Department of Health

Providing a 'safe space' in healthcare safety investigations

Consultation

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Contents

1. Executive summary

1.1. It is important that we create the right conditions for staff, patients and their families, friends and carers to be able to discuss errors and problems in care explicitly and thoughtfully. Academic evidence shows there is a strong connection between 'psychological safety' and a culture of learning within an organisation[1]. In a true culture of learning, staff can feel confident they will be treated fairly, and patients and families can be assured that errors and the causes of them will be fully explored. Creating and sustaining this broader culture of psychological safety and learning is down to leaders and managers in the system. But for them to be able to do so, the Department of Health, as steward of the health system, needs to set the right conditions for such a culture to flourish.

1.2. However, recent inquiries have illustrated that staff need to feel more confident that the information they give to safety investigations, which have the sole function of learning from errors, will not be used unfairly.

1.3. It is in this context that the Department of Health has been considering ways in which to create a culture of learning by enabling staff to feel supported to openly explore what lies behind errors (and, by association, giving patients and families reassurance that they know the facts and that lessons can and will be learned). It is here that the concept of a 'safe space' comes in - a proposed statutory requirement that information generated as part of a safety investigation will be kept confidential and will not be shared outside the investigation's boundaries, except in a number of limited circumstances.

1.4. The concept was explored and laid out by the Public Administration Select Committee (PASC) in its 2015 report, '*Investigating clinical incidents in the NHS*'[2], which stated that, in order to truly create a system where investigations drive learning and improvement, any investigation carried out by the new healthcare investigation body it was proposing: *'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'*.

1.5. The view of PASC was informed, in part, on the model used by the Air Accident Investigation Branch (AAIB), where investigators are able to offer this safe space to those they speak to, thanks to the robust statutory framework in which they work, arising from regulation-making powers in primary legislation. A key aspect of this

[1] Amy Edmondson, 'Psychological Safety and Learning Behavior in Work Teams', Administrative Science Quarterly, 1999.

[2] http://www.publications.parliament.uk/pa/cm201415/cmselect/cmpubadm/886/886.pdf

statutory framework is the duty not to share information given in the course of an investigation with any other individual or body, unless there is a High Court order, or in limited circumstances allowed under the EU regulation (ie, where there is evidence of criminal activity).

1.6. In March 2016 the Rt Hon Jeremy Hunt, Secretary of State for Health, outlined his intention to bring forward measures in this area. In this consultation, the Department of Health is seeking views on the creation of a statutory 'safe space' in healthcare safety investigations, modelling the approach of the AAIB. This consultation is issued on behalf of the Department of Health in England and the proposals would apply in the NHS in England. It seeks comments and views on the policy outlined in this document.

2. Introduction

2.1. If we want to achieve the ambition of the NHS becoming the world's largest learning organisation, staff must be empowered and feel able to challenge, learn and improve. This must be ingrained in the culture of the NHS.

2.2. There is a body of evidence to indicate that there is a gap between this culture we would expect to exist in the NHS and the one which does, as well as a gap between how investigations into errors should be carried out and how they are. There is variation across the health system in both aspects - providers do not consistently undertake investigations into serious incidents, and, if investigations are undertaken, the lessons of these are not always learned. At worst, they can be used erroneously to attribute blame.

2.3. Organisations need to demonstrate that they learn when things go wrong. This is already tested by the Care Quality Commission, which when inspecting providers looks at whether investigations are carried out when things go wrong, whether staff and people who use services are involved in the review or investigation, and whether lessons are learned and shared.

2.4. However, many believe that the creation of a type of 'strong wall' around certain health service investigations, so that information given as part of an investigation would only rarely be passed on, would provide a measure of 'psychological safety' to those involved in investigation, allowing them to speak freely. This will enable lessons to be learned, driving improvement and ultimately saving lives.

2.5. The proposal outlined in this consultation is to create a statutory prohibition on the disclosure of material obtained during certain health service investigations unless the High Court makes an order permitting disclosure, or in a limited number of other circumstances. This broadly mirrors the regime followed in the area of air accidents investigations.

2.6. However, there are challenges to creating this statutory 'safe space'. As we will see, some of these are cultural - particularly how can a safe space be implemented effectively in a system which has so much inherent variation. Other barriers are legislative as other organisations and individuals have statutory powers to call evidence. Creating a safe space is also a difficult balance to achieve - how can you, on one hand, reassure staff the information they give will not be passed on while also reassuring patients and families that they have the full facts of their, or their loved ones', care.

3. The case for creating a safe space

The context

3.1. One of the running themes through recent inquiries and investigations in healthcare - such as Mid-Staffordshire, Winterbourne View and Morecambe Bay – is a perceived or actual lack of openness. In healthcare it has sometimes been demonstrated by individual clinicians not being open about failings of care but, more often, organisations themselves having a closed culture which does not promote openness and honesty. In the most extreme cases a culture of fear pervaded organisations, as described by then Secretary of State for Health Andrew Lansley when he announced the Mid Staffordshire NHS Foundation Trust Public Inquiry:

> *'a culture of fear in which staff did not feel able to report concerns; a culture of secrecy in which the trust board shut itself off from what was happening in its hospital and ignored its patients; and a culture of bullying, which prevented people from doing their jobs properly'.*[3]

3.2. Since the publication of Sir Robert Francis QC's Inquiry report, much of the work around improving quality in healthcare has therefore been aimed at promoting a culture of openness, as well as focussing on regulation and structures – for example changes to the Care Quality Commission and the creation of NHS Improvement. This work has included the creation of a statutory Duty of Candour for organisations which came into force for NHS bodies in November 2014. It also includes a professional duty, introduced by the General Medical Council and the Nursing and Midwifery Council, so that action can be taken when healthcare professionals are not candid about errors with their patients. In addition a new criminal offence of providing false or misleading information was introduced on 16 April 2015 which applies to NHS Trusts, NHS Foundation Trusts and independent providers of secondary care services delivering NHS funded care.

3.3. During the current Parliament, the Government has led work looking at the importance of openness and honesty in promoting a learning culture within the NHS. This was prompted, in part, by the PASC report *'Investigating clinical incidents in the NHS'* [4] which looked at the quality of investigation in the NHS and concluded there is significant variation in the way NHS providers handle serious incidents, including what prompts a decision to investigate, the way the investigation is conducted, the timeliness of the investigation and the way patients and families are engaged in the process. One

[3] Hansard, 9 June 2010, Column 333

[4] http://www.publications.parliament.uk/pa/cm201415/cmselect/cmpubadm/886/886.pdf

specific criticism was that, even if an effective investigation was undertaken, the findings were not learnt from either locally or more widely.

3.4. In *Learning not Blaming*[5], the Government response to the PASC report, the Freedom to Speak Up report and the Morecambe Bay Investigation, the Government accepted the PASC recommendation to establish a new independent patient safety investigation branch to conduct investigations in the NHS. The Government concurred that there should be a capability at national level to offer support and guidance to NHS organisations on investigation, and to carry out certain investigations itself. One of the aims of this would be to promote a culture of learning and a more supportive relationship with patients, families and staff.

3.5. In Summer 2015 the Department established an independent Expert Advisory Group (EAG) to advise the Secretary of State. This Group has concluded its work and its advice was published in May 2016[6]. Following this, the Department of Health has taken steps to establish a new investigatory body of the kind referred to in the PASC report. This is the Healthcare Safety and Investigation Branch ('HSIB'), which is in the process of being established by the NHS Trust Development Authority pursuant to Directions given to it by the Secretary of State under section 7 of the National Health Service Act 2006 on 24th March 2016 and which came into force on 1st April 2016[7].

3.6. A positive culture is one in which staff feel empowered to speak up, and one where they believe they will be listened to. It is critical that this culture is one created and sustained by leaders and managers.

3.7. As we will see, one of the conclusions of these recent pieces of work is that staff need to feel more confident that the information they give to safety investigations, which have the sole function of finding fact to identify learning, will not be used inappropriately for other purposes. While some of this is down to leaders creating a culture which learns from mistakes rather than seeking to attribute blame, it is argued that there is also a place for creating a statutory 'safe space' for investigations which can offer additional reassurance and help support a learning culture.

Why is this being proposed?

3.8. Staff should be able to discuss errors and problems in care explicitly and thoughtfully. Academic evidence shows there is a strong connection between ‘psychological safety’ and a culture of learning within an organisation. This is particularly important when it comes to clinical errors, because, as Matthew Syed and others have shown, the

[5] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/445640/Learning_not_blaming_acc.pdf

[6] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/522785/hsibreport.pdf

[7] https://www.gov.uk/government/publications/nhs-trust-development-authority-directions-2016

tendency to look up to clinicians as heroic figures makes it hard for us (and for them) to make sense of clinical mistakes[8]. The work of Amy Edmondson (a Harvard management expert) and others has shown how teams learn most effectively under conditions of psychological safety (defined as a 'shared belief that the team is safe for interpersonal risk taking' and that the team will not 'embarrass, reject, or punish someone for speaking up').[9]

3.9. Creating and sustaining this broader culture of psychological safety and learning is down to leaders and managers in the system. By doing so staff can feel confident they will be treated fairly, and patients and families can be assured that errors and the causes of them will be fully explored.

3.10. However, many feel that this culture is not one which exists universally in the health system. Sir Robert Francis QC, in his Freedom to Speak Up report[10], concluded:

> *'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'.*

3.11. Evidence from the 2015 national NHS staff survey reinforces the point: in response to the proposition 'My organisation treats staff who are involved in an error, near miss or incident fairly' the agree / strongly agree figure is only 43% for all organisations (with 30% at neither *agree* nor disagree). This might suggest that even if justice is being done in respect of many people raising concerns, it is not being seen to be done. Earlier surveys also directly address the questions of learning and blame. In response to the statement 'My organisation blames or punishes people who are involved in errors, near misses or incidents' the split is as follows for acute Trust staff: 10% strongly disagree, 33% disagree, 44% neither agree nor disagree 11% agree and 2% strongly agree. Given the strength of the wording ('blames or punishes') these are not encouraging figures[11].

3.12. Evidence shared with PASC[12] showed that patients and families, who have already been harmed by an incident, have their distress heightened by entering into the complaints *process* (a route which many do not want to pursue, but feel they must in order to ascertain what went wrong with care and how it can be avoided in future.) The

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[8] Matthew Syed, *Black Box Thinking*

[9] Amy Edmondson, 'Psychological Safety and Learning Behavior in Work Teams', Administrative Science Quarterly, 1999.

[10] http://webarchive.nationalarchives.gov.uk/20150218150343/https:/freedomtospeakup.org.uk/

[11] http://www.nhsstaffsurveys.com/Page/1010/Home/NHS-Staff-Survey-2015/

[12] http://www.publications.parliament.uk/pa/cm201415/cmselect/cmpubadm/886/886.pdf

Committee heard that many feel vulnerable and fearful, including fears of being labelled as the 'difficult patient' and how this may affect their interactions with healthcare staff.

3.13. The EAG considered these shortcomings in its report[13], which concluded that investigations *were* often of variable or poor quality, conflated efforts to learn with allocating blame, and were poorly resourced. The report stated:

> *'Health service staff are also let down by poor quality investigations, and the prevalent conflation with blame-seeking leads to suspicion of the process and fear of the consequences.'*
>
> *'Patients, families and the public are too often let down by poor investigations, and the result is significant further distress on top of the harm caused by the events themselves.'*

3.14. It also concluded that securing the trust and confidence of healthcare professionals depends on establishing a 'just culture', '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'.

3.15. It is therefore clear that action needs to be taken to address what lies at the root of the issue - the concerns some staff have about how they are treated when things go wrong. Doing so will reinforce the creation of 'psychological safety' and a learning culture by enabling staff to feel supported to openly explore what lies behind errors (and, by association, giving patients and families reassurance that they know the facts and lessons can be learned). It is here that the concept of a 'safe space' comes in - the creation of an obligation to keep confidential information that is generated as part of an investigation, except in limited circumstances. The creation of this 'safe space' will complement and mutually reinforce a culture of learning (but it is important to remain clear that it cannot replace or be a substitute for the broader need for leaders and managers to promote this culture in the first place).

3.16. The concept of a 'safe space' for those involved in healthcare safety investigations was explored and laid out by PASC in its 2015 report. This stated that, in order to truly create a system where investigations drive learning and improvement, any investigation carried out by the new healthcare investigation body: '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 view was based on a

[13] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/522785/hsibreport.pdf

volume of evidence heard by the Committee that staff involved in incidents did not feel they could speak freely and in fact were fearful of doing so. The Secretary of State for Health told the Committee that: 'too many doctors, nurses and midwives think that, if they are found responsible for a death or a serious incident, they will be fired'. He said that 'the culture that we need is, 'If you do not tell the truth and help us to understand what happened, then you will be fired.'"[14] Dame Julie Mellor, the Parliamentary and Health Service Ombudsman, felt that a "safe space" was needed: "If you create that safe space to get at the facts of what happened and why, that is how we will get a learning culture."[15]

3.17. The view of PASC was informed, in part, by the model used by the Air Accident Investigation Branch, where investigators are able to offer this safe space to those they speak to, thanks to the robust statutory framework in which they work, arising from regulation-making powers in primary legislation. A key aspect of this statutory framework is the duty not to share information given in the course of an investigation with any other individual or body, unless there is a High Court order. In evidence, Keith Conradi, then Chief Investigator of the Air Accident Investigation Branch and who will take up the post of Chief Investigator of the Healthcare Safety Investigation Branch in the Autumn described how this enabled them to undertake effective investigations which fuelled learning. He said:

> *'People … have seen that, actually, we do hold that information confidentially. We do not release it and they can see that the output is purely safety recommendations back to the industry. Although there is an allowance for the co-ordination in investigations with other parties, they are very much separate'.*
>
> *'The perception and the reality of separation are all-important, and that is why we go to great lengths to actually make sure that we are completely separate from that type of investigation'.*
>
> *'It is a core part of what we do that actually people will open up to us, whereas perhaps they would be more reserved if they felt that there may be some incrimination that would come across if they said other things'.*

3.18. The Public Administration and Constitutional Affairs Committee (PACAC - formerly PASC) reinforced the point in a follow-up report PHSO Review: Quality of NHS complaints investigations[16], published in June 2016. The report also reiterated the

[14] http://www.publications.parliament.uk/pa/cm201415/cmselect/cmpubadm/886/886.pdf

[15] http://www.publications.parliament.uk/pa/cm201415/cmselect/cmpubadm/886/886.pdf

[16] http://www.publications.parliament.uk/pa/cm201617/cmselect/cmpubadm/94/94.pdf

Committee's view that it was essential that the principle of safe space be backed with primary legislation. The report stated:

> *'We regard the 'safe space' principle as being critical to the effective operation of HSIB. This protection is essential if patients and staff are to have the confidence to speak about the most serious risks to patient safety without fear of punitive reprisals. Its importance is underlined by the work of the Air Accidents Investigation Branch on which HSIB is modelled. In the Committee's view, the only way to effectively establish this 'safe space' is for the Government to bring forward primary legislation that will guarantee its inviolability'.*

3.19. The recommendations of the EAG also included the provision of a safe space. The relevant recommendation stated:

> *'We believe that, as part of the Branch's legislative base, there must be statutory protection of safety information provided to investigators solely for the purposes of safety investigation, to ensure that this information is not made available to other bodies.'*[17]

3.20. The view of the EAG was that this 'safe space' should not be absolute and there were occasions that it should not be enforced. One of these was where there was an immediate risk to patient safety, at which point the relevant bodies should be informed. It stated:

> *'We stress also that, should concern arise during a safety investigation over potential intentional wrongdoing, gross negligence, or other concerns that constitute an immediate danger to present or future patients, this would be notified to the relevant bodies for them to conduct their own investigation. 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.*

3.21. The EAG's report was equally clear that the provision of a safe space should not cut across the rights of patients and families to receive information about their or their loved ones' care. It stated:

> *'The Branch must provide families and patients with all relevant information relating to their care, reflecting the responsibilities of healthcare providers to uphold the duty*

[17] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/522785/hsibreport.pdf

of candour. To ensure the continued provision of safety information and the confidence of healthcare professionals, all other evidence collected solely for the purposes of safety investigation will be protected and will not be passed to any other body or be admissible as part of another body's proceedings, other than when required on the instruction of a court of law'.

What we have learnt so far

3.22. As part of the process of setting up the HSIB, the EAG undertook a programme of engagement. While this was focused on a number of issues, one of the clear messages heard during the process was that, for investigations to effectively drive learning, those involved in them need to feel they can safely speak up about failures of care. It was also clear that many clinicians, patients and families do not feel that this 'safe space' exists in investigations in the NHS. The evidence heard by the EAG in relation to safe space and promoting a learning culture is outlined below.

A focus on learning

3.23. There was a strong view from both staff and patients that removal of the 'blame culture' was important in facilitating learning and a desire to improve. An acceptance that people make mistakes would support a culture of learning. While the focus must be on learning, accountability was important and 'shouldn't be a dirty word'. Therefore, if during the course of an investigation, there is reliable evidence of deliberate harm, the appropriate authority should be informed. One participant contributed the following to the EAG's engagement exercise:

"The elephant in the room needs to be faced. Where senior staff, including board members, have lied, covered up, victimised whistleblowers and obstructed proper investigation, they are blameworthy and need to be held to account. People should not be blamed for genuine mistakes."

The impact of investigation on staff

3.24. The impact of blame on individuals was articulated by staff who said the investigation process is often seen with fear and mistrust, and individuals who provide evidence don't feel safe. They reflected that staff felt deep pain and fear when something went wrong and more compassion was needed rather than a 'witch hunt'.

'When something goes wrong people are accusatory, there is no support whatsoever for the staff, the individuals are bombarded with questions at a really stressful time and it is traumatising'.

'Most people make an error for which they're desperately sorry. How do you reach out and convince them that this is their opportunity to be open when a mountain of evidence tells them not to.'

'To be on the receiving end of an investigation is horrible; it cuts to the core of your professional being. Your professional self and reason for being is questioned. It affects your gut and your head'.

'When things go wrong sometimes a 'shield' goes up and hides the inner compassionate core of the healthcare workers involved.'

'A safe space is critical for learning from investigations to occur. A safe space with forgiveness.'

'There is a strong, compelling desire to tell the truth and to admit everything but to do this in a way that is a safe conversation. However, given how people are currently treated this is met with intense fear 'what is going to happen to me if I do'.'

Family involvement and sharing of information

3.25. While many of those who participated in the engagement accepted the need to create a safe space for those involved in investigations, many were concerned that this would cut across the rights of families and patients to get information about their or their loved ones' care. Staff said that patients felt cut out of the process of investigations and were fearful of 'cover ups'.

'The format is not patient friendly; patients feel that there is cover up of evidence and have experience of the withholding of information.'

'No trust at all in the current process and a real lack of care shown towards those investigated'.

3.26. Indeed, patients were more strongly in favour of HSIB having legislative independence from the NHS than staff members were, due to an apparent lack of trust in the healthcare system. The majority of staff felt that independence from the trust being investigated would suffice in order to ensure an independent investigation.

'To be a totally independent body which can't be leant on by politicians or people running the NHS or trusts'

'Patients & family would trust outcomes better if they knew their investigation wasn't being overseen or coerced by trust management.'

3.27. Removal of the 'blame' culture was important to both staff and patients in order to facilitate learning and a desire to improve. Both staff and patients stressed that patients and their families should be at the heart of HSIB and any investigative process it undertakes. However, they also noted that it was crucial to make staff feel safe to participate in the process too. Patients asked that HSIB try to change the way that complainants are perceived, i.e. as 'troublemakers' or 'sensitive', and remove the fear of raising complaints.

3.28. While supporting the fair treatment of staff taking part in investigations, the charity Action Against Medical Accidents (AvMA) felt that it would be inappropriate to place any restriction on the ability of patients/their family's ability to access and use information about their own treatment in the way they see fit.

3.29. 122 respondents to the EAG's call for evidence felt that there should be either legal powers or legislation for the immunity of those giving evidence. However, it was generally felt that any immunity granted should not necessarily extend to everything – ie if there was criminal negligence admitted for an avoidable death then the person/trust involved should still be prosecuted.

How safety investigation fits with other processes

3.30. In terms of sharing information on patient safety investigations with other organisations, most respondents to the EAG's Call for Evidence felt that anonymity would be vital unless patient and staff agreed for it to be waived or it was a matter of patient safety.

3.31. Some felt that publishing details of failings would be detrimental, as staff involved may have often already left and problems been addressed, so restricting the information to lessons learned maybe preferable,

3.32. There were questions about the legal and ethical parameters in which any sharing of information can happen – both with other organisations and publically. One respondent said:

'preferable if the initial presumption was that IPSIS[18] should not share information or place it in the public domain unless there is a clear public interest to do so and that such sharing or publication is consistent with the law and any relevant ethical considerations.'

[18] Note - the initial name of HSIB was the Independent Patient Safety Investigation Service (IPSIS).

3.33. A lot of the responses felt aligning processes with those of other bodies in the health and care system was either essential or required in specific circumstances for example sharing information with regulators, both in terms of existing systems (national reporting systems etc.) and findings, in order to reduce further incidents.

3.34. Relationships between HSIB and different organisations in the health and care system were deemed useful by both staff and patient groups, but only as long as they added value to HSIB's investigations.

4. The current position

How investigations are undertaken in the NHS

4.1. To understand the need for the creation of a 'safe space' in healthcare investigations, we must explore what currently exists - or does not exist - and where the shortfalls in the system are.

4.2. The process for investigations in the NHS is laid out in the Serious Incident Framework[19], with detailed guidance and tools[20]. All serious patient safety incidents are supposed to be investigated, with guidance on what constitutes a serious incident being laid out in the Framework. According to the Serious Incident Framework investigations into serious incidents can be:

- undertaken by healthcare providers;
- commissioned by healthcare providers;
- commissioned by local healthcare commissioners (ie. Clinical Commissioning Groups);
- commissioned by the national healthcare commissioner (ie. NHS England).

4.3. The nature, severity and complexity of serious incidents vary on a case-by-case basis and therefore the level of response should be dependent on and proportionate to the circumstances of each specific incident. The level of investigation may need to be reviewed and changed as new information or evidence emerges as part of the investigation process. Within the NHS there are three recognised levels of systems-based investigation (currently referred to as Root Cause Analysis investigation), summarised in the table below.

Level	Application	Product/Outcome	Owner
1. Concise internal investigation	Suited to less complex incidents which can be managed by individuals or a small group at a local level	Concise/ compact investigation report which includes the essentials of a credible investigation	Provider organisation (Trust Chief Executive/relevant deputy) in which the incident occurred, providing principles

[19] https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2015/04/serious-incidnt-framwrk-upd2.pdf

[20] http://www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/

			for objectivity are upheld
2. Comprehensive internal investigation (this includes those with an independent element or full independent investigations commissioned by the provider)	Suited to complex issues which should be managed by a multidisciplinary team involving experts and/or specialist investigators where applicable	Comprehensive investigation report including all elements of a credible investigation	Provider organisation (Trust Chief Executive/relevant deputy) in which the incident occurred, providing principles for objectivity are upheld. Providers may wish to commission an independent investigation or involve independent members as part of the investigation team to add a level of external scrutiny/objectivity
3. Independent investigation	Required where the integrity of the investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective investigation internally due to the size of organisation or the capacity/ capability of the available individuals and/or number of organisations involved	Comprehensive investigation report including all elements of a credible investigation	The investigator and all members of the investigation team must be independent of the provider. To fulfil independency the investigation must be commissioned and undertaken entirely independently of the organisation whose actions and processes are being investigated

4.4. Within the NHS, most serious incidents should be investigated internally using a comprehensive investigation approach. Independent investigations are undertaken, for example, where the provider is unable to conduct an effective, objective, or timely investigation, or where the incident in question represents a significant systemic failure, and/or where full independence is required to ensure public confidence in the findings.

Independent investigations must be commissioned by CCGs or NHS England. The latter has responsibility, for example, for commissioning an investigation when a homicide has been committed by a person who is, or has been, subject to a care programme approach, or is under the care of specialist mental health services, in the past six months prior to the event. Comprehensive internal investigations are undertaken by, or commissioned by, providers. The Serious Incident Framework is not on a statutory footing. However, there is an obligation on providers to pay heed to it in the NHS Standard Contract, which applies to acute, community, mental health and ambulance providers.

4.5. The Serious Incident Framework states that serious incident investigations are for learning purposes only, but does not explicitly provide for a 'safe space'. However, it is clear that: 'The needs of those affected should be a primary concern for those involved in the response to and the investigation of serious incidents. It is important that affected patients, staff, victims, perpetrators, patients/victims' families and carers are involved and supported throughout the investigation'. It also states that the provider organisation should be clear with staff that the investigation is separate to any legal or disciplinary process, that there should be zero tolerance for inappropriate blame or being 'unfairly exposed to punitive disciplinary action, increased medico-legal risk or any threat to their registration by virtue of involvement in the investigation process'.

4.6. However, while this is the framework within which investigations should operate, as we have seen in Chapter 3, in reality, investigations often do not meet the ideals laid out on the Serious Incident Framework and - as the EAG's report stated: *'there is a range of shortcomings in the existing response to adverse events across the healthcare system'*.[21]

The Healthcare Safety Investigation Branch

4.7. In July 2015, the Secretary of State announced that he wanted to create an independent patient safety investigation service, building on the recommendations of the PASC report. The Healthcare Safety Investigation Branch is in the process of being established by NHS Improvement, pursuant to Directions given to it by the Secretary of State under section 7 of the National Health Service Act 2006 ('the HSIB Directions')[22]. Keith Conradi, currently head of the Air Accidents Investigation Branch, will head up the branch and is expected to be in post by the Autumn. Once the Chief Investigator is in post he will be able to develop an operating model in accordance with the HSIB Directions. Paragraph 6 of the Directions provides that, for the purposes of that

[21] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/522785/hsibreport.pdf

[22] https://www.gov.uk/government/publications/nhs-trust-development-authority-directions-2016

paragraph, 'safe space principle' refers to the principle that, in the view of the Secretary of State:

- the Investigation Branch's function of providing findings, analysis and, where appropriate, recommendations pursuant to paragraph 5, is best informed by comprehensive and candid contributions from those whose actions come under consideration in the course of an investigation, bearing in mind the provisions in paragraph 5(3) and (4)(b);
- contributions that are comprehensive and candid are more likely to be made where they may be made in the confidence that they will be used not for purposes of apportioning blame or establishing liability but for purposes of identifying improvements or areas for improvement, if any, which may be made in patient safety in the provision of services as part of the health service or the conduct of other functions for purposes of the health service, and making recommendations in relation to such improvements; and
- unless there is an overriding public interest or legal compulsion, disclosures for purposes other than making recommendations as described in paragraph (b) of material gathered by the Investigation Branch should accordingly be avoided so as to preserve the confidence in the Investigation Branch's investigatory and reporting process of those whose contributions may be relied on for purposes of current and future investigations.

4.8. Paragraph 6(4)(h) provides that the Chief Investigator of the HSIB 'must provide information when required by a Court Order or as a matter of statutory requirement, but except as provided for in paragraph (b) (which deals with disclosure to patients and their families/representatives), in the absence of an overriding public interest, must otherwise seek to avoid voluntary disclosures of material gathered by the Investigation Branch'.

4.9. The Directions cannot amend or modify the application of existing legislation, and cannot require third parties seeking disclosure to apply to a particular court, nor for that court to follow a specific test in considering applications.

Other types of investigation

4.10. Part of the rationale of creating a statutory 'safe space' is the complex picture of individuals and bodies which conduct other types of investigation and what their powers to compel information are. Safety investigations conducted under the Serious Incident Framework (and those which will be undertaken by HSIB) operate within a complex system where a variety of other types of investigation operate with the aims of promoting patient safety, holding professionals to account and protecting the public. These investigations do not offer a statutory 'safe space' to staff.

4.11. Many of those organisations or individuals conducting investigations have statutory powers. It could be that safety investigations undertaken in the system or by HSIB could be running in parallel with these investigations, before them or subsequently. As will be explored below, all the investigations have different methodologies and aims.

Professional regulators

4.12. Regulatory bodies protect the public by ensuring that all who practise a health profession are doing so safely. Legislation has established nine independent health professional regulatory bodies including the General Medical Council (GMC) which regulates doctors in the UK and the Nursing and Midwifery Council (NMC) which regulates nurses and midwives in the UK. Regulatory bodies have the power to carry out four main functions:

- setting standards that professionals need to follow and continue to meet throughout their career and overseeing education and training;
- taking action when professionals are not fit to practise and pose a risk to the public or confidence in the profession for example because of poor health, misconduct or poor performance including removing them from the register and preventing them from practising;
- keeping registers of health professionals who are fit to practise in the UK.

4.13. All healthcare regulatory bodies have legal powers to enable them to take action where there is evidence that it is necessary to remove or restrict a healthcare professional's right to practise. Once a concern is raised about an individual the regulatory body will decide whether to carry out an investigation. In the case of the GMC for example this will include a disclosure of the complaint by the GMC to the doctors and his/her employer/sponsoring body, where the doctor will be given an opportunity to comment on the complaint. How the investigation is carried out will depend on the nature of the concerns raised. An investigation can include:

- obtaining further documentary evidence from employers, the complainant or other parties;
- obtaining witness statements;
- obtaining expert reports on clinical matters;
- an assessment of the doctor’s performance;
- an assessment of the doctor’s health.

4.14. An investigation can result in a number of outcomes which are related to the individual practitioner rather than the organisation. For example, if the GMC feels there is a realistic prospect of establishing that a doctor’s fitness to practise is impaired, the doctor

will be referred for a medical practitioners tribunal hearing. If this tribunal concludes that a doctor's fitness to practise is impaired it may take no action, accept undertakings offered by the doctor provided the tribunal is satisfied that such undertakings protect patients and the wider public interest, place conditions on the doctor's registration, suspend the doctor's registration or erase the doctor's name from the medical register, so that they can no longer practise.

Coroners and medical examiners

4.15. At present, deaths that appear violent or unnatural, the cause of death is unknown, or the person died in prison, police custody, or another type of state detention, are investigated by a coroner. For all other deaths, doctors determine the cause of death, where to the best of their knowledge and belief, the deceased died from a known and natural disease or condition and there are no unusual circumstances. A coroner is an independent judicial office holder, appointed by a local authority, following Chief Coroner and Lord Chancellor consent. Coroners usually have a legal background but will also be familiar with medical terminology. Coroners investigate deaths that have been reported to them if it appears that the death was violent or unnatural, the cause of death is unknown, or the person died in prison, police custody, or another type of state detention. In these cases coroners must find out, for the benefit of bereaved people and for official records, who has died and how, when, and where they died.

4.16. In the current system, if a death is regarded as natural and the coroner is not invited to investigate, an attending doctor completes a Medical Certificate of Cause of Death (MCCD) that allows bereaved people to register the death and arrange the funeral.

4.17. The murders committed by Dr Harold Shipman highlighted flaws in the current system of requiring independent investigation into deaths only where a case is reported to a coroner. This system does not provide safeguards against doctor, nurse or system failure or malpractice as there is no requirement for independent scrutiny of the cause of every death, the care provided nor the treatment received. Nor does it provide opportunities for learning if unusual patterns of deaths fail to be noticed or reported.

4.18. Reforms to the death certification process for England and Wales were proposed in 2003 in the Shipman Inquiry's third report. More recently, the Francis Inquiry strongly supported the introduction of medical examiners to the process of death certification. The Coroners and Justice Act 2009 provides the legal basis for implementing the changes and the Department of Health is in the consultation phase for implementing the medical examiner system.

4.19. For the new system, every death in England and Wales will be either scrutinised by a medical examiner (ME) or investigated by a coroner, with input from the bereaved invited in every case. The new ME service will aim to provide assurances and

safeguards to bereaved people, reduce bureaucracy and make the process simpler and more open. It will improve the accuracy of death certification to allow public health improvements based on more reliable data. It will ensure more appropriate referral of deaths to the coroner, avoiding unnecessary coronial investigations. And it will deliver better feedback to healthcare services that need to improve, because observations made by a ME during scrutiny of a death will be reported to the local clinical governance team for more rapid changes locally and learning from errors and poor practices.

4.20. MEs will be experienced and currently practising doctors, appointed to scrutinise the cause of every death where a coroner does not investigate. The ME will examine the relevant medical records that helped the doctor to establish a cause of death and will speak to a member of the family, specifically asking whether they have any concerns about the care provided. Neither of these safeguards occurs in every case at present. The ME will discuss the death with the doctor who completes the MCCD and may examine or request a non-forensic external examination of the body. Only after the medical examiner is satisfied the death was natural can the MCCD be finalised (or the death be reported to a coroner), the death registered and the funeral go ahead.

4.21. Scrutiny by an ME or investigation by a coroner will encompass all deaths that occur in care establishments, hospital environments and any other institution, as well as in the community.

Criminal and civil actions

4.22. Criminal investigations are the responsibility of the police and the Health and Safety Executive, and the decision to press charges is made by the Crown Prosecution Service. Primary legislation (mostly the Police and Criminal Evidence Act 1984, as well as others), case law, and the Criminal Procedure Rules collectively govern evidence in criminal matters, including the police's powers to collect evidence.

4.23. Civil claims are brought by individual patients (or their families) and are governed by the Civil Procedure Rules together with case law. Both the rules and the case law provide for Court Orders enabling a litigant to gather evidence.

4.24. The police in England and Wales may obtain a warrant from a magistrate in relation to indictable offences if the material sought does not consist of certain protected categories of material (section 8 of the Police and Criminal Evidence Act 1984 (PACE)). These protected categories include excluded and special procedure material. “Special procedure material” includes material held on an express or implied undertaking to hold it in confidence or which is subject to a restriction on disclosure contained in any enactment, and which has been acquired or created by the holder in the course of (inter alia) any paid office (section 14). “Excluded material” includes material of that description which consists of personal data about an identifiable individual’s physical or

mental health (section 11, as read with section 12). For material in these two classes, section 9 of PACE requires application to be made to a circuit judge under Schedule 1 to the Act. The application need not be on notice in the case of these two categories of material[23]. The tests that must be satisfied before an order to produce the material can be made are set out at paragraphs 2 and 3 of Schedule 1.

4.25. In addition to their powers to obtain a warrant to enter premises and seize evidence, the police in England and Wales also have general powers of seizure when lawfully on any premises. In section 19(3) of PACE, a constable may seize anything on the premises if he has reasonable grounds for believing that it is evidence in relation to an offence and it is necessary to seize it in order to prevent the evidence being concealed, lost, altered or destroyed. Under subsection (4), on the same grounds, the constable may require electronic information to be produced to him in a form suitable for taking it away from the premises. Only legally privileged material is exempted from these powers.

Public Inquiries

4.26. Similar provisions apply in relation to statutory inquiries under the Inquiries Act 2005, Chairmen have powers, by notice, to require disclosure of documents and other evidence. Like the coroner, the recipient of a notice may seek to resist the obligation to disclose or produce if he is unable or it is not reasonable to require compliance. The chairman decides the matter, applying a test similar to the coroner's: "…the chairman must consider the public interest in the information in question being obtained by the inquiry, having regard to the likely importance of the information."

How information is currently shared across the system

4.27. While the landscape of investigation is complex, that of information sharing is equally if not more so, with a number of processes in place which require or encourage the sharing of information across organisational boundaries.

4.28. Serious incidents must be notified without delay (or within specified timescales) to all relevant bodies via the appropriate routes. Where a serious incident indicates an issue/problem that has (or may have) significant implications for the wider healthcare system, or where an incident may cause widespread public concern, the relevant commissioner (i.e. lead commissioner receiving the initial notification) must consider the need to share information throughout the system i.e. with NHS England Sub-regions and Regions and other partner agencies as required. This is a judgement call

[23] Schedule 1, paragraphs 7 to 10 require applications in relation to journalistic material (as defined) to be made on notice. Paragraph 11 indicates that the applicant may apply on notice in respect of the other categories.

depending on the nature of the incident, although the scale of the incident and likelihood public concern will be a significant factor in deciding to share information.[24]

4.29. Depending on the nature of the incident this may include bodies such as the Care Quality Commission, the Health and Safety Executive, the Coroner, professional regulators, local authorities, NHS Improvement, Health Education England (HEE), Public Health England (PHE), the police, and the Medicines and Healthcare Products Regulatory Agency (MHRA). Appendix 2 of the Serious Incident Framework sets out how information on patient safety incidents should be shared across the healthcare system. For example, commissioners should be notified of serious incidents no later than two working days after the incident is identified.[25]

4.30. If grounds for professional misconduct are suggested it is important that the appropriate lead (e.g. the Responsible Officer/Medical or Nursing Director) within the provider organisation is alerted (within 2 days) to ensure that appropriate action is taken as and when required. Appropriate action includes the investigation and/or HR team taking time to carefully assess or refer on to experts the actions or omissions in question, within the context of the incident, to identify whether these are considered reckless or malicious, as opposed to slips, lapses, or a situation where there are others routinely taking the same route or in need of similar levels of support, supervision or training. [26]

4.31. A serious incident investigation concludes with an investigation report and action plan. This needs to be written as soon as possible and in a way that is accessible and understandable to all readers. Serious incident investigation reports must be shared with key interested bodies including patients, victims and their families. It is recommended that reports are drafted on the basis that they may become public, so issues concerning anonymity and consent for disclosure of personal information are important and should be considered at an early stage in the investigation process. Each NHS organisation has a Caldicott Guardian who is responsible for protecting the confidentiality of patient and service-user information and enabling appropriate information-sharing. Those investigating serious incidents can seek advice from the Caldicott Guardian if guidance is needed about the disclosure of patient identifiable information.[27]

4.32. Serious Incidents should be closed by the relevant commissioner when they are satisfied that the investigation report and action plan meets the required standard. Incidents can be closed before all actions are complete but there must be mechanisms

[24] https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2015/04/serious-incidnt-framwrk-upd2.pdf

[25] Ibid

[26] ibid

[27] Ibid

in place for monitoring on-going implementation. Commissioners and providers are also able to share relevant findings more widely if appropriate to further support the learning of lessons to prevent similar incidents recurring

4.33. NHS Improvement's patient safety team provides advice and guidance to the healthcare system in relation to mitigating risks to patient safety. It examines patient safety incident reports and alerts the healthcare system to emerging themes, trends and risks that healthcare providers may not already be aware of that are revealed by those incident reports. Where information is brought to light via an investigation, this could similarly be used to provide advice and guidance to the whole system by the NHS Improvement Patient Safety team. This team also publishes data on the number and types of incidents that are reported.

4.34. However, it is likely that the majority of lessons learned from a safety investigation will be specific to the provider or service in question and, as has already been explored, the extent to which this learning is taken on board is variable.

4.35. The way in which HSIB should share information in the context of a safe space is outlined in Directions[28]. These state that HSIB:

- '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 sub-paragraph must not volunteer to take further part in the actions that such a body or bodies may subsequently take;
- must seek to agree with professional regulatory bodies and other investigatory bodies which have statutory powers to require information, suitable protocols respecting the safe space principle in relation to the exercise of those statutory powers;
- must seek to agree with those bodies with which the Authority has a mutual duty to co-operate under section 290 of the Health and Social Care Act 2012 suitable protocols respecting the safe space principle which are to apply as between the Authority and those other bodies in discharging that duty.'

4.36. Once HSIB has created these protocols and agreements with professional regulators and others, the way in which they are applied, and the learning from this, could potentially be used to inform the development of primary legislation.

[28] https://www.gov.uk/government/publications/nhs-trust-development-authority-directions-2016

5. Proposed approach

5.1. As outlined, there is a body of evidence to indicate that there is a gap between the culture we would expect to exist in the NHS and the one which does, as well as a gap between how investigations should be carried out and how they are. There is variation across the health system in both aspects.

5.2. Many believe that the creation of a type of 'strong wall' around certain health service investigations so that information given as part of an investigation would only rarely be passed on would provide a measure of 'psychological safety' to those involved in an investigation, allowing them to speak freely. This will enable lessons to be learned, driving improvement and ultimately saving lives. This 'strong wall' does not currently exist in investigations which are carried out by, or commissioned by, Trusts. The Directions under which HSIB will operate provide some guidance on the 'safe space' principle in the context of investigations by HSIB, but the Directions cannot override existing legislation which allow organisations such as the police, coroners and professional regulators powers to compel the disclosure of information.

5.3. The present proposal is to therefore create a statutory prohibition on the disclosure of material obtained during certain health service investigations unless the High Court makes an order permitting disclosure or one of the specified exceptions applies. This broadly mirrors the regime followed in the area of air accidents investigations, which is discussed in further detail in "Creating a safe space" below.

5.4. While the exact split between primary and secondary legislation is for later consideration, the option favoured by the Department of Health is to create in primary legislation an enabling power to allow the Secretary of State to make regulations by providing for the confidentiality of investigatory material and for disclosure to be made only by order of the High Court or in other prescribed circumstances[29].

5.5. However, there are challenges to creating this statutory safe space. As Chapter 3 explored, some of these are cultural - particularly how can a safe space be implemented effectively in a system which has so much inherent variation in the approach to investigation. As outlined in Chapter 4, the policy could also have an effect on the statutory powers of other organisations. Creating a safe space is also a difficult balance to achieve - how can you, on one hand, reassure staff that the information they give will not be passed on while also reassuring patients and families that they have the full facts of their, or their loved ones', care.

[29] We would also envisage making necessary amendments to the HSIB Directions

5.6. The remainder of this chapter outlines the elements of the proposed policy to create a statutory ‘safe space’.

Creating a safe space

5.7. The specific policy under consideration seeks to create a 'safe space' during investigations conducted by HSIB, as well as by or on behalf of NHS Trusts, Foundation Trusts and other providers of 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.

5.8. The proposed model would allow an investigator to say ‘This investigation is not to attribute blame. The information you give me as part of this investigation will not be passed on to those not involved in the investigation unless there is a high court order, or if the information you provide demonstrates to me there is an active and ongoing threat to patient safety represented by the practice or actions of one or more individuals that requires action'. (The legislation would give the specific phrasing for how exceptions in the public interest were to be provided for.) This broadly reflects the model used by the Air Accidents Investigation Branch, which is widely credited with allowing the Branch to undertake effective investigations and to get openness from the people involved.

5.9. The Air Accidents Investigation Branch's legislative framework has a number of features that may provide a helpful model. The key features are:

- an explicit articulation of the purpose of investigations that makes it clear that apportioning blame is not part of the work of the investigation branch, with the same point applied to reports;
- an approach to disclosure that means that it only happens if there is a High Court order, but, in line with international obligations governing air accident investigations, also places a duty on the Court making an order to disclose to weigh up interests of justice against any detrimental impact on current or future investigations. The EU regulation that applies in this area also allows disclosure to the relevant authority (the police, in England, the UK) where there is evidence of criminal activity.

5.10. The relevant provisions concerning the work of the Air Accidents Investigation Branch are to be found in regulation 18 of the Civil Aviation (Investigation of Air Accidents and Incidents) Regulations 1996. Essentially, regulation 18 provides as follows:

- the Secretary of State (the Air Accidents Investigations Branch is an executive agency) is prohibited from disclosing specified classes of investigatory material unless a court order requires disclosure.

- if an application is not made in the course of other proceedings, regulation 18(2)(b) is understood to provide grounds for a free-standing application for disclosure.
- it expressly excludes from the prohibition the inclusion of material in the final report issue by the Secretary of State (ie, the Air Accident Investigation Branch).

5.11. Regulation 18 also prescribes a test for the court to apply when considering disclosure applications, and the court's scope to order disclosure is effectively subject to any rule of law authorising or requiring the withholding of any relevant record on grounds that disclosure would be injurious to the public interest.

5.12. The elements of the proposed policy to create a statutory 'safe space' in healthcare investigations, which would broadly mirror the elements of the AAIB model, are set out below.

Which investigations should the 'safe space' principle apply to?

5.13. As outlined in Chapter 4, investigations into incidents relating to patient safety are currently undertaken by or on behalf of providers and commissioners of NHS services, and, by the end of this financial year, HSIB will be undertaking its own investigations.

5.14. The way in which those investigations carried out by providers and commissioners should be undertaken is outlined in the Serious Incident Framework. While those delivering NHS-funded services under the NHS Standard Contract are required to comply with the Framework as a term of that Contract, it is clear from the PASC report and the testimony of patients, families and staff that the principles of the Framework are not always adhered to, and the quality of investigations - including how those involved in them are treated - is variable. The PASC report was equally clear that the capability of those undertaking investigations in the wider system is also variable.

5.15. As explained in Chapter 4, HSIB is in the process of being established by the NHS Trust Development Authority pursuant to Directions given to it by the Secretary of State. Those Directions provide a framework for the HSIB to conduct investigations in which witnesses can provide evidence in a 'safe space' in so far as possible without new primary legislation. The HSIB Directions outline the principles of a safe space and, to an extent, enable the Chief Investigator to use his or her discretion in how to apply them. The Department of Health would also anticipate the Chief Investigator drawing up protocols and agreements with other bodies around how information is shared and use these to further support the principle.

5.16. However, it is not possible to fully achieve the air accidents investigation model under the HSIB Directions and any such agreements and protocols alone. The Directions cannot amend or modify the application of existing legislation, and cannot require third

parties seeking disclosure of material, for example, to apply to a specific court, nor for that court to follow a specific test in considering applications.

5.17. It is therefore proposed that a new statutory prohibition on the disclosure of certain information should apply to information obtained during investigations by :

- the HSIB; and,
- investigations into incidents relating to patient safety conducted by or on behalf of NHS Trusts, NHS Foundation Trusts and other providers of NHS-funded health services (this would include where the commissioner of NHS-funded care initiates the investigation in accordance with the Serious Incident Framework).

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?

5.18. While the investigations undertaken by HSIB will be determined by the Chief Investigator, those undertaken in the wider NHS system will be much more numerous, with greater variety of approach, and potentially into a wider range of incidents. There are 30,000 serious incidents reported annually, and each one should trigger an investigation (although many are at Trust level).

5.19. Given the concerns of PASC and others about the level of investigative capability in the wider system, there is uncertainty over its readiness to give effect to an obligation to create a 'safe space' in investigations.

5.20. It may therefore be appropriate to adopt an approach in the wider NHS which allows for a phasing in of implementation over time, potentially focusing on a subset, specific class or type of investigation at the outset. This would allow for the approach being tested on a smaller scale and learnt from before being rolled out more widely. One option would be to test this in the area of maternity, as there is a clear focus on improving safety over the coming years.

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?

What information should it apply to?

5.21. As outlined in Chapter 4, a large amount of information is generated and shared across the health system. The proposed prohibition on disclosure would only apply to information generated during the course of an investigation for example transcripts, witness statements, notes written by investigators, electronic recordings of interviews. It is not intended to cover information which is generally available to the public, , and it is not intended to impact on the duty on providers to give patients an initial account of the known facts concerning an incident, nor eventually to share the outcome of further enquiries.

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

Obtaining a High Court order

5.22. The proposal is that there should be a statutory prohibition on the disclosure of information gathered during certain healthcare investigations unless disclosure is required by an order of the High Court. This prohibition would apply to all organisations involved in the investigations we have described in Chapter 4 (except under some limited circumstances, as detailed below.)

5.23. It is hoped that having an outright prohibition against disclosure save by order of the High Court or in prescribed circumstances, staff and others who contribute evidence and information to an investigation by the Investigation Branch will have a clear picture of the limited circumstances in which the evidence they provide may be disclosed.

5.24. It is 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.

5.25. This should be weighed up against any adverse impact which disclosure may have on:

- the effectiveness of the relevant investigatory body's investigatory processes (ie, the processes in reporting on and making recommendations about patient safety, both in relation to the relevant investigation into the accident or incident to which the record relates or to any relevant investigation into any future accident or incident which may be undertaken in England), bearing in mind the importance of eliciting frank and candid contributions from those providing evidence to the investigation, and

- ultimately, the discharge by Secretary of State of his duty under section 1A of the 2006 Act to exercise his health service functions with a view to securing continuous improvement in the outcomes achieved from the provision of services, in particular outcomes relating to the safety of the services.

5.26. The High Court will have to determine the question where disclosure is sought on a case-by-case basis, but there will be a single test applied by the court and over time, we would anticipate that it should become clear how the court will apply it. This would avoid the uncertainty that the current diversity of processes presents for HSIB and NHS investigations mentioned above, and to provide a uniformity of approach, with a single jurisdiction determining requests for disclosure by reference to a single test, which recognises the particular purposes of the patient safety investigations.

5.27. While the High Court jurisdiction is England and Wales, the provision is to apply in relation to material gathered in the course of investigations carried out in England only.

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?

Exceptions to the 'safe space' principle

5.28. As already outlined, the existence of a blanket safe space would mean that information generated by a safety investigation could not be shared with any other bodies or individuals, except in cases where a High Court order had been obtained. However, there are circumstances in which it is considered that the prohibition on disclosure of investigatory material should not apply.

5.29. For example, if it were clear that there was an immediate risk to patient safety it would not be right to withhold information from the appropriate authorities, for example, professional regulators or the police. The safe space approach is intended to address patient safety issues and improve patient safety standards over time, by constructive lesson learning from mistakes. But it is not intended that more immediate, clear patient safety risks that the investigator uncovers should not be acted on. In this context the risks we would focus on for providing for such an exception could include situations such as where there was evidence of criminal activity by anyone concerned in the care under scrutiny, or serious misconduct or seriously deficient performance on the part of a

registrant. As outlined in Chapter 4, the way in which HSIB works with other organisations such as professional regulators in its application of safe space under Directions could helpfully inform the way in which these thresholds and processes are outlined in future legislation.

5.30. It is therefore envisaged that the circumstances in which disclosures may be made without a High Court order being necessary would include:

- disclosing concerns to the police or health professions' regulatory bodies if there is a serious and continuing risk to patient safety; and
- informing the police where it appears that a criminal offence has been committed.

5.31. There has been some suggestion that there should also be an additional exception in relation to sharing information with patients and members of his or her family. The difficulty here is that sharing certain information with patients and their family could potentially compete with the imperative to provide a 'safe space' to enable contributors to speak candidly to the person or body carrying out the investigation. As the EAG recognised, there is a tension between the protection of the information given by witnesses and the needs of families and patients to be given information pertaining to their or their loved ones' care. It will be necessary to consider how the 'safe space' principle could apply without cutting across these needs and potentially lead patients and families to feel there had been a degree of cover up.

5.32. We have also seen that the EAG was clear that patients and families should receive all relevant information about their care. The Serious Incident Framework states that patients and families should be involved in the investigation at every stage (including seeing draft reports and final reports). The Framework also recommends that, in investigations for learning, issues concerning anonymity and consent for disclosure of personal information are important and should be considered at an early stage in the investigation process, and considered on the basis that information may become public.

5.33. However, it has also been mooted that the very existence of these exceptions could negate the entire principle of safe space, ie having them would lead those involved in giving evidence to investigations to conclude that the 'guarantee' of not passing on information was too qualified for them to trust it, and would thereby deter them from being fully open.

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?

Impact on other processes

5.34. As outlined in Chapter 4, while safety investigations are undertaken by providers (and, in time, HSIB) other processes described above (in Ch. 4) are in place to hold professionals to account and ensure the safety of the public. These include fitness to practise investigations, Coroner's investigations and - more rarely - police investigations and criminal or civil actions.

5.35. The provision of a 'safe space' in healthcare investigations is not intended to reduce the effectiveness of these processes. In terms of chronology, many of these processes could be happening, and coming to conclusions, in advance of, or at the same time as any safety investigations. It is possible that information gathered by a safety investigation may not be of use or interest to those conducting other types of investigation. Also, one of the anticipated exceptions to the safe space principle (ie a scenario where the investigator's information could lawfully be shared) is if there was an immediate risk to patient safety.

5.36. However, notwithstanding this, creating a system where a High Court order is required to gain access to information obtained during certain healthcare investigations will cut across existing statutory powers which a number of organisations - for example some professional regulators, Coroners, the courts and police - have. There could be concerns that the creation of a safe space could hamper the holding to account of individuals. This view is demonstrated in some of the evidence outlined so far.

5.37. In relation to disclosure powers held by other authorities, the policy is to avoid the uncertainty that a diversity of processes presents, and to be able to provide for a uniformity of approach, with a single jurisdiction determining requests for disclosure by reference to a single test, which it is intended will recognise the particular purposes of patient safety investigations.

5.38. The proposal would not prevent other investigations from continuing - they would still be able to proceed - but it would be necessary for other investigatory bodies or individuals to apply to the High Court if they wanted to obtain material that had been gathered by the body carrying out the investigation into healthcare services, or they would be free to use their own investigation processes. In the case of some professional regulatory bodies, for example, they have powers to require disclosure of information (unless the law prohibits its disclosure) and then to go to the court to seek an order for disclosure if it is unforthcoming, while other such bodies can require the information but do not have an express power to apply to the court. The proposed approach for the safe space policy would have the effect of providing the same process for all such cases, based in a test that the high court would apply as prescribed in the relevant legislation.

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?

5.39. It is envisaged that information obtained during healthcare investigations would not be disclosable under the Freedom of Information Act 2000 and the Data Protection Act 1998

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?

How should the creation of a 'safe space' be supported?

5.40. As explored in Chapter 3, there is considerable variation in how investigations are handled (and learned from) within the healthcare system. While investigations undertaken by HSIB will be under the auspices of the Chief Investigator who can test the approach from the beginning of this financial year under HSIB's Directions, those within the wider system will be handled by investigators who may not have had any direct experience of creating a 'safe space' around their investigations.

5.41. There is therefore a question around how, or whether, those undertaking investigations will require additional support in applying safe space and making the judgements underlying the approach. This could take the form of guidance to the system.

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?

6. Impact of proposals

Public Sector Equality Duty

6.1. The Public Sector Equality Duty in section 149 of the Equality Act 2010 requires public sector organisations to have due regard to the need to: eliminate unlawful discrimination, harassment, victimisation and any other conduct prohibited by the Act; advance equality of opportunity between people who share a protected characteristic and people who do not share it; and foster good relations between people who share a protected characteristic and people who do not share it.

6.2. The general equality duty that is set out in the Equality Act 2010 requires public authorities, in the exercise of their functions, to have due regard to the need to:

- eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Act;
- advance equality of opportunity between people who share a protected characteristic and those who do not;
- foster good relations between people who share a protected characteristic and those who do not.

6.3. The 'relevant protected characteristics' are: age, disability, gender re-assignment, pregnancy and maternity, race, religion or belief, sex and sexual orientation (see section 149(7) of the Equality Act).

6.4. We do not envisage that the policy of providing for a safe space in health service patient safety investigations will have a negative impact on individuals sharing the other protected characteristics under the Equality Act 2010 because we would expect the policy to affect staff fairly equally, regardless of protected characteristics. The same could be said of patients and families. However, this is a developing analysis, and if you do have any concerns that the policy may have an impact in people sharing protected characteristics, we would welcome your comments.

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? If you envisage negative impacts on such people, please explain.

Family Test

6.5. This is another duty that should be considered in all policy development. We are required to consider:

- what kinds of impact might the policy have on family formation?
- what kinds of impact will the policy have on families going through key transitions such as becoming parents, getting married, fostering or adopting, bereavement, redundancy, new caring responsibilities or the onset of a long-term health condition?
- what impacts will the policy have on all family members' ability to play a full role in family life, including with respect to parenting and other caring responsibilities?
- how does the policy impact families before, during and after couple separation?
- how does the policy impact those families most at risk of deterioration of relationship quality and breakdown?

6.6. We believe that the proposed safe space policy will have a positive impact on families. The policy is intended to help the health service learn lessons from when things go wrong, and to help investigators reach robust and sound analyses as to what went wrong and how it can be avoided in future. We anticipate focussing in the first instance on maternity investigations, and this should help improve learning about patient safety within the NHS, benefiting parents and infants.

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

Impact on business

6.7. Government policy requires us to give consideration to the impact on business and put a cost value on the impact. We have considered how the implementation of this policy will impact on different sectors and concluded that the proposed policy does not impact on business. This is because they are only applicable to a defined list of NHS public bodies; which are for this purpose not classified as businesses.

7. Consultation questions

7.1. The Government invites comment on any aspect of its approach to the drafting of the regulations. However, the following are of particular importance and the Government seeks your views on them in particular.

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.