transparency and a culture of being candid, for example the Freedom to Speak Up Review and the whistleblowing policy for the NHS. We are concerned that, as currently outlined, 'safe space' may in fact discourage raising concerns with the regulators if people are more inclined to contact the HSIB instead under a, perhaps, false assurance of their disclosure remaining confidential within 'safe space'. We are unclear about how the 'tension' between non-disclosure of information gathered through investigations and the legal duty to act in an open and transparent way as required by the Duty of Candour is intended to be resolved. The duty of candour is embedded within our standards for pharmacy professionals, and is a provision which is similar to that, for example, of the General Medical Council and Nursing and Midwifery Council.

We also note the work occurring in Scotland in this area, particularly through the Apologies (Scotland) Bill which is intended to stop apologies being used as evidence of liability in most civil legal proceedings in Scotland. The aim is to bring about social and cultural change in relation to professionals apologising for mistakes and, through this, enhancing better customer/patient engagement and learning.

Exceptions to the prohibition on disclosure of information

Circumstances where disclosing information given as part of a protected 'safe space' would be acceptable appears to include:

- where there is a High Court order
- in limited circumstances allowed the EU regulation (ie where there is evidence of criminal activity or negligence)
- where there is an immediate risk to patient safety (ie potential intentional wrongdoing, gross negligence or other concerns that constitute an immediate danger to present or future patients)
- where there is an overriding public interest
- where there is an active and ongoing threat to patient safety represented by the practice or actions of one of more individuals that requires action

These exceptions are inconsistently used throughout the consultation and we would ask for further clarity on the instances when the HSIB would disclose information and what level of detail would be disclosed.

The consultation acknowledges that having exceptions to 'safe space' could negate the principle itself. We are uncertain whether the HSIB would have powers to compel information where required, as the AAIB does. We note that whether the provision of information is truly voluntary or not is likely to impact on the perception of a participant 'feeling' safe.

The proposal that professional regulators and other investigatory bodies would need to apply to the High Court to gain access to information obtained during investigations by the HSIB is difficult to comment upon without further information in relation to how these bodies would know when to apply for such disclosure. Would the HSIB advise what they are investigating or what they have discovered? While we are reassured by the notion of an independent decision maker, we envisage that needing to apply to High Court for the disclosure of information will add significantly to the burden of regulation with a disproportionate impact upon the time within which regulators can investigate concerns brought to our attention. It will also add significantly to regulatory costs.

Further information from the HSIB will assist us to make a more meaningful contribution, but we note that, currently, such a proposal is inconsistent with the legislation currently covering the GPhC's power to seek disclosure of information.

We are uncertain about the practical implications of section 6(4)(c) of the Directions¹:

"The Chief Investigator... must inform the appropriate health service regulator, professional regulatory body or other investigatory body or bodies should the Investigation Branch become aware of evidence of a serious, continuing risk to patient safety, but subject to this subparagraph must not volunteer to take further part in the actions that such a body or bodies may subsequently take;"

Guidance and clarification around the level of detail or information which the HSIB would disclose to the regulator, if the information meets the exception threshold, would need to be clear. We would welcome reassurance that the HSIB's understanding of what constitutes 'a patient safety risk' aligns with our own thresholds for this. We are aware that, often, our investigations are not only based on one-off concerns but on a series of lower level incidents that may not, on their own, meet the threshold but may indicate a wider pattern. Without access to this knowledge, the HSIB may not be aware of the full facts surrounding a particular professional or provider when deciding if disclosure to the regulator is necessary.

Our concern is that the regulator(s) may not be informed if information that could have an important impact on a fitness to practise case or inspection does not meet the HSIB's disclosure threshold. In order to carry out our functions effectively, we would require full and timely disclosure where there is a current risk to patient safety, where we need to act in accordance with our statutory responsibilities.

¹ National Health Service Trust Development Authority (Health Safety Investigations Branch) Directions 2016

Existing investigations and processes

While we acknowledge that the purpose of an HSIB investigation will not be to attribute blame, holding individuals and, if necessary, organisations to account for issues which may have resulted in patient deaths, patient harm or patient safety being compromised is an important public policy function which should not be diluted.

Given there is the potential for regulators and the HSIB to be carrying out parallel investigations, we are concerned there may be duplication in investigations and increased costs associated with this. We are also concerned about the additional burden which would be placed on individuals being investigated by two separate bodies either concurrently or consecutively. Information gained through one investigation may inadvertently discourage or compromise other witnesses from coming forward in another investigation.

It is unclear how, in practice, the 'safe space' proposals will fit in with existing statutory powers of healthcare and professional regulators, and other investigation bodies, to require people to provide evidence as part of their own investigations. It is also currently unclear what, in practice, would be the legal or professional expectations on 'witnesses' who were prepared to assist the HSIB investigation but not the regulatory one or vice versa.

There is a range of legislation that already protects whistle-blowers and we query whether increasing legislation to this effect may duplicate the safeguards already in place.

If the HSIB secures legislation to implement a 'safe space', we would welcome further clarity on which legislation would take precedence – the investigatory powers of a regulator or the 'safe space' provision to protect those participating in a HSIB investigation. This would need to be clear so all stakeholders fully understand their duties and obligations.

The Disclosure and Barring Service or Disclosure Scotland could be a good case study to reflect on and consider learnings about how similar independent bodies have been implemented, in the first instance without legislative powers.

Practical implications and risks

We believe primary legislation is needed to secure a statutory 'safe space' in which health and social care professionals, patients, their families and carers, can speak candidly about the most serious risks to patient safety. Whether 'safe space' is indeed 'safe' will very much depend on the culture that develops around it and the statutory scheme which is implemented.

It may be difficult for the public to know who to go to with a concern, whether it is the regulator, police, NHS agency, the organisation where the incident occurred, the CQC or the HSIB. But when an incident is so serious it must be immediately referred for a regulatory or criminal investigation, would 'safe space' apply at all?

In terms of the Freedom of Information Act 2000 and the Data Protection Act 1998, the wording around the 'safe space' in legislation would need to be drafted carefully to ensure the information gained through an investigation would not be disclosable.

Adding value

The principles and objectives of the HSIB may also be applied in several other contexts that maximise the value of a 'safe space' whilst minimising the risk of duplication in investigations.

We would suggest there may be real practical benefit in the HSIB conducting its investigation stage after a fitness to practise case, criminal prosecution or regulatory intervention is complete. The HSIB could then bring together all the relevant information from across the wider healthcare system. In this instance, it would be practical to implement the proposed 'safe space', in that the immediate risk to patient safety should have been remedied, it would uphold the Duty of Candour, and it minimises the risk of duplication in parallel investigations. We believe this is where the HSIB would be most effective.

Regulators also receive a range of concerns that are often out of their remit, but a coordinated approach for multi-profession/multi-disciplinary team issues would certainly add value and enhance the learning which can then be applied across the sector. The HSIB could monitor these complaints and maintain oversight of the types of issues that arise across the various professions including whether they may indicate a broader issue.

However, in addition to contributing to improved learning, such a cross sector approach could also identify areas of best practice which can be shared and applied across all areas of professional practice and without geographical limitation. We wonder whether the HSIB could also have a role in investigating incidents of serious 'near misses'. These are the circumstances surrounding incidents which did not eventuate but which could have had severe and wide ranging consequences. There are a variety of issues that can go beyond the actions of an individual professional or a particular profession.

We are keen to continue to work closely with the HSIB as they develop and implement their investigative processes, to ensure we can have a mutually beneficial relationship which, above all, upholds patient safety and protects the public interest.

If you would like further information on any of the points in this response, or any other aspects of the GPhC's work, please do not hesitate to contact us on the details provided below.

Yours sincerely,



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