



RESPONSE TO

**DEPARTMENT OF HEALTH CONSULTATION:
PROVIDING A 'SAFE SPACE' ON HEALTHCARE SAFETY
INVESTIGATIONS**

DECEMBER 2016

Introduction

Action against Medical Accidents (AvMA) is the UK charity for patient safety and justice. We support around 3,000 people each year who have been affected by lapses in patient safety which gives us a unique insight into what patients and families go through in these circumstances. We also work with health professionals, NHS, regulators and the Department of Health to improve patient safety and the way patients or their families are dealt with following patient safety incidents. We welcome the opportunity to respond to this consultation. However, we are very disappointed that the Department of Health have refused our request to allow the Government's own recommended minimum period for a formal consultation of 12 weeks. Insufficient time has been allowed for many stakeholders to consider the proposals and respond. A reasonable period for consultation on these proposals is all the more important given that they are radical and have far reaching implications, and in respect of the proposal to extend "safe space" arrangements to local investigations rather than just HSIB, there was little or no pre-consultation engagement with stakeholders. This proposal has come "out of the blue". Unless the Department of Health extends the period of consultation or confirms it is not going ahead with this element of the proposals, we think that it is imperative to start a new consultation on extending 'safe space' to local investigations.

Below we provide our response to each of the questions as set out in the consultation document.

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

No. We do not believe that the prohibition on disclosure of investigatory material should apply to either HSIB or local provider led investigations in the form it is described in the consultation. However we think it is important to distinguish between the arrangements which may be suitable for a HSIB investigation and those that may be suitable for a local provider-led investigation. We discuss these separately below.

However, we need to challenge the impression given by the consultation document that there has already been widespread discussion of the principles of the so called 'safe space' which justifies the proposals. There was some limited engagement with health professionals and patients over HSIB itself, but extending arrangements to local investigations was never discussed. Whilst some health professionals expressed support for protection from employers or regulators, there was no proposal that the 'prohibition' on disclosure of information might include prohibiting of disclosure of information from patients/families even where it is relevant to what happened in their treatment. The soundings we have taken from health professionals and other stakeholders confirm that the vast majority of people agree it would be completely wrong not to disclose relevant information to patients/families. The patients and patients' organisations consulted in the development of HSIB were unanimous on this point. It was also one of the main recommendations of the Expert Advisory Group for HSIB that all relevant information "must" be disclosed to patients/families.

The "safe space" proposals for prohibiting the sharing of information are not backed up with any significant evidence, and neither are alternative methods for addressing the perceived problem explored. The studies quoted in the consultation document are both old and relate to safety and investigations in a completely different context than the NHS or even healthcare. No consideration has been given to the experience of other health systems where the emphasis on openness, honesty and full disclosure rather than a prohibition on disclosure have been seen to have had the desired results. We particularly recommend consideration of the work carried out in the Michigan Health System, where their insistence on full disclosure to patients alongside support for health professionals has led to a far healthier 'patient safety culture' and reduced the money spent on litigation dramatically (see <http://www.med.umich.edu/news/newsroom/Boothman-ACHE-Frontiers.pdf>). The Swedish health system, so much respected by the Department of Health that it has modelled its "Rapid Response and Redress" proposals around it, also has at its heart a commitment to full disclosure to patients/families. This is seen as essential to the system's success in improving patient safety and building trust with patients. The current 'safe space' proposals would take the NHS in the opposite direction, would create massive distrust amongst patients and would result in the opposite of the intended consequences.

We strongly support initiatives that would genuinely support and protect health professionals who take part in investigations but which do not conflict with the ethical and professional need to be fully open with patients. Rather than concentrating on prohibiting disclosure of information, we suggest the Department of Health should be concentrating on the cultural issues which lead to health professionals being mistreated. Proper enforcement of the Fit and Proper Persons test; acting on concerns raised by

staff; and better protection for ‘whistle-blowers’ are far more urgent and practical measures than seeking to prohibit disclosure of information.

Local investigations

We most strongly object to the extension of the ‘safe space’ prohibition of disclosure to local investigations – particularly if disclosure of information to patients/families is not made an exception to the arrangements. It is wholly inappropriate to extend the ‘safe space’ arrangements to local investigations by providers themselves. This would create a serious conflict of interest as these NHS bodies would be investigating themselves and making decisions about what they do and do not disclose. It would mean that every Serious Incident investigation carried out in England (estimated 30,000) a year would have a prohibition on the disclosure of material. Any patient or family whose treatment was the subject of a local NHS investigation would need to be aware that the NHS may well hide from them crucial evidence directly relevant to what actually happened in their treatment. This would be deeply damaging to trust between patients and health professionals and the NHS and would have serious unintended consequences. It is inconsistent with the NHS Constitution and directly contradictory to the Serious Incident Framework currently applied to local investigations, which requires full involvement of patients/ families and full openness with them. You cannot be properly involved in an investigation when you are deprived sight of potentially crucial evidence about your own or a loved one’s treatment. This would lead to investigations failing to get to the truth. In our experience, confirmed by the views of experts in patient safety investigations we have consulted, often it is the ability to test evidence gathered with the patient/family that identifies inconsistencies and leads to the truth being arrived at. This would be prohibited if ‘safe space’ was applied to local investigations.

Applying a prohibition on disclosure in local investigations would also seriously compromise the statutory Duty of Candour. It would be impossible to guarantee full honesty with patients if crucially important information was prohibited from disclosure. We note that the Department of Health does not intend these consequences, but believe that it has failed to properly consider the risk of them occurring as a result of the proposals. For example, the consultation document states: *“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”*. However, it goes on to say: *“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”*.

One has to consider what information it is about patients’ own treatment that the Department of Health thinks organisations should be prohibited from disclosing to them and why. The Department of Health has already ignored the advice of the Expert Advisory Group set up to advise the Secretary of State on HSIB. They recommended that all relevant information *“must”* be shared with the patient / family, but the Department of Health’s statutory Directions on HSIB put the emphasis on non-disclosure. Indeed, the HSIB can only provide patients /families with material gathered by the investigation (a) if they request it and (b) the chief investigator believes this to be consistent with the safe space principle. The Duty of Candour requires organisations to be open and honest with patients when things go wrong. If organisations are prohibited from sharing with them information relevant to their own care they cannot comply with the Duty of Candour. Indeed if the Department of Health were right in their assumption that these proposals would not affect the Duty of Candour and that patients/families will be told everything about their treatment, then exactly what protection is being offered to those giving evidence by hiding the information from the patient/family?

Although it is not stated in the consultation document itself, we suspect that litigation is something the Department of Health has in mind. In a speech on 9th March 2016 the Secretary of State said:

“The results of such investigations will be shared with patients and families, who will therefore get to the truth of what happened much more quickly. However, unlike at present they will not normally be able to be used in litigation.”

If making it more difficult for people to obtain compensation is one of the aims of these proposals then the consultation document should have said so. If it is not, then serious consideration should be given to this inevitable unintended consequence of the proposals. Being able to obtain disclosure of relevant evidence is vital to many clinical negligence claims and the proposed prohibition on disclosure would deny access to justice for many injured patients/families. The NHS Constitution says that injured patients have the right to seek compensation for negligent treatment, and up to now Government policy has always been that patients injured through negligence should be compensated. The consultation document says that the aim is to protect those giving evidence from being *“inappropriately blamed or penalised”*. However, there is nothing inappropriate about a patient seeking compensation for negligently caused injuries. Nor is a clinical negligence claim a punishment. Prohibiting disclosure would take away an important civil right that is enjoyed by litigants in any other kind of civil litigation.

Ironically, patients injured by the NHS would be in a worse position than those injured in the private sector, where this prohibition would not apply. However, it is important to stress that we can see no evidence that the fear of litigation from patients/families impacts on health professionals' willingness to provide evidence to patient safety investigations anyway. If this were happening, it is a serious breach of health professionals' professional codes of conduct. Health professionals working for the NHS in any case are covered by the NHS indemnity arrangements – they are not personally subject to clinical negligence litigation. The NHS Litigation Authority advises that being fully open and honest is likely to reduce the risk and the cost of litigation. In a speech on the 3rd March 2016 the Secretary of State himself said:

“And when we give patients an honest account of what happened alongside an apology, what is the impact? Countless academic studies have shown there is less litigation, less money spent on lawyers and more rapid closure, even when there have been the most terrible tragedies”.

We can confirm that this is borne out by our experience at AvMA.

The experience in Michigan and elsewhere also suggests that an emphasis on honesty and full disclosure can massively reduce the cost of litigation. Ironically, we believe that the suspicion and distrust that would be created by prohibiting the disclosure of relevant information from patients would lead to much more litigation and complaints. No patient/family could have faith in investigations which by definition prohibit the sharing of relevant information with them and will seek other methods to get to the bottom of the issue and seek accountability.

Finally, as confirmed by the recent CQC report on the investigation of deaths (<http://www.cqc.org.uk/content/learning-candour-and-accountability>) most local NHS bodies simply do not have the experience and expertise available to them to enable them to carry out existing types of investigations well – leave alone be trusted with running such a new style investigation and have the power to withhold information.

HSIB investigations

We accept that slightly different arguments apply to investigations carried out by the HSIB. HSIB is independent and so does not have the conflict of interests which exist for local investigations. It will also be a highly specialist investigatory body, benefitting from staff with specialist investigatory skills and experience, which is not available at the local level. We are prepared to accept the principle of limited prohibition of the HSIB disclosing certain investigation materials **but only on the basis of it being a requirement for HSIB to share all relevant information about a patients' treatment with the patient or their family, as per the recommendation of the expert advisory group.** The HSIB Directions should be amended with immediate effect to reflect this. Guidance should also be developed to aid the chief investigator in determining what is “relevant” information if there is any doubt. The emphasis should be on disclosing any information or evidence to the patient/family that either they may be able to ‘test’ or comment on, or which could potentially shed light on what happened in their treatment or the circumstances which may have contributed to it.

- 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?**

As discussed above we strongly advise that the safe space approach is not extended in any way to local investigations.

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

As recommended by the Expert Advisory Group, all information relevant to the treatment of a patient which is part of the investigation should be made available to the patient/family. We have no problem with witness statements and other evidence not being published in the public report and being protected from disclosure to other organisations provided that this does not apply to patients/families or their representatives or in the other suggested exceptions for these arrangements.

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?

We strongly disagree that if these proposals go ahead a patient or family may have to apply to the High Court for an order to have access to what an investigation has discovered about their own treatment. Anything discovered which is relevant to the patient's treatment should be regarded as theirs. Applying to the High Court will normally mean instructing lawyers and the cost would be prohibitive. To the degree that there may be any prohibition from disclosure yes we agree that the High Court should be able to order disclosure.

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

We would like to re-state that a patient or their family should not be required to apply for a High Court order simply to have access to information which is relevant to their own treatment. If patients/families are forced to have to apply to the High Court to seek disclosure of relevant information, then the NHS should bear the cost of the application. If the High Court is to consider applications for disclosure from patients/families it should base its decision on whether the information which is subject to the application is relevant to the treatment of the patient in question. If it is, then disclosure should be ordered and the organisation responsible for not disclosing in the first place should have to meet all the costs of the application.

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?

If a prohibition on the disclosure of material obtained in investigations either by HSIB or local providers and commissioners is to be created, it is essential that an exception is made in respect of patients (or their family, where appropriate). As advised by the Expert Advisory Group, all information relevant to their treatment must be shared with them.

We recommend that an exception also be made in respect of coroners. Inquests are not established to apportion blame or liability and already have discretion not to publish certain information put before them. We think it would be unjust for a bereaved family to be denied the opportunity for an inquest to get to the bottom of why their loved one died because of a prohibition on sharing such information from the coroner. Coroners also play a vitally important role in identifying patient safety issues and issuing Prevention of Future Deaths letters. Denying them the ability to test evidence would make this role more difficult if not impossible.

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?

Clearly, criminal acts and issues which pose a direct threat to patient safety should be passed on to the relevant bodies as proposed. However we would argue that there are other serious issues which should prompt disclosure to other bodies. Suppose for example it is discovered that an individual health professional clearly is or has been acting in a way which is completely incompatible with professional standards by bullying colleagues; failing to report incidents; and/or covering up the truth from patients or families. Such behaviour may not be defined as having a "direct impact on patient safety" but is nonetheless totally unacceptable and suggests the individual is not fit to practice. Potential fitness to practice issues such as this should be disclosed to the appropriate regulator.

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?

No. Certainly the many health professionals we speak to confirm that they do not desire any protection in the form of hiding the truth about what happened in their treatment from patients or their families. Nor, we suspect would the great majority of health professionals think that referring criminal activity; threats to patient safety or serious unprofessionalism as described above to the relevant authority is not the right thing to do.

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

Yes, we do. However, we would suggest that a ‘just culture’ has to apply to patients as well as health professionals. We would refer you to the “Charter of Understanding between Health Professionals and People affected by Medical Accidents” developed by AvMA in partnership with health professionals and others years ago. This Charter has been endorsed by a wide range of health professional and regulatory bodies. (See attached). A prohibition on patients or their families obtaining information about what investigations discover about their treatment is wholly inconsistent with a just culture. In fact that would have serious unintended consequences which directly harm what the Department of Health is trying to achieve. It would lead to a breakdown in trust between patients and health professionals and the NHS. Patients and families would be much more inclined, in the knowledge that any NHS investigation was being undertaken on the basis that it is prohibited from disclosing even relevant information from them, to take the strongest possible action against those concerned. It would lead to an explosion in complaints, referrals to regulators and litigation.

We believe that before making these proposals the ‘just culture taskforce’ should have been established and its findings considered. This would have confirmed, we believe, that what health professionals need protection from is bad employers or bullying peers and possibly overzealous regulators – but not from patients or families knowing the full truth about what investigations learn about their treatment.

We look forward to the opportunity to contribute to the just culture taskforce.

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 - e.g. should they see a pre-publication draft report for comment?

Any relevant information about a patient’s treatment discovered by the investigation should be shared with them, as per the expert advisory group recommendation. The HSIB Directions should be amended with immediate effect to reflect this. Guidance should also be developed to aid the chief investigator in determining what is “relevant” information if there is any doubt. The emphasis should be on disclosing any information or evidence to the patient/family that either they may be able to ‘test’ or comment on, or which could potentially shed light on what happened in their treatment or the circumstances which may have contributed to it.

We would have thought that seeing a pre-publication draft of the report is the very least any patient/family should be entitled to expect. However, that in itself is nowhere near enough involvement or openness nor anywhere near the level of involvement in the investigation that the Serious Incident Framework requires. As the Expert Advisory Group recommended, patients/ families must be provided with any information that is relevant to their treatment. Good practice in investigations would suggest that evidence should be shared with those who may be in a position to test or challenge it as soon as possible. The Duty of Candour requires sharing information about incidents as soon as reasonably practical from having knowledge of it. This would mean it has to be during the course of the investigation rather than at the end of it.

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

Yes. This would prevent or delay these bodies from fulfilling their duties, which in turn could create threats to patient safety and other unintended consequences. We are particularly concerned about the difficulties this would pose for coroners and regulators. The cost of applying to the High Court would probably be prohibitive for coroners’ courts.

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?

We believe that “safe space” is an inappropriate and misleading phrase. It creates an expectation that neither HSIB nor local investigations can guarantee. Prohibiting disclosure of information can not in itself create a ‘safe space’. What HSIB and other investigations should ensure is that they follow existing guidance and frameworks e.g. they are about learning and not about apportioning blame. They can do that without a prohibition on disclosure of information – certainly without withholding relevant information about their treatment from patients. One suggestion (assuming the proposed prohibition on disclosure to patients/families does not go ahead) is to refer to an “open and fair” investigation framework. The patient safety movement has long moved on from inappropriate terminology such as “no blame”. “Open and fair” incorporates the principles of transparency and just culture.

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

We question whether this is appropriate, particularly in relation to the Data Protection Act where the exemption would be a serious infringement of patients’ rights and protection.

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

Yes. Support should be developed and/or commissioned for both staff and patients/families who are involved in investigations.

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?

Yes. This could take away the need for prohibition of disclosure. We would be happy to work on this with stakeholders. We suggest that guidelines on how patients/families should be involved and treated is equally as important and could draw on the existing Serious Incident Framework. Moreover, there are other steps the Department and others could be taking to protect and support staff which would be far more helpful than prohibiting the sharing of evidential material. For example proper enforcement of the Fit and Proper Person’s Test; acting on concerns raised by staff; and setting up an independent whistleblower advice and support service.

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?

People sharing protected characteristics are more likely to be poor and unable to afford the legal costs involved in instructing lawyers and applying for High Court orders.

People with disabilities caused by clinical negligence may find themselves unable to get the compensation they need and deserve because of the difficulties prohibition of disclosure pose for the legal process.

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

Having a family member who is harmed or dies as a result of a patient safety incident obviously has a devastating effect on families. Being put in a situation where the NHS is prohibited from fully involving you in investigations or allowing you to see evidence about your own or your loved one’s treatment will seriously aggravate their distress and lead to a lack of trust in health professionals and the NHS. Patients or families who need financial compensation in order to have a reasonable quality of life following negligent treatment may be denied this because of the difficulties prohibition of disclosure pose for the legal process. In our experience this sort of stress can lead to the break-up of families.

A CHARTER OF UNDERSTANDING BETWEEN HEALTH PROFESSIONALS AND PEOPLE AFFECTED BY MEDICAL ACCIDENTS

- The practice of medicine and undergoing medical treatment carry with them risks. These risks should be explained by health professionals in a way the patient can understand.
- Patients' physical and mental health must remain the paramount concern of any treating health professional, whether or not there is a dispute over treatment or a medical error is alleged to have been made.
- There will be occasions when an adverse outcome is unavoidable. Avoidable injury may also be caused by system failures or by human error on the part of health professionals. When it appears avoidable injury has occurred, the patient or (where appropriate) the patient's partner, close relative or friend should be informed and have the circumstances fully explained.
- Committing an error is not in itself an indication of incompetence or negligence.
Health professionals should be supported in (and indeed applauded for) reporting errors honestly and openly without fear of unreasonable consequences. The safety of patients must always be paramount in assessing what should happen next.
- Health professionals should receive help and support in coming to terms with having caused or been involved in causing unintentional harm to their patients and in learning lessons from any errors in order to prevent further accidents. It is also the responsibility of health care organisations to identify and learn from system failures which may be the root cause of accidents, including individual errors.
- Medical accidents have a real and deep impact on peoples' lives. Patients (or their partners or relatives) who have been affected by a medical accident have a perfectly reasonable right to explanations and to seek apologies, assurances and/or financial compensation for injuries caused where appropriate.