



Department
of Health

Providing a 'safe space' in healthcare safety investigations

Summary of consultation responses and next
steps

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- NHS Staff (past and present)
- NHS Employers
- Professional regulators for the healthcare professions
- Trade Unions
- Patients and families
- Providers
- Commissioners

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1. Foreword

When I launched the Department of Health's consultation on our proposals to provide a 'safe space' in healthcare safety investigations on 17 October 2016, I said:

“there is a culture within many parts of the NHS which deters staff from raising serious and sensitive concerns and which not infrequently has negative consequences for those brave enough to raise them”.¹

These proposals are designed to bring about a transformational change in how the NHS approaches learning for safety improvement on par with other safety-critical industries, such as aviation, which is credited for its high safety record. Such a change is fully supported by the Public Administration and Constitutional Affairs Committee (PACAC) in its recent report *Will the NHS never learn?*²

However, I do not underestimate the tough challenge ahead. The scale of this challenge was set out clearly in the Care Quality Commission's report on *Learning, Candour and Accountability*³, which I commissioned in response to events in Southern Health NHS Foundation Trust. Put bluntly, when things go wrong, the NHS is failing to properly learn and implement the lessons, thereby letting down patients, as well as its own staff.

In the course of a safety investigation contributions are more likely to be comprehensive and candid if they are made in confidence and used solely for the purpose of identifying improvements in safety. This in turn should help to get to the root of the problem far more quickly and provide for a better and faster way of learning from healthcare harm, preventing incidents from being repeated.

The consultation sought views on the aim to create a balanced 'safe space' whereby staff would feel confident that the law would prevent the disclosure of information they provided to a safety investigation; and patients and families would be reassured that as a result of the safety investigation, they would learn the facts of their, or their loved ones', care and what could be done to improve the safety of that care.

The responses to this consultation, particularly those from patients and their families, but also those from serving frontline NHS staff, have reinforced my determination that those who use and work in the NHS deserve better. And they have also provided further inspiration to make sure we can do better, as well as very helpfully highlighting options,

¹ Sir Robert Francis QC, Freedom to Speak Up report -

<http://webarchive.nationalarchives.gov.uk/20150218150343/https://freedomtospeakup.org.uk/>

² <https://www.publications.parliament.uk/pa/cm201617/cmselect/cmpublicadm/743/743.pdf>

³ <https://www.cqc.org.uk/sites/default/files/20161213-learning-candour-accountability-full-report.pdf>

risks and opportunities. The Government's response set out in this document draws on these helpful contributions and I am grateful to all of those who responded. I would particularly like to thank the members of the Department of Health's Expert Advisory Group on setting up the new Healthcare Safety Investigation Branch (HSIB), who have continued to provide expert advice and support on these complex issues.

The majority view was that the 'safe space' proposal would be of most use for HSIB in carrying out its investigations. Many respondents in fact felt that HSIB would not be able to function properly without the creation of a 'safe space' for the contributors to its investigations.

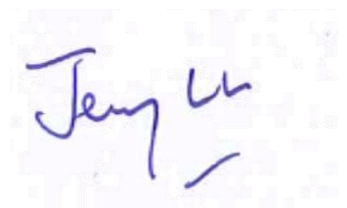
However, there was also concern about allowing NHS Trusts, NHS Foundation Trusts and other providers of NHS-funded health care to take a 'safe space' approach to their own investigations and that any extension of the 'safe space' principle to local investigations would be premature.

If the NHS is to learn at local, as well as at national levels, it should in time be able to benefit from the use of 'safe space' principles in local safety investigations. But clearly, a majority of respondents to our consultation have concerns about how those principles could be misused in practice.

I want to be clear that existing accountabilities and duties, including the statutory duty of candour will remain in force and will not change. Patients, families and staff therefore only gain from these proposals.

Bearing these points in mind, should we proceed in future to extend the protections offered under 'safe space' principles to local level safety investigations, we will do so only following further consultation, and only as agreed by the HSIB.

I am sure that the proposals set out in this response will enable the NHS to make real gains in improving patient safety.



Jeremy Hunt

2. Executive summary

Introduction

2.1. On 17 October, the Department launched a consultation on “Providing a 'safe space' in healthcare safety investigations”⁴. In line with the Cabinet Office’s Consultation Principles, it was a nine-week exercise that closed on 16 December. There were 145 responses including 107 online responses, supplemented by 37 contributions received by e-mail and post.

Summary of responses

2.2. There were two main questions in the consultation:

- should the Healthcare Safety Investigation Branch (HSIB) be allowed to conduct reviews to learn lessons from safety incidents, which generate material (such as transcripts, witness statements from staff and patients involved in the incident, notes written by investigator, electronic recordings of interviews and other information generated by the investigation) that are non-disclosable and inadmissible, except on the order of the High Court – the ‘safe space’ principle, as exercised in other areas such as air safety?
- should NHS Trusts, NHS Foundation Trusts and other providers of NHS-funded health care be given the same ‘safe space’ function in their own lesson-learning reviews, additional to and separate from their liability-determining investigations?

2.3. In summary the responses to these questions told us that, on HSIB and ‘safe space’:

- there was widespread support for HSIB’s leadership role in creating a learning culture, and a recognition that HSIB’s credibility rests on its ability to do this job well;
- over 60% of respondents were in favour of creating a ‘safe space’ at national level for HSIB investigations, and many saw this as critical to the effective operation of HSIB.
- it was recognised that it will take time for HSIB to build up trust with patients and staff.

⁴ <https://www.gov.uk/government/consultations/providing-a-safe-space-in-healthcare-safety-investigations>

2.4. On extending 'safe space' to NHS Trusts, NHS Foundation Trusts and certain other NHS organisations:

- there was general recognition that the standard of some investigations in the NHS was poor and there were reservations about whether this approach would help with the underlying problems with NHS investigations;
- patients and staff alike did not yet trust the NHS locally to use this fairly or properly – patients saw it as a way to avoid accountability, while staff saw it as a potential way for their employers to force self-incrimination;
- if the use of 'safe space' were extended to NHS Trusts, NHS Foundation Trusts and other providers of NHS-funded health care, its implementation should come with clear guidance and the development of support for staff;
- whilst some favoured the idea of starting with maternity services, a large number of respondents, particularly from the NHS, thought it should be piloted or tested before roll out;

2.5. On restricting information-sharing with patients, families and other organisations in all 'safe space' investigations (HSIB and NHS):

- there was general support from professionals and staff for material as cited in the consultation remaining confidential, unless disclosure was required through a High Court order; but patients, their advocates, and the regulatory bodies expressed concern that it could be seen as a way of evading accountability;
- patients and their representatives were worried that the requirement to apply to the High Court to access the material was a barrier to getting to the truth;
- restricting information sharing was also seen as a barrier to proper inter-agency collaboration on learning lessons and disseminating them.

2.6. There were some concerns about using the term 'safe space' to describe the investigations carried out by HSIB, as it could be confused with safety issues, and it is not clear what people are 'safe' from. There was general support for the principle of a Just Culture⁵.

⁵:A just culture has been defined as „one in which healthcare professionals are able to report safety incidents, and participate in safety investigations secure in the knowledge that they will not be inappropriately blamed or penalized for any actions, omissions or decisions that reflect the conduct of a reasonable person under the same circumstances.”

See the Expert Advisory Group report: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/522785/hsibreport.pdf

Conclusions and next steps

2.7. We have concluded that:

- the use of a 'safe space' approach on a national basis to HSIB investigations is welcome;
- respondents felt that the 'safe space' principle should only be extended to local NHS investigations once an organisation had proven that it can be trusted to use 'safe space' procedures appropriately;
- consultation responses have emphasised that local NHS reviews and investigations need to also improve and HSIB has a role to play as an exemplar; and
- the term 'safe space' accurately reflects the conditions we are trying to achieve in healthcare safety investigations to ensure maximum learning.

2.8. Therefore, from 1 April, HSIB will be up and running and will be expected to conduct its investigations using the safe space principles as set out in the NHS Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016. Unless we are able to legislate we cannot subject disclosure of material under HSIB investigations to a general prohibition. However, the Government remains open to the considering the option of legislation.

2.9. In time, and only at the point where the principles of 'safe space' have been tested and trusted at a national level will we consider extending the adoption of 'safe space' to investigations undertaken by or on behalf of providers and commissioners of NHS-funded care. This will be on three conditions:

- that they initially use it to investigate patient safety cases in other NHS-funded organisations, as invited external reviewers, before any extension which allows NHS Trusts, NHS Foundation Trusts and other providers of NHS-funded health care to conduct their own 'safe space' investigations;
- that they meet certain criteria such as training or accreditation, to be agreed with HSIB.
- that a further consultation with stakeholders is undertaken before we implement.

2.10. The material that we intend the safe space to apply to would be material generated by the investigation. Such material would include transcripts, witness statements from staff and patients involved in the incident, notes written by investigators, and electronic recordings of interviews. This would also include draft factual analyses, opinions, and

working documents developed and obtained by the investigators for purposes of reaching conclusions and making recommendations.

3. Introduction

- 3.1. On 17 October, the Department of Health launched a consultation on “Providing a 'safe space' in healthcare safety investigations”⁶. In line with the Cabinet Office principles on consultations, it was a nine week exercise that closed on 16 December.
- 3.2. The proposals outlined in our consultation were aimed at providing a legal framework for ensuring that information that staff provide as part of a health service investigation will be kept confidential except where the High Court makes an order permitting disclosure. This broadly mirrors the procedures followed in air accident investigations by the Air Accident Investigation Branch (AAIB).
- 3.3. The aim is to create a ‘safe space’ during investigations conducted by HSIB, as well as by or on behalf of NHS Trusts, Foundation Trusts and other NHS-funded health services, so that contributors to the investigation are encouraged to provide information in the knowledge that it will not be passed on unless one of the exceptions set out in the legislation applies. In addition, the aim is to reassure patients and families that they will be fully involved in HSIB investigations and that, as a result of the safety investigation, they would learn the facts about what had happened and what could be done to improve the safety of the care they, or their loved ones had received and lessons will be learned for the benefit of future patients and families.
- 3.4. The consultation proposed that there should be a statutory prohibition on the disclosure of information gathered during ‘safe space’ healthcare investigations unless disclosure is required by an order of the High Court.
- 3.5. It also proposed that the High Court may order disclosure of information obtained during the course of an investigation if disclosure to the applicant is, in the context of judicial proceedings, necessary in the interests of justice; or, where there are no existing proceedings, is necessary under such circumstances as give rise to the application. The consultation proposed that there are circumstances in which it is considered that the prohibition on disclosure of investigatory material should not apply.

⁶ <https://www.gov.uk/government/consultations/providing-a-safe-space-in-healthcare-safety-investigations>

4. Response to the consultation – key messages

Consultation responses

- 4.1. The Department of Health received 145 responses including 107 online responses, supplemented by 35 contributions received by e-mail and two by post.
- 4.2. There were 18 questions in the consultation (set out at **Annex A**). The responses were varied, and there was a clear distinction between the views of NHS staff, NHS bodies, professional organisation and regulators; and on the other hand the views of patients, families and organisations representing them.
- 4.3. A number of national organisations responded, including the General Medical Council and the Nursing and Midwifery Council and other regulators and professional bodies. There were also thorough and thoughtful contributions from legal firms, organisations representing patients and families, front line NHS staff, individual patients and concerned members of the public, as well as policy think-tanks and academics. The list of organisations which responded is attached at **Annex C**.
- 4.4. We have highlighted the key themes emerging from the responses below with a more detailed account attached at **Annex B**.

Should there be a safe space for HSIB and Trusts? (Question 1)

- 4.5. There were two main proposals to this question:
 - should HSIB be allowed to conduct investigations to learn lessons from safety incidents, which generate material that is non-disclosable/inadmissible, except on the order of the High Court, i.e. in a 'safe space'?
 - should NHS Trusts, NHS Foundation Trusts and other providers of NHS-funded health care be given the same 'safe space' function in their own patient safety investigations, additional to and separate from their liability-determining investigations?
- 4.6. There was widespread support for the 'safe space' principle and the aim of creating a learning culture and an environment where professionals can openly discuss issues to improve performance and patient care.
- 4.7. Over 60% of respondents were in favour of creating a 'safe space' for HSIB investigations, and many saw this as critical to the effective operation of HSIB. Some

argued that HSIB and its 'safe space' investigations needed to be enshrined in primary legislation, for HSIB to have the tools it needs to succeed:

“Without strong legislative underpinning, HSIB’s ‘safe space’ investigations will be undermined from the start and the desired impact of those investigations will be compromised.” (PACAC).

- 4.8. Approximately 40% of these responses (or 24% of all responses) thought that the approach should apply to HSIB only or should be tested by HSIB first before applying to patient safety investigations conducted by or on behalf of NHS Trusts, NHS Foundation Trusts and other providers of NHS-funded health care. It was recognised that HSIB needs time to demonstrate 'safe space' is working and can act as an exemplar before it is extended to local investigations. Those who supported 'safe space' applying to NHS Trusts, NHS Foundation Trusts and other providers of NHS-funded health care patient safety investigations as well as HSIB investigations recognised that those NHS bodies will still need to investigate many more patient safety incidents than HSIB, and therefore it was important that protection of information should apply to all such safety investigations. It was also recognised that HSIB would need to take a greater role in providing appropriate training and guidance for investigators, so that the quality and credibility of investigations are maintained.
- 4.9. However, there was some confusion about whether 'safe space' would apply to all investigations or whether 'safe space' investigations should be different from other types of investigation, such as serious incident investigations. In addition, there was still doubt expressed as to whether this approach would help with underlying problems in NHS investigations that also need to be addressed, such as the variable quality of NHS internal investigations, a somewhat patchy record on applying the duty of candour, and a generalised feeling that the interests of organisations were sometimes put before those of patients, families or staff.
- 4.10. There was therefore a strong call to develop a support package for staff, developed by HSIB in partnership with patients' and professional groups, backed up by clear and firm messages to Boards of NHS Trusts, NHS Foundation Trusts and other providers of NHS-funded health care about the need to support staff and foster a learning culture.
- 4.11. Over one third of respondents (35%) were opposed to prohibiting disclosure and the principle of 'safe space' altogether. This view was mainly expressed by patients, families and their representatives and some legal organisations. Their concerns focused on the importance of full sharing of information with patients and families, that 'safe space' "contravenes the ethos of the NHS constitution and duty of candour" and could remove accountability.

4.12. There was no significant support for local NHS reviews or investigations using the 'safe space' approach, unless local NHS organisations could show that they could be trusted to use 'safe space' appropriately and not to cover up mistakes. This caution was in line with those who were opposed to applying 'safe space' to NHS investigations because they were concerned about the poor quality of NHS internal investigations in general.

4.13. Regulators believed that extending the prohibition on disclosure to investigations carried out by other NHS Trusts, NHS Foundation Trusts and other providers of NHS-funded health care could impact on their own investigation processes and responsibilities to protect patients:

"It would have a negative effect on fitness to practice investigations and ultimately on patient safety. It will permit the creation of a "strong wall" prohibiting regulators from accessing information which could be used to hold an individual to account. It will also limit the ability of patients and the public to understand the reasons why things went wrong, and in certain circumstances why their family members were harmed."
(General Optical Council)

For NHS investigations, should it apply first to maternity services? (Question 2)

4.14. There were a range of responses to this question including restricting investigations to maternity services initially, starting in other areas (e.g. Never Events)⁷ or not necessarily starting in only one clinical service area.

4.15. Significantly, a large number of respondents, particularly from the NHS, thought it should be piloted or tested before roll out:

"Whilst we do not have strong views on the area of maternity to be the test case, we strongly encourage the development of a clear implementation plan for the roll out of the proposed approach across the NHS" (RCGP)

4.16. Those who were opposed to 'safe space' in response to Q1 also replied that the prohibition should not apply in any part of the NHS.

Other key messages

4.17. The consultation also sought views on how 'safe space' might work in practice.

4.18. Responses were also sought on the type of information that should be protected from disclosure (Question 3), whether the disclosure of confidential information should be

⁷ A 'never event' is a serious, largely avoidable patient safety incident that should not occur if the available preventative measures are implemented.

subject to a High Court decision (Question 4 and 5), and exceptions that would apply to the prohibition on disclosure of information (Question 6-10).

- 4.19. Opinion differed between professionals and staff who were broadly in favour of protecting the information set out in the consultation document (with the caveat that patients/families need to see all other material) unless required by a High Court. Patients, their advocates, and the regulatory bodies expressed concern that it could be seen as a way of evading accountability and a barrier to getting to the truth.
- 4.20. On the proposal of a High Court order (Questions 5 and 6), there was general support from professionals and staff for material remaining confidential, unless disclosure was required through a High Court order. In contrast, applying to the High Court was generally felt by patients' groups and others to be a barrier (and an expensive one) to patients' getting at the truth – not as a guarantor of HSIB's trustworthiness. The response from the legal profession was less sceptical, although concerns were raised about the potential impact on courts and costs.
- 4.21. Staff were broadly positive of the proposed exceptions to the prohibition on disclosure of information without a High Court order (such as disclosure to the police or professional regulatory bodies if there is a serious and continuing risk to patient safety) but wanted to know where the bar should be set.
- 4.22. There was general agreement that patients and families needed to be properly engaged in the investigation process and receive a full account of what happened, the outcome and lessons learned. Transparency of the investigation process and how information would be shared with patients and families was key.
- 4.23. There were some concerns raised about using the term 'safe space' to define investigations carried out by HSIB, when the main purpose of such investigations was to provide for a better and faster way of learning from healthcare harm.
- 4.24. There was support for the wider principles of a 'just culture' in healthcare, with the caveat expressed by some patients that in practice it should not compromise the duty of candour or proper accountability.

5. Conclusions and next steps

Conclusions

- 5.1. This consultation has shown that the use of a 'safe space' approach in HSIB's investigations is generally welcome. The Government believes its use will contribute to ensuring safe, effective care is delivered and that we learn from our experiences to continually improve.
- 5.2. We also believe that there should be a prohibition on disclosure save by order of the High Court, as happens in relation to investigations carried out by the Air Accident Investigation Branch, subject only to very limited exceptions e.g. circumstances such as immediate risk to patient safety or the commission of a criminal offence.
- 5.3. The circumstances under which we intend the safe space to apply would be material generated by the investigation. Such material would include transcripts, witness statements from staff and patients involved in the incident, notes written by investigators, and electronic recordings of interviews. This would also include draft factual analyses, opinions, and working documents developed and obtained by the investigators for purposes of reaching conclusions and making recommendations.
- 5.4. Respondents felt that the 'safe space' principle should only be extended to local NHS organisations once an organisation had proven that it can be trusted to use 'safe space' procedures appropriately. We agree that it is important that HSIB demonstrates how 'safe space' can be applied appropriately and consistently and that the 'safe space' principle should be extended only to those fully trained to gather evidence in this way.
- 5.5. The consultation responses have emphasised that HSIB needs to play a strategic role in the improvement of local NHS reviews/investigation. We expect HSIB to develop guidance on conducting its own 'safe space' safety investigations, to publish principles on protecting information and support a measured expansion to 'safe space' investigations by and on behalf of local NHS Trusts, NHS Foundation Trusts and other providers of NHS-funded health care.
- 5.6. Finally, the consultation revealed that there are concerns and some misunderstandings about how the concept of 'safe space' might be applied to safety investigations carried out by HSIB and other NHS organisations. Therefore, we intend that from 1 April, HSIB will be up and running and will be expected to conduct its investigations using the safe space principles as set out in the NHS Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016. Subjecting disclosure of material under HSIB investigations to a general prohibition requires legislation, and as HSIB begins its work we will keep its legislative framework under scrutiny. These investigations will be distinct from other investigations conducted in healthcare and should not conflict with other

reviews and investigations such as the Parliamentary Health Service Ombudsman (PHSO). This will require cooperation between HSIB and bodies that carry out other reviews and investigations at a national level such as professional regulators. The HSIB Chief Investigator is developing protocols with regulators and other authorities who have a right to investigate which will set out the agreed arrangements for sharing information.

- 5.7. It is also important to stress that the principles of 'safe space' are not intended to replace existing policy on openness and candour including the statutory duty of candour on provider bodies, the professional code of conduct on candour and current legislation and policies on whistleblowing.

Next steps

- 5.8. The Government proposes to pursue the option of developing a 'safe space' approach for HSIB's investigations. The Government also notes concerns raised by PACAC and others that without strong legislative underpinning, HSIB's 'safe space' investigations will not be able to protect from disclosure the material which is generated and the desired impact of those investigations may be compromised.

We recognise that HSIB will need time to establish itself. Our view is that HSIB should act as the exemplar for the 'safe space' model, and HSIB will be publishing the principles for its investigations by April 2017. This will provide clarity to the NHS about how such investigations should operate.

- 5.9. We accept the concerns raised in the consultation about the quality of NHS local investigations and the risk of extending the 'safe space' to NHS Trusts, Foundation Trusts and other NHS-funded health services before the 'safe space' principle is embedded in HSIB's investigations. We will only extend the 'safe space' approach to local NHS investigations on three conditions:

- that they initially use it to investigate patient safety cases in other NHS-funded services, as invited external reviewers, before any extension which allows NHS organisations to conduct their own safe space investigations;
- that they satisfy criteria developed by HSIB and are accredited to undertake 'safe space' investigations.
- that a further consultation with stakeholders is undertaken before we implement.

- 5.10. To support the NHS to improve the standard of other investigations, NHS Improvement will be developing the serious incident framework which governs serious incident investigations.

- 5.11. The Government will continue to work with patients, families and organisations representing health professionals and staff to ensure a shared understanding of ‘safe space’ and to work through the detail of what is proposed. We will also work with colleagues at the Ministry of Justice to assess the impact of these proposals on court processes.
- 5.12. We note the concerns raised about the term ‘safe space’ to define HSIB’s investigations. We are content that the term ‘safe space’ accurately reflects the importance of creating the right conditions to enable people to speak candidly in order to obtain learning to improve the quality of care as a result of these investigations.
- 5.13. We also welcome the support for the principle of a ‘just culture’ and we will give further consideration to how we can work with patients, families, NHS staff and the NHS itself to further develop such a culture, as recommended by the External Advisory Group, in its report published in May 2016.⁸

⁸ The Expert Advisory Group was set up in July 2015 to advise on setting up HSIB.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/522785/hsibreport.pdf

Annex A: Consultation questions

The full list of questions in the consultation document is set out below:

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?

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?

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

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?

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?

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?

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?

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?

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?

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?

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?

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?

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?

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

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?

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?

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

Annex B: Review of responses to the consultation

Should there be a 'safe space' for HSIB and Trusts? (Question 1)

60% of respondents were in favour of creating a 'safe space' for HSIB investigations. 40% of these responses (or 24% of all responses) thought that the approach should apply to HSIB only or should be tested by HSIB first before applying to patient safety investigations conducted by or on behalf of NHS Trusts, NHS Foundation Trusts and other providers of NHS-funded healthcare.

Over one third of respondents were opposed to prohibiting disclosure and the principle of 'safe space' altogether. Their main concerns focused on restricting information sharing with patients and families; about the poor quality of NHS internal investigations in general and in particular the lack of independence in the conduct of local investigations.

For NHS investigations, should it apply first to maternity services? (Question 2)

There were a range of responses across all groups. Whilst there was some support for restricting to maternity services initially, there was more support for testing or piloting how 'safe space' might work before rolling out across the NHS. Others wanted the prohibition on disclosure to apply to all investigations for reasons of consistency. Those who were opposed to 'safe space' in response to Q1 also replied that the prohibition should not apply in any part of the NHS.

What information should be protected from disclosure? (Question 3)

Opinions were divided about whether information generated by the investigation itself (e.g. statements, notes of interviews etc) should be protected from disclosure. Staff were broadly in favour of protecting the information listed, with the caveat that patients/families need to see all other material. Patients, their advocates, and the regulatory bodies expressed concern that it could be seen as a way of evading accountability.

Obtaining a High Court order (Question 5 and 6)

There was general support by professionals and staff for material being confidential unless disclosure was required through a High Court order. However, some concerns were raised about its impact on the principle of 'safe space'. In contrast, applying to the High Court was generally felt by patients' groups and others to be a barrier (and an expensive one) to patients' getting at the truth.

Exceptions to the 'safe space' principle (Question 6, 7 and 8)

Staff were broadly positive of the proposed exceptions to disclose information without a High Court order (eg to disclose to the police or professional regulatory bodies if there is a serious and continuing risk to patient safety). They agreed it should be modelled on the approach taken by the Air Accident Investigation Branch (AAIB). Some patients were opposed to this and expressed the need for clarity on how the investigator should make this judgment call. Patients were more concerned. Many were opposed or were not sure how the investigator can make this judgement call.

On where the bar should be set for passing on concerns to other organisations (Question 7), staff felt that this should only be where intentional or deliberate harm has been caused. Patients were mostly opposed.

Question 8 asked whether the exceptions proposed could undermine the principle of 'safe space'. Staff felt that in order to maintain the benefit of the legislation investigations should not routinely go to the High Court.

Just culture (Question 9)

The majority of respondents across all groups were supportive of the principle of a "Just Culture". Staff said that given the potential psychological impact of reporting incidents, the procedure to expose negligence or recklessness needs to be completely separate from the procedure to investigate and improve. There should be an expansion of human factors approaches in the NHS that do not punish people for making mistakes and speaking honestly about their involvement in errors in the delivery of care. Many patients were also supportive, with some highlighting the importance of open communication of pertinent information to from patients or their families.

Sharing information with patients and families (Question 10, 16 and 17)

Staff and organisations were generally supportive of allowing disclosure of information to patients and families - that families should be informed about why the incident happened. They should be made aware of its root cause e.g. systems failure, individual human error. Patients and families were strongly in favour of disclosing information to the patients/families concerned and that patients and families should be involved throughout and have access to all the material, so that they can challenge it.

Impact on other processes (Questions 11)

On requiring investigatory bodies to apply to the High Court to gain access to information obtained during 'safe space' investigations, staff views were mixed. Some preferred full disclosure, not subject to a High Court order; others saw the need for non-disclosure as key to

preserving the 'safe space' necessary for learning and some were concerned that it would create a vast new legal industry.

Patients and their groups were less in favour: they were concerned that this could impede the uncovering of the truth, or add to the feeling of a cover up culture; and shared concerns about the risks of creating a whole new legal industry in satellite litigation.

There was agreement that 'safe space' should operate separately from existing processes such as professional regulation by the GMC and NMC.

Use of 'Safe Space' (question 12)

Staff were largely in favour of the phrase 'safe space' and felt that it describes what they want it to be and found the words reassuring. It was recognised that 'safe space' alone may not create the conditions of psychological safety. Patients' and families' views were more negative, they felt that 'safe space': describes something they don't want; misleadingly implies this will improve safety for the patient, and preferred full disclosure.

Freedom of Information/data protection regimes (Question 13)

Staff broadly agreed with the proposal to exempt information obtained during healthcare investigations from access under the Freedom of Information and data protection regimes, but some were worried that the public will take a lot of persuading to trust the process; others saw the value in replicating the AAIB approach. Patients supported the proposal, as long as the safety investigation report includes everything that should be of interest to the wider public; but others preferred to maintain protections of Freedom of Information and Data Protection.

How should the creation of a 'safe space' be supported? (Questions 14 and 15)

Both groups recognised the role of HSIB in raising the standard of investigations generally and felt that current investigatory practice very much needs to be improved first. Staff agreed that additional guidance would be helpful. Patients also stressed the need to tackle the cover up culture in the NHS and that more needs to be done to support whistleblowers; and that patients and families also need support.

Impact of proposals under the Equality Act 2010 and on families (Question 16 and 17)

Staff felt that some help or adjustment might be needed for vulnerable groups. There were concerns that this will make the search for justice more difficult for patients and families, particularly the cost of the increased litigation. There should be high levels of openness and transparency about information that can be shared with families to avoid negative impacts on families.

Annex C: List of respondents (organisations only)

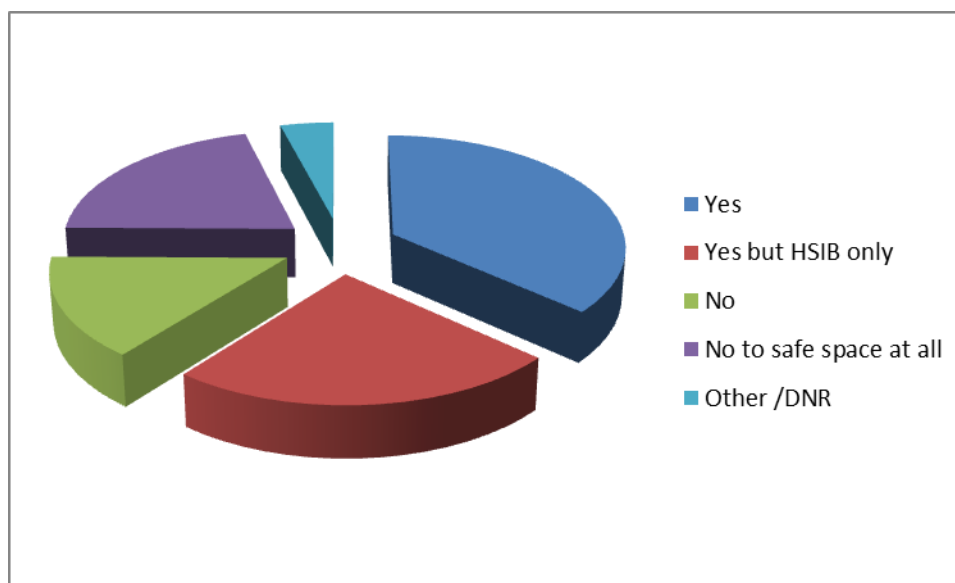
Heart of England Foundation Trust
HEE Yorkshire and Humber
NHS Hospital
Higher education institution
Kent Community Health NHS Foundation Trust
Yorkshire Housing
Homerton University Hospital
Salisbury NHS Foundation Trust
AVMA
Royal College of General Practitioners
Hugh James
Luton & Dunstable University Hospital NHS Foundation Trust
RCN Mental Health Forum, and Birmingham & Solihull Mental Health Foundation Trust
NHS England (London)
Brighton and Sussex University Hospitals NHS Trust
University College London
Leeds Teaching Hospital
Ashford and St Peter's Hospitals NHS Foundation trust
Liverpool Heart and Chest Hospital
Frimley Health NHS Foundation Trust
North East London NHS Foundation Trust
West Hertfordshire Hospitals NHS Trust
Sandwell & West Birmingham Hospitals NHS Trust
West Hertfordshire Hospitals NHS Trust
UHB NHS FT
CCSVI.org
Royal College of Physicians of Edinburgh
Sheffield Teaching Hospitals NHS Foundation trust
NELFT
Medical and Dental Defence Union of Scotland
Association of Personal Injury Lawyers
Torbay and South Devon NHS Foundation Trust
PHSO
NHS Camden CCG
News Media Association
Clinical Human Factors Group
Care Quality Commission
Kingsley Napley LLP
Royal United Hospital, Bath, NHS Foundation TRust
Wrightington, Wigan and Leigh NHS Foundation Trust
The Royal College of Anaesthetists
Leicestershire Law Society

Association of Anaesthetists of Great Britain and Ireland
Pinsent Masons LLP
Royal Free London NHS Foundation Trust
The Royal College of Surgeons of England
South Western Ambulance Service NHS Trust
Optical Confederation
Royal College of Nursing (RCN)
Royal College of Physicians (RCP)
NHS Lambeth CCG
Hundred Families
Calderdale and Huddersfield Foundation NHS Trust
Age UK
Leicester Leicestershire and Rutland CCG
Browne Jacobson LLP
Information Commissioner's Office
Mid Essex Hospitals Services Trust
The Forum of Complex Injury Solicitors (FOCIS)
Mid Essex CCG
Sands and Bliss
Newcastle Hospitals NHS Foundation Trust
DAC Beachcroft LLP
Barcan+Kirby
Mothers Instinct
Royal College of Pathologists
NHS Employers (email responses)
PACW
General Medical Council (GMC)
General Optical Council (GOC)
MPS
Professional Standards Authority (PSA)
APL
Campaign for Freedom of Information
Royal College of Pathologists
NHS Providers
Law Society
King's Fund
Royal College of General Practitioners (RCGP)
Royal College of Psychiatrists (RC Psych)
Unite the Union
Healthwatch England
Berrymans Lace Mawer LLP
PHSO
Pharmacy Voice
General Pharmaceutical Council
Cambridge University
London region Nursing and Medical Directorate
British Medical Association (BMA)
National Midwifery Council (NMC)
NHSE South Region

Family victim of MH homicide
Dorset County Hospital FT
Hundred Families
Society of Radiographers
Parliamentary Administration and Constitutional Affairs Committee (PACAC)
Patients
Families

Annex D: Breakdown of responses to first 2 questions

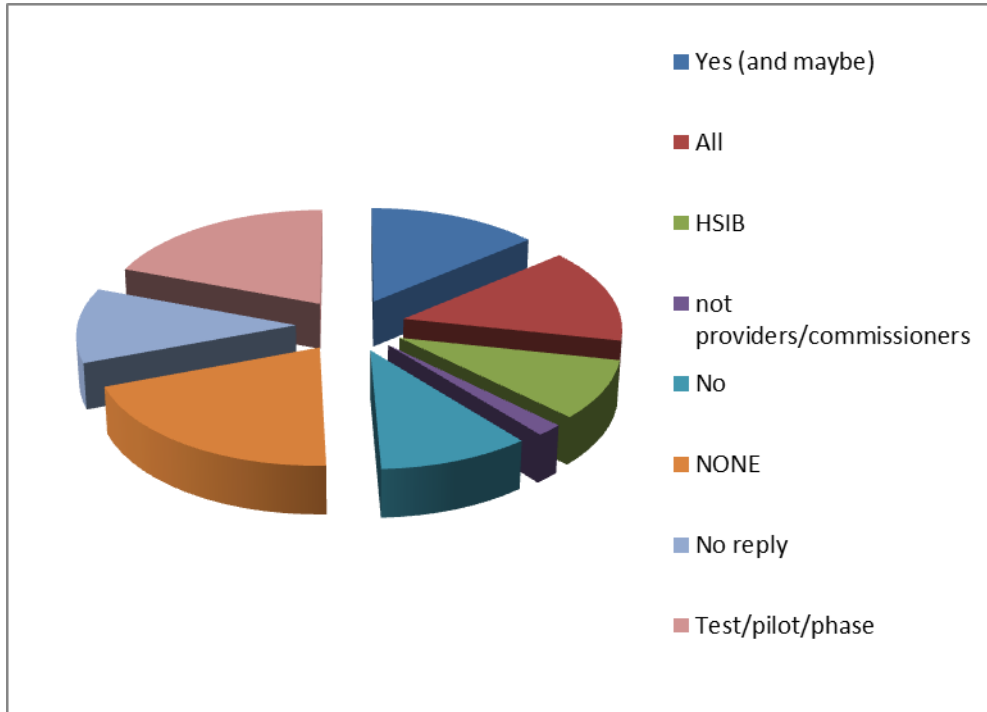
Question 1: Should 'safe space' apply to both HSIB and local NHS investigations?



Question 1: Should 'safe space' apply to both HSIB and local NHS investigations?		
Summary of responses	Numbers	% (of 145)
Yes	53	36.6
Yes but HSIB only	35	24.1
Sub-total of "Yes"	88	60.7
No	21	14.5
No to 'safe space' at all	30	20.7
Subtotal of "No"	51	35.2
Other /DNR	6	4.1
TOTAL	145	100%

* More than one response

Question 2 – start with maternity?



Question 2: Start with maternity?		
Response	Number	%
Yes (and maybe)	23	13.9
All	24	14.5
HSIB	15	9.1
not providers/commissioners	3	1.8
Subtotal of YES	65	39.3
No	17	10.3
NONE	33	20.0
Subtotal of NO	50	30.3
No reply	19	11.5
Test/pilot/phase	32	19.4
	165*	

