MID STAFFORDSHIRE NHS PUBLIC TRUST INQUIRY

CLOSING SUBMISSIONS
ON BEHALF OF
ACTION AGAINST MEDICAL ACCIDENTS

References to documents on Lextranet are to the reference of first page of Lextranet document followed by the internal number. References to evidence on LiveNote is to the date, followed by the page and where necessary, the line.

A summary of AvMA's recommendations will be found at Appendix A.

INTRODUCTION

1. Action against Medical Accidents (AvMA) is an independent UK charity established in 1982 to promote patient safety and justice for people affected by medical accidents. AvMA defines medical accidents broadly, to include any occasion when unintended harm is caused as a result of both treatment or a failure to treat patients appropriately or very simply, when "things go wrong" in healthcare causing harm. AvMA has been grateful for the opportunity to participate in the Public Inquiry into the operation of commissioning, supervisory and regulatory bodies in relation to the monitoring role of the Mid Staffordshire NHS Trust (the Trust). AVMA have been reassured by the extent to which Inquiry Counsel has explored the complex factual background relating to the flow of communication between the various bodies connected to the Trust and recognises that the Chairman faces an enormous challenge in extracting the key lessons from what happened in Mid Staffordshire in order to provide recommendations for the NHS as a whole. The ongoing process of NHS development, alongside the proposed fundamental legislative reform going through Parliament, and which, fundamentally alters the structure of the NHS, compounds this challenge.

2. In these circumstances, in order to identify how to best move forward further to the failings in Mid Staffordshire, AvMA understand the importance of recognising how far the NHS has developed since 2001. The Royal Bristol Infirmary Inquiry recommendations made in 2001 provided a foundation for many of the changes made in the last decade, especially with respect to the importance of patient consent and the development of evidence based practice. Other issues, such the importance of learning from adverse incidents, have received considerable attention, although the systems established need to be revisited. Yet other issues were identified in this current Inquiry which have not been addressed in any practical sense the intervening period, especially with respect to openness and candour. Whilst firmly bearing in mind the developments which have occurred, AvMA do ask the Chairman to question why progress in some areas has lagged behind.

3. Meanwhile, the focus on patient safety as a separate and essential area for consideration has developed over this time. Sir Liam Donaldson's key report, Safety First, in 2006 placed patient safety higher on the NHS agenda. Since this time, as demonstrated by the analysis undertaken by Nigel Edwards of the Kings Fund, patient safety has gained increasing importance within the NHS trust board room: "Quality, service reviews and patient experience increase in importance from 2001 to 2011. By 2011, they are discussed every month and take up the most space in the minutes" (Seminar paper "Balancing external requirements and a positive internal culture" by Nigel Edwards and Ruth Lewis).

4. Although the legislative reform has introduced a fresh approach, the momentum with respect to patient safety which has built over the last decade needs to be protected. It is recognised that the NHS has limited resources and it is within the interests of everyone for those resources to be used in such a way as to ensure the best possible access to the highest quality care. However, in dealing with efficiency, sight should not be lost of effectiveness. The three core areas of measurement within the newly introduced Outcomes Framework; safety, effectiveness and patient experience provides some reassurance that these issues are being considered but care needs to be taken to ensure that these become fundamental to the provision of service.

5. In its submissions, AvMA do not intend to address each area of reform, with respect to which the Inquiry has received the benefit of expertise and experience of those responsible for these changes, those working within the NHS and experts responsible for conducting research into the workings of the NHS. Rather, it will focus upon selected issues most relevant to its expertise and experience in patient safety and justice where it might best add value and assist the Inquiry.

6. Although "patient safety" has been high on the NHS agenda for many years, the most immediate conclusion which can be drawn from the events in Mid Staffordshire is that there is a considerable gap between the rhetoric and the reality of patient safety within the NHS. As the Chairman has heard within the recent seminar, effective change depends on ensuring that structural, strategic, cultural and technical aspects of the system are addressed. In focussing upon the evidence relating to the Trust, the terms of reference require the Chairman to consider the lessons to be drawn for the future with respect to the NHS as a whole. Incidents of poor care and treatment continue to occur throughout NHS organisations. AvMA therefore urges the Chairman to consider both the means by which in future "failing hospitals" can be identified, and how the system can identify and respond to warning signs to eradicate poor care and treatment and to help trusts avoid the downward spiral of self-fulfilling failure.

7. The focus of these submissions is on why the clear message being relayed from the frontline of healthcare – the patients and staff – was not heard within the wider system of bodies surrounding the

Trust. Most importantly, AvMA wish to ensure that the patient's perspective and experience of the systems in place "when things go wrong" remains central to the Chairman's consideration of his recommendations.

STRUCTURE OF SUBMISSIONS

The core issues which AvMA will address in these submissions relate to the following areas of evidence:

Part One: Identifying and responding to "when things go wrong"

8. The evidence with respect to three core areas of clinical governance within the Trust has been considered, both with respect to evident failure of the Trust and the various external bodies to consider this information and importantly, emphasising the extent to which the central role of the patient has been recognised within the various processes in place.
   A. Complaints
   B. Incident reporting and Patient Safety Alerts
   C. Inquests
   D. Risk management

Part Two: Being open with patients

9. The evidence with respect to the four areas above demonstrates the importance of patients and their carers/relatives being considered central and indispensable to the processes of identifying and responding to "when things go wrong," as well as the failure of the trust recognise this. In this section, the critical importance of being open with patients is examined as being the foundation of a truly open safety culture.

Part Three: Raising concerns and whistleblowing

10. The ability of staff to raise concerns is another prerequisite of an open and learning culture. The experience of the staff in the Trust is considered in this section, including the limitations of the formal processes of "whistle blowing" and the role of agencies beyond the employer.

Part Four: Professional responsibility, accountability and regulation

11. This section examines how so many individual health professionals at the Trust let their standards fall so low and in particular the loss of "caring" as an aspect of professionalism, and how the situation might be improved.

Part Five: Performance management, commissioning and regulation

12. This section examines the respective roles of commissioning and regulation in preventing and in intervening over health system failures, including how the system of commissioning can respond to trusts facing financial, leadership and organisational difficulties. It also examines how regulatory systems can respond to such trusts.

Part Six: The future of patient and public involvement

13. This section reviews the history and role of patient and public involvement and discusses how the new system and in particular plans for Healthwatch can be improved.

Part Seven: Dealing with the aftermath of healthcare failings

14. This section considers the response to the HCC report and the eventual establishment of a public inquiry. It discusses how systems can be improved to ensure a more appropriate response when significant failings affecting many patients occur, both in terms of support for patients and families and maximised opportunities for learning.

Conclusions and recommendations

15. AvMA have identified a number of key conclusions drawn from the evidence examined within the submissions. Some are broad principles which it suggests should underpin consideration of the practical detail of recommendations for the future. Others are specific changes which AvMA think are needed now.

16. AvMA of course recognise that recommendations arising from this Inquiry are a matter for the Chairman alone. However, AvMA have outlined the changes that it would like to see in the future throughout the body of these submissions, which are replicated in annex A. Many of these are simple practical measures, often with the intention of ensuring consistency and improving communications. Although the Chairman's recommendations may not be able to deal with this level of detail, it is hoped that these provide working examples of steps to put into practice the principles which AvMA consider important within the impending reforms. Whilst care has been taken not to trespass on the same territory covered by the first Francis Inquiry, some of the issues outlined in the Chairman's original conclusions have been addressed on the basis that these are seen to fall within the terms of reference of this Inquiry. Where possible, this has been done in the context of the Government's proposed reforms.

Part One: Identifying and responding to "when things go wrong"

I believe that complaints from patients are said to be gold dust. You should use those to improve your service, and similarly reports from staff of problems are equally gold dust in improving the service (evidence of Professor Jarman, LiveNote 13.06.11, 10:9).

A. THE COMPLAINTS PROCESS

The relevance and importance of effective complaints handling

17. The importance of effective complaints handling processes and the central role of the patient within this process has been recognised for many years. The following extract is from "NHS Complaints Reform: Making Things Right" (HCC0039000197) published by the Department of Health in February 2003:

> *2.7 In a patient-centred NHS, patients should feel able to express their views – positive and negative, complaints and concerns – about the treatment and services they received, in the knowledge that they will be:*
>
> - *taken seriously,*
> - *given a speedy and effective response,*
> - *that their views will inform learning and improvements in service delivery, and*
> - *that there is a system for taking action to address the full range of problems which occur – from minor difficulties to major failures in treatment and care.*
>
> *2.8 Patients and staff have told us – informally, and formally through an independent evaluation study and subsequent listening exercise – that this is often their experience of the NHS approach to complaints at the present…*

18. Since this time, there have been two significant changes in the regulatory structure for complaints: in 2004 and 2009. Dame Janet Smith published her fifth report on December 2004 following her Inquiry into Dr Harold Shipman, specifically dealing with the failures in complaints handling within primary care. Nine years later, the Chairman has been asked to consider exactly the same issues with respect to the failures identified in Mid Staffordshire from 2005 – 2009.

19. The Inquiry has considered extensive evidence with respect to the role of the complaints process in the systemic failure to identify the failings within the Trust. In the case of the Trust, the Inquiry has heard that the day-to-day failings in feeding, cleaning and toileting patients had been allowed by some to become the "status quo." The patients' families, on the other hand, expressed shock and

dismay upon discovering that basic needs were not being met – highlighting their key role within the process of monitoring care. Yet, when they complained, little was done to identify and solve the problems.

20. The fact that Cure the NHS was the driving force behind bringing the issues within the Trust into the open demonstrates the need for a fundamental shift in the structures and practices of regulatory, supervising and monitoring bodies.

21. A healthy and effective complaints process should provide the patient and families with effective resolution to their concern, give a trust board essential information concerning what is in fact happening in its hospitals and enable external bodies to monitor both the nature of concerns which are raised and the trust's ability to learn from these concerns. At a time when the focus of the NHS has moved to the "patient experience," it seems that the first place to look is the NHS complaints system, which turns entirely upon patients' experience of "things going wrong." However, in the case of Mid Staffordshire, the evidence is unequivocal that the complaints system was inconsistent, ineffective and not given the resources, attention or concern which it deserved, and is an example of how despite the considerable attention paid by the Department of Health (DOH) and the Parliamentary & Health Service PHSO (PHSO) to the complaints process in the last decade, there has been very little progress in changing the approach of trusts to handling complaints openly, using the knowledge they could gain from the process to enhance the quality of services, and making the complaints process effective.

22. The evidence suggests that the most important lesson to be learnt is that irrespective of the processes or structure in place, the complaints-handling processes will never be effective if the system as a whole does not back up the numerous policy and guidance documents with sufficient resources, effective regulation and a cultural change. In other words changes do not go deep. At the Inquiry's seminar on Commissioning, (3 November 2011) it was commented that if only you could call complaints something else, as the term itself is a problem. This demonstrates the intrinsic difficulty all trusts face in learning to accept that complaints are a necessary part of a service, occasionally unavoidable, and that everyone can learn from the process. Whilst the complainant is seen as the adversary, and the process as a precursor to litigation or further criticism, rather than an opportunity to learn from mistakes and correct the problems caused to the complainant.

Patient Advice and Liaison Service

23. It is important that every hospital have a strong, effective, visible Patient Advice and Liaison Service (PALS) given that it will often be the first place a patient will go to voice a concern with care or treatment. It is in effect a 'customer care' service and has potential to 'nip problems in the bud' and

to provide important feedback internally on patient satisfaction and quality it also has potential to imbue the complaint process with worth within trusts, and it should not be forgotten that PALS should be the interface between the complainant and trust staff, enabling them to find the information they need to make the complaint in an informed way and enabling staff to understand the need for the complaint to be dealt with. Medicine is complex. Doctors and nurses are in a position of power as the individuals giving the needed medical treatment and with the knowledge of what treatment is needed, and when things go wrong the knowledge of what went wrong and why. PALS may be able to even out the imbalance of power to a degree, alongside independent complaints advice bodies, and so lead to easier and effective resolution of complaints. However at the Trust, its role became confused with the complaints process itself and with independent advice giving.

24. Patients and their relatives who have given evidence to the Inquiry gave strong message that PALS at the Trust was at best, ineffective and at worst, a barrier to the complaints process. Several patients described PALS as being uninterested or unhelpful (Christine Dalziel WS0000000007, paragraph 55, Patient relative A WS0001000621, paragraph 4 – 13), ineffective in dealing with the concerns (Elizabeth Cowie WS0000000140 paragraph 75 – 77, Gillian Peacham WS0002000060, paragraph 9, 13) and in some cases, after registering a complaint, witnesses described receiving either late responses or in certain cases, no response at all (Patient Relative C WS0000000797, paragraph 160). One witness, Beverley Howell, stated that she believed the:

> *PALS office is run on the basis that 90% of people will just become so frustrated and worn out by complaints process that eventually they give up (*WS0002000001, *paragraph 38).*

25. Whilst PALS is the first point of contact for many patients, contact with PALS should not be a pre-requisite of taking further action in accordance with the NHS complaints policy. Chris Bostock, lead for complaints policy within the DOH since 2003, stated that PALS is not a gateway to the complaints system and with the exception of informal resolution of an issue within 24 hours, all complaints need to be handled through the complaints system. (WS WS0000056086, paragraph 69).

26. It is clear from the witnesses' evidence that many did not distinguish the PALS office from the complaints-handling function and there was misunderstanding with respect to their role, for example, Thomas Bentham confirmed that he had thought that it was an independent organisation like a Citizen's Advice Bureau (WS0000001717, paragraph 18 – 23).

27. The confusion with respect to the role of PALS was not helped by the fact that over the relevant period, it had been moved within the Trust structure a number of times. After its launch in 2003, it was joined with the complaints service in mid 2007, until the functions were again separated in 2009 after the publication of the Healthcare Commission (HCC) report (statement of Sharon Llewellyn

WS0002000457, 29, 32, 90). Lack of clarity in this regard, from the perspective of both patients and the staff who come into contact with PALS / complaints staff, can undermine the effectiveness of these services.

28. Sharon Llewellyn described the PALS as being understaffed and overwhelmed. At the time she was responsible for PALS, the staff were the same grade as porter / housekeeper and were not able to challenge the more senior members of staff upon which they relied in order to resolve complaints raised by patients. There were no national standards and it was a matter for each trust as to how this service was structured. In her role, she referred to working between 50 – 75 hours per week due to the lack of support (LiveNote 17.01.11, 31, 165 – 166, 169).

29. It is clear that the provision of PALS needs to be carefully re-examined. Unless the status of this service is recognised and resourcing provided to ensure that the service is provided to a consistently high standard throughout the country, it has the potential to cause more harm than good. In response to the Health Committee's recommendations that first, PALS needed to be more visible and better signposted, the Government confirmed that this was a matter for local organisations who were best placed to ensure that there was a visible profile (paragraph 49 and 52). Given there is not even a statutory requirement to provide PALS, AvMA believes that this will only perpetuate the current situation where the standard of PALS will mirror the overall standards in the organisation - but strong and effective PALS are particularly crucial within organisations which are struggling in other respects.

Recommendations:

- PALS should be clearly defined as an internal customer care or 'trouble shooting' service, quite distinct from the formal complaints process. PALS role in formal complaints should be restricted to explaining the procedure and signposting to appropriate staff and sources of independent advice. There should be no suggestion that in order to make a complaint people have to go through PALS first. It should be clearly explained that PALS staff are <u>not</u> independent but a service provided by the Trust itself.

- There should be provided clear minimum standards with respect to the provision of PALS (including opening hours, information to be provided to patients) and clear central support and guidance with respect to best way to provide effective PALS, based on the experience throughout the country. These should be communicated clearly and widely, both by means of printed media and on trust websites. The information should be easy to find on the website with an obvious link from the trust's landing page.

- Trusts should ensure that there is understanding throughout the organisation in relation to the importance of role of PALS, in particular understanding by those senior medical staff who may be the first point of contact for PALS staff.

- PALS must have clear channels of communication and information sharing agreements with the local HealthWatch. As set out below, AvMA considers that independent complaints advocacy should be provided by local HealthWatch but in the event that it is provided by third party providers, this communication should extend to these bodies in addition to HealthWatch itself.

- Patients must be informed of basic information in a clear and consistent manner, including:
  - Clarification of the role of PALS as an internal "customer care" service – separate from complaints;
  - Information on the availability of independent advice and support with complaints (ICAS and more specialist advice agencies such as AvMA);
  - The difference between raising a concern and making a complaint and how to do the latter;
  - The system of local complaints resolution within the NHS complaints system, including how to make a complaint and what to expect thereafter;
  - Possibility of PHSO reviewing the complaint, how and when to do this and what to expect thereafter;
  - Role of other bodies including Core Quality Commission (CQC) and (in the future) Clinical Commissioning Groups (CCGS)

- PALS should be monitored by local commissioning bodies to assess the quality of the service provided but also as part of the commissioners' early warning system, as it will highlight developing and potential problems with particular services and/or service providers. . The quality of the service lends itself to be simply and easily measured through patient feedback and data kept on the nature of the comapoints and departments/teams against whom they were made will feed into an early warning system.

Quality of local investigation and resolution of complaints

30. Local resolution has been long considered as the best way of ensuring that trusts are able to respond to the particular needs of individuals quickly and effectively. AvMA believe that providing a high level of individual discretion to trusts, with correspondingly light monitoring and a lack of sufficient central guidance, has allowed the quality of complaints handling to become weak and inconsistent.

31. AvMA's long history of dealing with patients in these circumstances provides AvMA with an insight into what patients want to happen in the wake of poor care, treatment and clinical incidents. AvMA's experience is that patients and their families invariably want two things: firstly, to know what happened and why and secondly, to be reassured that it will not happen to anyone else. "Patient involvement" is not achieved through surveys, consultation or committees. It is achieved through treating the patient as an active participant in the process, who should be involved throughout, rather than a passive recipient of services. This principle is not new, but it seems that real and practical steps are required to make it a reality. The complaints process needs to re-focus upon the central role of

the patient and their family, who in the course of an initial meeting could clarify the real concerns within a written complaint – and provide valuable background information concerning the course of care provided and other specific areas of particular concern.

32. Dr Laker, lead clinician response for the Independent Case Notes Review (ICNR), commented in his statement that he

> "*got the feeling that, for a lot of families, the initial meeting with me was the first time that anyone had listened sympathetically to their concerns of complaints. I believe that this was an indictment of the Trust's complaints process overall*."

(WS0000002471, paragraph 33). He further confirmed that of the 46 patients who had made complaints, mostly the complaints had been borne out by the review and more importantly, most had not led to satisfactory outcomes (LiveNote 14.02.11, 86:10 and MON00030009262, 9). In particular, he commented:

> *Often families had been involved in the Trust's complaints process and they were sure that what they had said and what they had been told had not been acted upon (WS0000002471, paragraph 33).*

33. The written responses to complaints by the Trust were considered formulaic and insincere. As described by Julie Hendry:

> *… the responses were definitely defensive. They were what I would call mechanistic. Apart from taking the names out you could almost transpose some of the responses between complainants. And I think they used terminology that would be quite offensive to a complainant, such as "We are sorry that you feel that." If I made a complaint and somebody sent that to me, I would immediately think that the organisation wasn't listening. (LiveNote 07.03.11, 161:17)*

34. This was of course exacerbated by the absence of effective clinical governance processes governing complaints at the Trust. Martin Yeates confirmed that when he arrived in the Trust in 2005:

> *"There were no coherent systems in place for actioning or responding to letters of complaint ... It is fair to say that in the early days, we didn't have any systems in place of any continuity in terms of who was dealing with complaints" (WS0000074921, paragraph 74).*

35. Julie Hendry, when she arrived at the Trust as interim Director of Patient Experience in June 2010

identified similar failings, with delays of up to 10 weeks and a backlog of 216 complaints. She described how the complaints staff, who had no clinical training and held reasonably low administrative grade, would spend inordinate amounts of time chasing various clinicians and nurses for information. They would themselves prepare a response for the consideration of the Chief Executive and throughout, the associate director with responsibility for the process effected little oversight or control (LiveNote 07.03.11, 150 – 153).

36. Further, there appeared to be little evidence of clear policy and practice in place with respect to the involvement of an independent investigator within local investigations, although Sharon Llewellyn said that the SHA kept a list of clinicians available for independent review (LiveNote 17.01.11, 22:8 – 23:10). Julie Hendry clearly recognised the importance to the patient of independent input when she arrived in post confirming that frequently, where a patient was "starting off with very little confidence" or where they were unhappy with the initial trust response, she would suggest an external review (LiveNote 07.03.11, 163).

37. The idea of an external review process is supported in principle by the DOH, with Chris Bostock stating the aims of the 2009 reforms including making local resolution more effective, which "in some situations it could be appropriate to have an independent investigation, such as someone from a different department, different trust or someone from outside the NHS such as retired police officer, investigating the complaint depending on how serious it was. This is reflected in the DOH's guidance on serious complaints" (WS0000056086, 50). However, it is apparent that, within trusts, there needs to be clearer guidelines in place for those responsible for complaints investigation to introduce an independent investigator when a complaint involves complex clinical matters, serious harm or death. Importantly, patients' view on this issue should be sought – although there may be some concerns which can be resolved through open discussion and reassurance, there may be real concerns with the independence of a particular individual which, if ignored, will mean that the patient will be unlikely to accept the conclusions of the trust response.

38. Another issue of concern is the difficulty encountered by patients and their families in obtaining their patient notes. William Hudson described chasing the Trust after receiving the first batch of incomplete medical notes. He understood from the Trust representative that the second batch were also incomplete or missing (WS0000001443, paragraph 31, 35). Castell Davies describes again receiving incomplete batches of medical notes after considerable chasing and ended up writing to the PCT, her local MP, the Prime Minister and the Information Commissioner with respect to missing material – to no avail (WS0000001056, exhibit CD/11).

39. Further to the 2009 Regulations being introduced, Chris Bostock confirmed that no guidance was provided with respect to complaints handling, on the basis that trusts would be able to tailor their

response to individual needs (WS0000056086, 56). Again, AvMA believe that this is a mistake and inevitably leads to inconsistency of approach. Clear central complaint handling guidance is essential in order to ensure consistency and enable learning to be shared, as well as allowing complainants and staff working on complaints to know where they stand. This does not mean that there cannot be some flexibility. The key principle should be that variations from guidance are agreed with the complainant.

40. In AvMA's experience, and as various witnesses have commented, complaints staff have a very demanding and vitally important role. However the status and salary levels of complaints staff vary considerably across the country and there is variable training and support available for complaints staff. In AvMA's view this variability directly impacts on the quality of complaints investigation and responses.

41. Meanwhile, it is clear that policies and guidance alone will do little to remedy the failings of the complaints system without an overall adjustment of priorities within the NHS and culture within Trust. Julie Hendry noted:

> *"I think people saw a complaint as -- I'm not saying a nuisance. I don't think anybody ever saw complaints as a nuisance, but they -- they saw them as quite challenging, and -- and they -- they didn't always, I think, see them as an opportunity to learn about what was really going on in the area. It was more that "Oh, how am I going to find the time to investigate that properly?" (LiveNote 07.03.11, 160:8)*

Recommendations:

- Patients should be involved throughout the course of the complaint investigation, including the offer of an initial meeting with relevant clinical staff. Julie Hendry confirmed that this was a practice which she considered helped enormously to enable the patient to ask questions and the clinician to understand the impact of the matter upon the patient. This also avoids miscommunications arising with respect to written responses (LiveNote 07.03.11, 165:6).

- Trusts must ensure that there is integrated system for patients to obtain copies of their medical notes, within the required time limit. From the patient perspective, it should not matter whether the request is made to PALS, through the complaints process or the Trust solicitors. All requests, made to any part of the Trust, should be dealt with centrally;

- Consideration should be given to model person specifications and grading for complaints staff; training and development needs of complaints staff should be addressed

- Consideration should be given to the creation of an independent investigation unit either within an existing body (for example, the CQC) if not a new body entirely devoted to investigating cases where death or serious injury has occurred, or where it is determined that internal investigation is not appropriate or possible.

- At the very least, there should be a more co-ordinated approach to providing for a more arms length / independent element in complaints investigations concerning serious injury or death. This could draw on existing examples of good practice for example Devon & Cornwall and guidance be issued to ensure consistency of approach.

- A central database of clinical staff with the willingness and ability to conduct investigations of this nature should be developed. (On occasions AvMA has been asked to recommend such people from its existing database of medico-legal experts. This can help ensure that the investigation is as independent as it can be and perceived as such).

- Patients making complaints should be informed from the outset of the circumstances in which the local investigation may be conducted by an independent investigator, including what this means in practice ie. whether independent to service, site or trust. This information, which should be set out on the website, and written material provided to complaints, will ensure that expectations are clear.

Second and third tier complaints process

42. Dr Laker noted that if a complainant was not happy with the response from the Trust, that there was very little scope for them to take their complaint further internally (WS0000002471, paragraph 35). Rather, they were reliant upon the review function available through the HCC and PHSO.

43. The period of the Inquiry's consideration covers two distinct complaints regimes. From July 2004, a three tier complaints process was in place under the National Health Service (Complaints) Regulations 2004 ("2004 Complaints Regulations"). After local resolution, an individual was able to refer their complaint to the Healthcare Commission and thereafter, to the PHSO. HCC complaints handling was regarded by some as having limited success. . However, AvMA believes, based on its experience, that the problems with this second stage lay more with the rest of the system rather than the HCC or the second stage itself. Marcia Fry of the HCC referred to the sense that trusts were not taking responsibility for resolving complaints at a local level and were instead "passing the buck" (LiveNote 06.05.11, 126); and the HCC itself was overwhelmed with the number of complaints, leading to substantial delays in resolution at the second tier (WS0000026566).

44. Whilst the HCC operation of the second stage independent review of complaints was not perfect, AvMA believe that the HCC had begun to get on top of the problems by the time it was abolished and that many complainants and the NHS as a whole benefitted from at least having access to independent reviews . By placing this function within the regulator, it was able to use this information in exercising its regulatory functions. In particular, they had begun to take action with regard to trusts whose complaints handling was unsatisfactory.

45. After this second tier was removed through the introduction of the Local Authority Services and National Health Service Complaints (England) Regulations 2009 ("2009 Complaints Regulations"), the PHSO became the only body with responsibility for reviewing complaints.

46. The PHSO has considered 15,529 health complaints in the 2009 - 2010, of which she found that 58% had not been not properly made or were premature; 346 (2.2%) complaints were accepted for investigation and 219 were resolved through intervening with the relevant body, which together amounts to just 4.4% of complaints (PHSO's review of complaint handling by the NHS 2009 – 2010, "Listening and Learning", 13). Nearly 27% of complaints were not accepted on a "discretionary basis". AvMA is concerned that there is apparently a large group of people who are now not eligible to have their complaints reviewed by an independent and external body.

47. With respect to the availability of review by the PHSO, the Health Committee indicated in its June 2011 report on complaints and litigation that it was "of the view that a complainant whose complaints is rejected by the service provider should be able to seek independent review" and recommended that the legal and operational framework of the PHSO's office should be reviewed to make it effective for this purpose (paragraph 50). The Government responded that it would rely upon the PHSO's stated position that she had the authority to review any complaint referred to her by a complainant (paragraph 48).

48. The evidence given by the PHSO demonstrates the extent of the discretion she exercises and the possibilities for inconsistency to arise in terms of the cases which are investigated. Although the PHSO has discretion to investigate within the statutory terms of section 3 of the Health Services Commissioners Act 1993, guidance had been formulated that a complaint would be unlikely to be considered if there was no prospect of a "worthwhile outcome", which she described in the following way: "can the ombudsman deliver the outcome that the complainant is seeking? And if not, is there another worthwhile outcome, possibly the wider public interest, which would justify the PHSO taking on this case for a formal investigation?" She emphasised that a lot of their work involves informal intervention, which often produces the outcome sought by the complaint, for example, an apology and there will be many circumstances where a full investigation is not necessary (LiveNote 29.06.11, 10 – 16). The PHSO confirmed that she accepts that the wording should be reviewed on basis of

recommendation from the Health Committee. However, AvMA are also concerned that the guidance is also redrafted to specifically acknowledge that there will be circumstances in which the "worthwhile outcome" is independent scrutiny of the trust's internal investigation and response where the complainant remains dissatisfied and the assessment shows they have a reasonable argument. We find it hard to believe, based on our experience, that the majority of complainants who are turned down on the basis of the PHSO assessing that there was no prospect of a worthwhile outcome would agree that that was the case. Establishing that the Trust is wrong, its process inadequate or that a complaint is justified are in themselves 'worthwhile outcomes' without which NHS bodies will not learn to improve, and the complainant will remain dissatisfied.

49. AvMA also remain concerned with respect to the interpretation and application of section 4 of Health Service Commissioners Act 1993 by the PHSO to exclude complaints from second tier review where a clinical negligence claim has been made. This provides that the PHSO shall not conduct an investigation in respect of action in relation to which the "person aggrieved" has or had a right of appeal, reference or review or else, a remedy by way of proceedings in any court, unless she considers it not reasonable to expect that person to resort or to have resorted to it. AvMA consider that any decision to exclude a complainant simply on the basis that they are making or planning to make a clinical negligence claim is inappropriate. Such complainants will invariably be seeking different forms of redress from their complaint to the PHSO than they are from making a clinical negligence claim. Such litigation is the means available for individuals, who have suffered harm, to obtain financial compensation. This process is lengthy and subject to particular rules restricting disclosure. Litigation is not designed to provide the other forms of remedy available from the PHSO, including apologies, explanations, improvement to services and putting right injustice. This appears to have been recognised by the Law Commission, which has indicated that this provision should go, with a consultation due in July (LiveNote, 29.06.11, 21 - 26). However, having seen recent examples of inappropriate advice to members of the public on this issue and refusals to take on cases from the PHSO's staff, AvMA recommend that pending any potential change to the regulations, clearer guidance is issued throughout the PHSO's office to ensure that there are clear limits upon the exercise of this discretion. It was agreed that the complaints process under the 2009 Regulations would be reviewed after three years and the Government, in its response to the Health Committee's report, states that this review should follow the Chairman's recommendations in this Inquiry, emphasising that this is one area which would merit the Chairman's careful attention (paragraph 30).

Recommendations:

- Clear guidance should be provided to trusts to encourage them to reconsider an investigation once a response is issued should the patient have concerns with respect to the findings. This should involve clear communication as to the area of dispute and the option of independent review. It should, however,

remain the complainant's choice whether it is re-opened by the trust or is taken by the PHSO/independent review body.

- AvMA agrees with the Health Committee that the current arrangements are unsatisfactory. Consideration should be given either to returning to a three stage complaints procedure with more access to independent reviews and a link to the regulatory role OR changes in the remit and capacity of the PHSO so that she can take on many more cases for investigation. In the meantime, the PHSO guidance on a "worthwhile outcome" should be redefined to explicitly include:
  - Where the trust's conclusions are disputed by the complainant and an investigation by the PHSO may arrive at different conclusions;
  - Resolving disputes over facts;
  - Where the NHS body's investigation or response is inadequate;
  - Where there is an unfair refusal to investigate certain issues.

The role of other bodies in considering individual complaints

50. In Staffordshire, due to the failings of processes of "local resolution" within the Trust, patients were left to pursue almost every other avenue available to them, including contact with the local MPs and the DOH. AvMA is concerned that there is a lack of clarity with respect to the role of some of these bodies in terms of complaints and the expectation raised that reporting would lead to investigation.

51. At present, an individual with concerns may also report an incident anonymously to the National Reporting and Learning Service (NRLC), register their concern on the NHS Choices website and contact the CQC. Although each has a slightly different role, none of these provide the patient with feedback or means of resolution. It is understood that information received by National Patient Safety Agency (NPSA) or the NHS Choices website, as well as individual concerns raised with the CQC, are potentially fed into the CQC's Quality Risk Profile designed to identify trusts at risk of non-compliance for the purposes of informing its monitoring activities. However, although a single serious issue may reflect a pattern of underlying problems, individual concerns will only be considered within the context of organisational non-compliance (see evidence of Baroness Young, LiveNote 04.07.11, 31).

52. The CQC accepts that wider issues requiring its intervention or investigation might well be brought to its attention by individuals and specifically welcomes feedback from individuals. However, information on its website suggests otherwise; it is not made clear how to report serious concerns about the safety of healthcare provider, or organisational / system failures with the CQC itself. Instead, people are directed to information about the NHS complaints procedure or local safeguarding arrangements if an individual is at risk. There is no information about how to raise concerns with a view to encouraging the CQC to conduct a reactive investigation (www.cqc.org).

53. The complexity of the situation becomes even more apparent when considering the position of the HSE within the regulatory framework. Gillian Astbury died in Stafford Hospital in April 2007 after received appalling care, contracting clostridium difficile and not having been given insulin for more than 48 hours. The police commenced an investigation the following year and in March 2008, sought the involvement of the Health & Safety Agency (HSE), which at that point took the view that the matter would be best dealt with by the HCC. Although section 3 of the Health and Safety at Work Etc Act 1974 (HSAW) did provide the HSE with jurisdiction to investigate such a death, the organisation's underlying policy confirmed that within a healthcare setting, HSE would be primarily concerned if "there was something physically wrong with the hospital" (LiveNote 30.06.11, 30) and matters involving individual clinical judgment should be dealt with by "other better placed" regulators. By January 2010, the CPS confirmed that the police investigation would not be taken further and the case was handed to the HSE. Ron Street, Gillian Astbury's friend and carer, received a further letter from the HSE on 28 January 2010 confirming that section 3 of the Act was not generally used "where other regulators (such as the Care Quality Commission) are better placed to act." (Street Exhibit RS/22, WS0001000669, 97). The CQC, however, do not investigate individual cases, and so will not act in the very cases that the HSE will not investigate because they understand it to be within the CGQ remit.

54. Following the inquest into Gillian's death in September 2010, Ron Street renewed his communications with the HSE but by June 2011, when Clive Brooks of the HSE gave evidence, a decision had still not been made with respect to whether HSE would undertake a prosecution. Clive Brooks explained the difficulty which he faced was "opening the floodgate" commenting:

> *"Which family do I disappoint and say, "I can't take yours forward"? How many families do I disappoint by saying, "We've looked at this but we can't do anything about yours"? I don't know where it will begin and end." (LiveNote 30.06.11, 161:2)*

55. In seeking to ensure that the death of his friend was properly investigated and if necessary, prosecution brought, Mr Street encountered a complete lack of understanding and co-ordination between the three primary bodies involved: the police, the HSE and CQC. His evidence demonstrates that Gillian Astbury's case fell through a regulatory gap between the HSE and the CQC, which exists primarily because the HSE simply are not equipped with the resources in order to fulfil their statutory function.

56. Inevitably, and especially if internal systems are not working properly as was the case at the Trust, some people will either by pass the official route for raising concerns or making a complaint or become frustrated and contact other bodies / people such as their MP, the DOH or Ministers, or other

bodies with a role with regard to the Trust. For example, with regard to the Trust this included the SHA, PCTs and Monitor. The experience of people from Staffordshire shows that there is a danger that simply because people use a route that is not part of the usual 'road map', their concerns and the potential they have for raising the alarm about a failing trust might be missed. The inquiry heard that the DOH has reviewed and changed how it deals with correspondence received from members of the public, which is welcome. More clarity about how MPs should deal with complaints received and other bodies would also be helpful.

57. Under the current reforms, the Clinical Commissioning Groups and the NHS Commissioning Board will have a crucial role. Clarity is needed about their role with regard to receiving complaints or concerns about Trusts or indeed GPs and other primary care practitioners. Members of the public might also contact a Health Scrutiny Committee or Health & Wellbeing Board of a local authority. Or, as discussed later, they might contact a health professional regulator.

Recommendations:

- The CQC's role in dealing with individuals' concerns about a registered healthcare provider should be clarified and better publicised, including how individuals (or organisations for that matter) can alert the CQC to a possible need for a reactive review of a registered provider;

- The HSE's statutory responsibilities with respect to investigating health and safety failings need to be revised to ensure that there is absolute clarity with respect to when they will and will not become involved;

- Comprehensive Guidance should be issued for patients which covers the respective roles of MPs, the DOH, NHS and other public bodies and what each can and should do with complaints or concerns received about health services.

The availability of independent complaints advocacy, support and advice

58. There are recognised barriers to patients making complaints, including not wanting to make a fuss or to be seen to be making a fuss, a fear of effecting an ongoing relationship with a medical practitioner and sheer fatigue with the complaints process (evidence of Ann Abraham, LiveNote 29.06.11, 44) Many patients will be elderly, in poor health and some will not have the support of the kind of committed and available families and friends as have given evidence to this Inquiry. By definition, the patient group will include some of the most vulnerable members of the community and as has been demonstrated above, navigating the complaints process can involve considerable determination and resourcefulness.

59. Mrs Robinson provided a clear endorsement of the importance of independent advice and assistance:

> "*… there is only so far you can go on your own, not having the knowledge. I think we've done pretty well so far, but we do need support from someone else. We do need someone else's advice." (LiveNote 23.11.10, 173:12)*

60. Further to the abolition of Community Health Councils (CCHCs) in 2004, the DOH commissioned the provision of "Independent Complaints Advocacy Services" (ICAS) from independent providers. Presently, there are three separate providers providing ICAS nationally, with PohWER providing the service in Stafford. Although some excellent work is carried out by ICAS within the constraints of the system in which they have to work, there are concerns with respect to the way these services are commissioned and provided. Firstly, it appears few knew about this service in the local Stafford area. Julie Bailey confirmed that she was unaware that ICAS operated in the Stafford area until the HCC report was published (LiveNote 23.11.10, 108:25). Other patients were similarly unaware of their existence (evidence of Christine Dalziel, LiveNote 24.11.10, 102), Sandra Whitehouse, LiveNote 29.11.10, 60 and Beverley Howell, LiveNote 29.11.10, 191). Elizabeth Cowie, the single witness who does provide evidence concerning ICAS, confirmed that they were helpful in preparing for her meeting with the Trust, although obviously overstretched (LiveNote 30.11.10, 69).

61. The definition of the "advocacy" commissioned from ICAS providers is limited by agreement with the DOH, described by Chris Bostock as being based on the model of "empowerment" rather than what he described as a "barrister led" model in which an advocate takes a lead in representing someone (WS0000056806, paragraph 73). The literature produced by PohWER with respect to ICAS services confirms that role of an ICAS "advocate" is to "assist you in understanding the complaints process, writing letters, going through replies, preparing and attending meetings and referring you to other sources of support where required." An advocate could not "tell you what you should do, contact people without your agreement or make up your mind for you but we can offer you information and support to make an informed choice. We cannot provide medical or legal advice." (PohWER FAQ, PA0006000060, 4).

62. In evidence, it became apparent that in practice, it is difficult to clearly distinguish the definition of "advocacy" from the common understanding of "advice". It appears the distinction is between simply informing a patient of their options and helping them express their opinion, as opposed to giving some form of opinion (for example on the credibility of a response to a complaint) and advising them which options should be considered further on the basis of the information available. In practice, it will be of little benefit for a patient to be informed that they are able to make an application to the PHSO, make a complaint to the General Medical Council (GMC)/Nursing and Midwifery Council

(NMC), or consult specialist clinical negligence lawyers without first being equipped with some understanding as to whether there is a medical failing which would warrant a further independent clinical review, regulatory complaint or legal claim for compensation. Given that ICAS do act as a sign posting service with respect to referrals to the GMC or litigation (LiveNote 13.01.11, 130), it is clear that contrary to the clear message within its literature, ICAS do provide a view with respect to the substance of a complaint and credibility of the Trust response. When pressed with respect to the distinction, Valerie Harrison confirmed as follows:

> *"A […] And I think where we've reached the point we've reached in ICAS is, it's an established and experienced service. It cannot stand back from trying to give clients the fullest help, support and, yes, if you want to use the word, "advice", but that it can. But the pure description would be the one that is here. But what we don't have, I think, in ICAS is - and something we touched on earlier, that sort of sufficiently regular review from the Department to say "Look, the practice is evolving like this. Can we now change that?" And I don't think we'll get it now, this side of reviewing the whole shooting match as the contract is reformulated for the future.*
>
> *THE CHAIRMAN: Yes. I mean, would you, given a free hand, want the advocacy service to be able to be freer in the advice it gives clients?*
>
> *A. Yes."(LiveNote 13.01.11, 169:18).*

63. It seems that a strict "empowerment" model of advocacy is difficult to implement and in practice, ICAS operate within an ill-defined "grey" area. AvMA believe that there needs to be careful reconsideration of the remit of ICAS to clarify this.

64. Further, AvMA remain concerned that there is no provision within the current funded system of complaints advocacy for specialist advice and assistance in serious and complex matters where ICAS is unable to assist, particularly with respect to clinical, regulatory and medico-legal matters. Although ICAS can and do provide a "sign-posting" service, it is clear that patients and their families need specialist advice and assistance in making decisions as to next steps and then, taking matters further. For example, patients may need advice of a clinical and medico-legal nature in order to make informed decisions about which procedures to follow. This is beyond the remit and expertise of ICAS providers whose role is to help complainants "navigate" the NHS complaints procedure. Currently ICAS providers tend to signpost cases needing specialist advice to other more specialist advice providers. In the case of medico-legal issues this is often AvMA. There is no formal, funded arrangement for the provision of this sort of advice although it was the intention that there should be when CHCs were being abolished and ICAS established. As discussed elsewhere, it has been

particularly acknowledged that there is a gap in the availability of specialist advice and support for people who may want to refer health professionals to a regulator such as the GMC or NMC.

*ADD evidence re people not being told about AvMA and the Trust's practice in raltion to this changing – relates to late recommendation you could say "Evidence was heard from Julie Bailey and other families that they were not aware of AvMA's existence until after the HCC report and that had they known they would have gladly asked for their assistance. Again the Trust's failure to advise patients of the availability of independent advice and assistance with respect to complaints reduced the effectiveness of the complaint process, and in fact in most cases at the Trust the process failed."

65. It is understood that ICAS contracts have been extended until April 2013, at which point it is intended under the Health and Social Care Bill that responsibility for commissioning ICAS will be handed to local authorities (WS0000056806, paragraph 77). The Bill allows local authorities to commission advocacy services from three sources: solely by a third party provider, by local HealthWatch through third party provider, or solely by local HealthWatch, on the basis of the following reasoning:

> *"We have considered making independent NHS complaints advocacy an integral part of local HealthWatch but believe it is appropriate for the delivery of local services to be determined locally. We do not believe that providing NHS advocacy services through HealthWatch would necessarily lead to consistency and may increase costs. Third party providers of advocacy services will employ appropriately skilled and experienced advocates, and it seems inappropriate automatically to exclude them from the process. Nevertheless, having independent NHS complaints advocacy services delivery by local HealthWatch is an option available" (DOH Briefing Paper on HealthWatch DH00000004590, 2).*

66. It is noted that the Government relies heavily upon the establishment of local HealthWatch in obtaining the views of people about their experiences of local health services and providing scrutiny of the complaints handling in strengthening current complaints handling within the NHS. It is proposed that local HealthWatch will be able to submit views, reports and recommendations, to which under the existing Bill, the organisation would be required to "have regard" (Government Response to Health Committee's Sixth Report on complaints and litigation, September 2011).

67. AvMA are concerned that currently, ICAS providers do not take sufficient advantage of their knowledge and experience gained through its role to improve services. The contract with the Department of Health for providing ICAS represents a huge percentage of current provider's income, which may be a disincentive to 'rock the boat'. Citizens Advice had been the single biggest provider of ICAS. It had started to publish highly critical reports based on its experience. Its contract was not renewed when the contracts were re-tendered. Valerie Harrison explained that PohWer did not take

on a "campaigning role" after receiving feedback from patients that they were fearful that this would undermine their relationship with the NHS, (LiveNote 13.01.11, 14). There is no reason to suggest that ICAS providers' approach would be any different in the future, if these organisations continue to provide complaints advocacy services. If the ICAS function is provided by different organisations than HealthWatch this also inevitably makes the sharing of information and a joined up approach more difficult. This risks the possibility that the valuable information obtained through complaints advocacy may not be used to strengthen HealthWatch's ability to influence change unless there is more of a joined up system which some have described as a 'one-stop shop'. National HealthWatch could set and monitor standards for the service and collect lessons centrally from this work. This arrangement would have the benefit of creating a more consistent service nationally than is currently possible through three different bodies commissioned to provide ICAS. It would also provide the 'join up' between complaints from the public and the monitoring or watchdog role of Healthwatch, allowing it to be more in touch with and to be able to respond more quickly to concerns arising. It would enable a return to the model of a local "one stop shop" for patients and the public, similar to that which had been provided by CHCs and which was the stated policy intention even when creating the system to replace CHCs. The Government's current proposal to leave these decisions in the hands of each local authority would make the achievement of a consistent model of this kind impossible to achieve. Huge differences in allocation of resources for this would result.

68. AvMA also remain concerned that a model which allows provision of complaints advocacy by third party providers will perpetuate the current situation in which the provider is reliant upon contractual income from the same body with which it is expected to raise concerns and press for change. By bringing complaints advocacy within a single organisation, this potential conflict is removed.

69. The Inquiry has heard about difficulties families have had with being empowered within the Inquest process and in the ICNR process set up with regard to the trust. The establishment of a specialist national resource for specialist advice of this nature would not only be an invaluable adjunct to and resource to which the ICAS service could refer, but would also be a resource which could be called upon if (when) future large scale problems affecting patients occur in the NHS.

70. Finally, the current provision of ICAS by independent providers highlights the danger of inconsistent policies and practice developing in different areas, especially given the fine definitions applied to the nature of "advocacy". From the point of view of patients, provision of independent complaints advocacy through a single provider, HealthWatch, would ensure that there is a single coherent approach to this important function. National HealthWatch could set and monitor standards for the service and collect lessons centrally from this work. This arrangement would have the benefit of creating a more consistent service nationally than is currently possible through three different bodies commissioned to provide ICAS. It would also provide the 'join up' between complaints from the public

and the monitoring or watchdog role of Healthwatch, allowing it to be more in touch with and to be able to respond more quickly to concerns arising. It would enable a return to the model of a local "one stop shop" for patients and the public, similar to that which had been provided by CHCs and which was the stated policy intention even when creating the system to replace CHCs. The Government's current proposal to leave these decisions in the hands of each local authority would make the achievement of a consistent model of this kind impossible to achieve. Huge differences in allocation of resources for this would result.

Recommendations:

- There should be a requirement on trusts to provide consistent, appropriate information about how to access independent advice in any case where there has been a patient safety incident resulting in harm, a case is notified to the coroner, or a serious untoward incident or other investigation is carried out.

- Information to complainants should include information about ICAS and how to access its services. There should be no suggestion that potential complainants should have to go through PALS first. Information should also be provided on sources of specialist independent advice such as AvMA.

- ICAS services in the future should be provided by local HealthWatch organisations through staff specifically working with HealthWatch for that purpose.

- AvMA recommends that resources are allocated to local HealthWatch for ICAS provision according to an agreed formula, and not directly from local authorities, or directly from the NHS or DOH. ICAS needs to be independent and be perceived as being independent to enjoy public confidence. If the service were to be commissioned by local authorities an inevitable conflict of interest arises, as ICAS will be supporting people with complaints about the same local authority social care services.

- As well as the generic ICAS type support with NHS complaints, provision should be made for the more specialist independent advice referred to above including help with making complaints (referrals) to the GMC and NMC, but also potentially helping members of the public understand clinical, regulatory and medico-legal aspects of their case so as to make informed decisions about which processes to follow. This should include support with inquests into healthcare related deaths. National HealthWatch could be given the role of commissioning such a specialist service from suitably experienced and specialist organisations.

Trust learning from complaints and other concerns

71. Sharon Llewellyn described the process in place before 2007 at the Trust whereby every complaint

was considered by a Complaints Review Panel. These were held on a quarterly basis with every Directorate and attended by the Heads of Department, any relevant staff members and the complaints manager. Each complaint that had been received in that period would be reviewed, including the complaint itself, the response and the action which had been taken in light of the response. As the panels were chaired by Non-Executive Directors, they were able to feed relevant information to the Trust board and to provide feedback to staff (LiveNote 17.01.11, 8 – 09). Despite the reported efficacy of the system of scrutiny and feedback, Martin Yeates indicated in his statement that until Helen Moss arrived in 2007, the hospital was not actively monitoring the nature or source of complaints in order to build up a picture of problems (WS0000074921, paragraph 74).

72. The new system introduced in 2007 included Quality Monitoring Panels, which fed into the Executive Governance Groups, which then reported to the Audit Committee, which reported to the board (Statement of Moss WS0000009450, 75). Sharon Llewellyn confirmed that the Quality Monitoring Panels did not consider the content of each and every complaint, but rather considered the high-level detail concerning "five top themes."

73. In accordance with regulation 21 of the 2004 Complaints Regulations, quarterly reports were prepared for the board, consisting of the number and subject of complaints, as well as how they were handled, including the outcome of the investigations. Complaints reporting to the board was suspended entirely between 2003 – 2006. The reports which were produced included little more than figures with respect to compliance and a list of "top five themes;" "Communication," "Attitude of staff" and "General Standards of Cleanliness" frequently topped the table throughout this period (see evidence of Helen Moss, LiveNote 28.03.11, 95-96). It is unsurprising that the complexity of the clinical governance system meant that the important detail was filtered out before information was received by the board.

74. Meanwhile, it is apparent that even the top five themes were not being given the attention which they clearly warranted. Dr Laker, upon undertaking his review of complaints available to him, noted that "There were many themes in the complaints made, but one common issue was the nursing care" (WS0000002471, paragraph 46).

75. Positive steps were taken from 2007 to create a comprehensive database of information arising from complaints. SafeGuard, an internal computerised risk management system consisting of a number of modules which developed over the relevant period. Although SafeGuard incorporated key information in relation to complaints and later, incidents, inquests and litigation, it appears that only a small number of people were able to access this information for the purposes of preparing reports. It is notable that Dr Durrans, the General Surgery Lead and Assistant Medical Director, commented that he had only accessed Safeguard twice (LiveNote 03.03.11, 166).

76. As importantly, clinicians at Mid Staffordshire complained that consultants did not receive feedback in relation to complaints handling with Dr Durrans commenting

> *"If I don't know the frequency or type of complaints that are against my practice, then how do I alter it?"* (Dr Nakash, LiveNote 01.03.11, 42 and Dr Durrans, LiveNote 03.03.11, 169:11).

77. Dr Coates, Clinical Governance Lead, confirmed that there were no real processes in place for ensuring that lessons were learnt from complaints (LiveNote 02.03.11, 138).

78. The Inquiry has been told that significant improvements have been made by the Trust. These include the implementation of clearer lines of accountability whereby the Associate Director of each Division, rather than the Complaints Manager, is responsible for ensuring that complaints are handled in a timely fashion and information required is fed back to the complaints and clinicians concerned. Further, the executive meeting now receives a weekly update of every single complaint to enable themes to be addressed (evidence of Dr Obhrai, LiveNote 10.03.11, 132 – 137). Julie Hendry confirmed that complaints were now categorised on SafeGuard in accordance with NPSA guidance concerning incidents, creating some consistency; and these can be broken down by clinical area, ward or department, in order to identify where problems in fact lay and the particular individuals about whom complaints have repeatedly been made (LiveNote 07.03.11, 189 – 191).

79. PALS, as the first point of contact for a patient, also receives important information which does not ever become a formal complaint. Some patients will simply report a matter "so that someone knows" rather than enter into the formal complaints process. It is these "concerns" which will provide a Trust, and commissioners of services, with vital information concerning day to day care within its wards. Julie Hendry claims that both complaints information and "concerns" are now distilled into reports for the Trust Board (LiveNote 08.03.11, 9).

Recommendations:

- Independent lay representatives from local HealthWatch (and possibly other organisations) should be invited to take part in reviewing complaints within a group within trusts with responsibility for complaints review. The role could include consideration of actual complaints (within protocols covering patient confidentiality etc) but also retrospective review of complaints and consideration of issues arising of them and monitoring of implementation of recommendations.

- Annual surveys of all complainants should be conducted by trusts in conjunction with local HealthWatch to elicit feedback on the experience of and satisfaction with the process and outcome

External monitoring of complaints processes

80. The evidence heard by the Inquiry confirms that there was a lack of effective monitoring of the detailed content of complaints information throughout the NHS system. Rather the focus was upon compliance with time limits. Thus the substance of the complaints themselves, as direct evidence of the patient experience, appears to have been overlooked throughout the system.

81. The quality of internal complaints handling may have been in part explained by the regulatory focus at the time. Compliance with a timetable fixed by regulation for provision of an acknowledgement of the complaint within 2 days and substantive response within 20 or 25 days naturally led to the production of these two written documents, by the deadline, as being evidence of effective complaints handling. It appears that focus needs to be turned to maintaining line of communication with the complainant throughout the process – and for the quality of the process to be measured by the complainant's own experience of the process.

82. The 2004 Regulations reports prepared for external monitoring were clearly inadequate for any purpose other than monitoring the ability of a trust to comply with these time limits. They consisted of an annual report prepared for the SHA and HCC, described by activity in terms of times and targets; and an annual complaints return, known as a KO41, forwarded to the NHS Information Centre for consideration by the DOH, essentially dealing with the extent to which complaints were being dealt with in the 20 or 25 day time limit applicable at the time.

83. Chris Bostock confirmed that the PCT is primarily responsible for monitoring performance with complaints-handling within the context of its commissioning agreement with the provider (WS0000056086, paragraph 58). It appears that the PCT were only provided with quantitative data in relation to complaints handling. Helen Moss does not recall ever providing detailed complaints reports to the PCT (LiveNote 28.03.11, 124 – 125) and Julie Hendry confirmed that the PCT were not even aware of the complaints backlog she found upon joining the Trust (LiveNote 08.03.11, 45).

84. Meanwhile, during the period that HCC dealt with second tier complaints, the regional inspection teams did not have access to details concerning complaints and there was no indication that information flowed from complaints team to regional teams (evidence of Gordon LiveNote 05.05.11, 71-72). Martin Bardsley confirmed that his team relied only on summary data information provided by trusts and obtained by its own complaints team, conceding that the substance of complaints would have been useful (LiveNote 11.05.11, 121).

85. In the wake of the HCC report, the CQC continues to focus upon compliance with standards of

complaints-handling without any consistent recognition of the importance of the content of complaints information. Regulation 19/outcome 17 of the CQC quality standards relates to standards of complaints handling and CQC can and will scrutinise complaints handling. Julie Hendry described a recent unannounced visit from the CQC in which it sought extensive evidence with respect to both the process and outcomes. However, the CQC did not consider any of the actual complaints correspondence, with the exception of "thank you" letters written by patients at the end of the process, on the basis that "it would not be right" without seeking the permission of complainants (LiveNote 08.03.11, 20:12). Amanda Sherlock commented that they do not request complaints information as they "do not want to dilute responsibility from the trust concerned" (LiveNote 17.05.11, 99:19). Richard Hamblin also provided a more pragmatic reason for their current position:

> *The issue I think with complaints is -- is slightly about scope, because actually a lot of what the complaints are, are things that are not directly germane to what we obviously are concerned about in our regulatory processes. It, to us -- I mean, it is -- it is undoubtedly a -- a piece of information which would be very valuable. But we would need to get it in the right way to be able to use it effectively, and certainly at the moment, without the sorts of ways of very quickly dealing with a large amount of qualitative information, to suddenly have every NHS trust in the country send us through every single one of their complaints, leaving aside, actually, what I think might be the perverse effects on the way that complaints are held national -- at a local level, I believe that would just -- just swamp us under far too much data that we would not be able to deal with at the moment. (LiveNote 18.05.11, 95:13)*

86. When asked whether there had been any consideration of the substance of complaints through more sophisticated filtering of complaints information, Mr Hamblin confirmed that there had not been any discussions with the DOH but this may be an area which the Inquiry considering in its recommendations *(LiveNote 18.05.11, 93 – 96).*

87. Given this lack of clarity and consistency with respect to who is responsible for monitoring complaints information, and what they are monitoring, AvMA agrees with the conclusion and recommendation of the Health Committee in its June Report on Complaints and Litigation in which it stated:

> *The Committee finds that in the absence of clear national standards for complaints handling, and with no one organisation taking the lead on assessment of performance, it is extremely difficult to ascertain which organisations are performing well on complaints. There is significant potential for duplication by different regulators and for failing organisations to be overlooked (paragraph 86).*

88. The Health Committee recommends that this responsibility rests with HealthWatch England. Although

there should be a strong role for HealthWatch regarding monitoring complaints handling, AvMA consider that CQC, as the regulator, should have responsibility for monitoring compliance with its own standards. The issue is more whether they have the necessary resources and commitment to monitor this and take action when needed.

89. This should be informed by HealthWatch's monitoring. Further, it is clear that CQC should use content of complaints in order to inform itself as to risk of non-compliance with its registration regulations and guidelines.

90. The Government indicated that it does not believe that responsibility for monitoring complaints-handling should rest with a single organisation, stating "All organisations within the overall health system have an important role to play in better ensuring effective complaints handling, whether as providers, commissioners, regulators or the PHSO." (paragraph 78). AvMA agree that a number of organisations have a role in monitoring complaints handling but are concerned that this appears to be a continuation of the same approach towards complaints, relying on high-level non-specific goals and without a single central body to monitor the information filtered throughout the components of the commissioning and regulatory structure. There needs to be much more clarity about who is meant to be monitoring what, and how they should share information about any concerns arising.

91. Meanwhile, the Government has agreed with the Health Committee's emphasis upon the importance of the provider being required, through its contractual duties to provide robust comparable data with respect to complaints-handling as part of the process of accountability to its commissioner, with strong reliance upon the input of local HealthWatch (paragraph 90, 91, 96 and 101 of the Health Committee report and paragraphs 80 – 82 of the Government response). AvMA agrees that, subject to robust regulatory oversight from the CQC, the provision of high standards of complaints handling properly falls to be considered within the commissioning relationship as an essential element of the service being provided.

Recommendations:

- Clear guidance should be provided on who should be monitoring what in terms of complaints handling – not just in terms of process but also content including any worrying trends or serious failings in care – and how to escalate any concerns. Ultimately, the CQC should be informed of and take action about any potential breaches of its standards.

- In order to make monitoring possible all trusts (including Foundation trusts) should be required to share data form PALS as well as formal complaints with commissioners and with HealthWatch. This must contain qualitative as well as quantitative information, including results of surveys of complainants

- Representatives of commissioners should also be members of the internal trust groups to monitor complaints and implementation of actions resulting from complaints

B. INCIDENT REPORTING

92. As with complaints, the value of incident reporting has been recognised for many years. In "An Organisation with a Memory" published in 2000 it was said:

"We believe that, if the NHS is successfully to modernise its approach to learning from failure, there are four key areas that must be addressed. In summary the NHS needs to develop:

- Unified mechanisms for reporting and analysis when things go wrong;
- A more open culture, in which errors or service failures can be reported or discussed;
- Mechanisms for ensuring that, where lessons are identified, the necessary changes are put into practice;
- A much wider appreciation of the value of thr system approach in preventing, analysing and learning from errors." However, as with complaints, it appears that the incident-reporting system at the Trust relied almost entirely upon the good sense of individual staff members, was poorly managed and monitored and unsurprisingly, the issues that were apparent to staff were not identified or addressed by the organisation.

Failure in Trust processes

93. Trudi Williams, upon joining the Trust in 2004, immediately recognised there was a problem with incident-reporting. This developed over time but she noted:

> *"I think there were areas that weren't getting reported and it was more around what types of incident were reported. I think I refer to sometime later in my statement that quite often things were dealt with from a clinical side rather than being seen as an incident to report, and they'd be either passed on to the coroner or through other routes and, therefore, there was a lack of understanding as to what type of things constituted incidents." (LiveNote 07.10.11, 19:22).*

94. Martin Yeates, who arrived in late 2005, described the process as follows:

*"They would bypass any clinical governance system and were sent off site to someone whose role it was to process them who never provided any feedback on them…. Initially we implemented a manual system so that there was at least a system in place". (*WS0000074921, *paragraph 114).*

95. By early 2007, the situation had not improved. Dr Coates stated that Helen Moss discovered a large stack of paper clinical incident reports on the floor of someone's office which clearly had not been entered on the SafeGuard system. (LiveNote 02.03.11, 138:22 and see also evidence of Karen Morray, LiveNote 24.03.11, 107 – 108).

96. Even after the new clinical governance system was introduced by Helen Moss, it took considerable period for a reporting culture to be instilled. The NPSA had identified that the Trust did not submit timely incident reports to the NRLS until March 2007 and did not demonstrate good levels of reporting until 2009 (statement of Suzette Woodward, ws0000044963, 94). Dr Coates continued to identify unreported incidents through reading complaints and notes (LiveNote 28.03.11, 115), and further incidents were picked up by Antony Sumara upon his taking up post in 2009 (LiveNote 16.03.11, 118).

97. Specifically with respect to Serious Untoward Incident (SUI), Dr Turner stated that he did not have a clear understanding of the SUI policy when he joined the Trust. Dr Turner was aware of the seriousness of clinical incidents being downgraded by management staff (LiveNote 02.03.11, 43). Dr Durrans had also heard of this occurring (LiveNote 10.03.11, 176:5).

98. Dr Coates, Clinical Governance Lead, confirmed that unless an incident was so serious as to be classified as a SUI and generate an immediate investigation, clinical incident forms would be amalgamated into themed groups within a monthly report. When asked whether anybody had specific responsibility for following through, he said:

"Well, again, this is -- this is -- this is the deficiency of the system. Each of these incident reports would generate a series of managers' actions and an action plan, and to be fair, the action plans were virtually probably always identical in terms of, for example, slips, trips and falls. And my frustration arose from the fact that we were doing lots of action plans but I was not convinced that the next slip, trip or fall would be prevented by the presence of an action" (LiveNote 02.03.11, 177:24).

99. In these circumstances, the accounts provided by staff with respect to incident-reporting are unsurprising. Helene Donnelly, Staff Nurse in A&E department 2004 – 2008, confirmed that she made

50-100 incident reports during her time at the hospital with respect to issues such as faulty equipment, poor staff skill mix and understaffing. Despite always ticking the box indicating she would like feedback, she never received any. Nor did any of the other staff – an issue which was frequently discussed. Sometimes she did not complete the forms given she was so pressed for time whilst on shift and "The last thing I wanted to do was stay later to complete the form which past experience had led me to conclude would not be acted on and / or was likely to be ignored" (WS0000022296, paragraph 5). This was quickly recognised by Stephen Moss when he joined the Trust:

> *"And I think there was a culture there which inevitably and not uncommonly happens in situations where hospitals fail, where there's a sort of conditioning of the staff that there's no point in raising concerns about this, because nobody listens and nobody does anything about it anyway." (LiveNote 16.03.11, 144:12)*

100. It is clear that the Trust did not give adequate consideration to the information contained in the incident reports that were made. Perhaps most strikingly, inquiry Counsel referred up to 1,700 reports being made on staffing levels between 2005 – 2009 (see LiveNote 24.03.11, 123:18).

101. Although Trudi Williams confirmed that it was a decision of an executive member of the Board to decide whether an incident should be classified as an SUI (LiveNote 07.10.11, 25), SUIs were not considered by the Board (evidence of Toni Brisby, LiveNote 03.10.11, 62). Manjit Obhrai confirmed that themes are now picked up by clinical directors attending the Patient Safety Group to enable wider organisational learning. These then filter down through the clinical governance structures, although:

> "*I'll happily say are not [sic] anywhere near where we should be. I think learning from incidents in any organisation is not as good as it should be," with some departments being much better than other departments.*" (LiveNote 10.03.11, 92:11).

102. It is of obvious concern that this situation was allowed to persist for so long, with clear evidence available to the Trust that incidents were not being reported and where they were being reported, no process existed for learning and feedback. It is apparent that there was lack of clarity in definitions of incidents, insufficient training and understanding amongst staff and a failure to join up complaints with incidents and separate investigations streams.

Recommendations:

- There should be, at Board level, an individual accountable for the accuracy, completeness and appropriate analysis of the information arising from "when things go wrong", including the consistency and co-

ordination of investigation processes. The approach described by Professor Elliott in his seminar presentation provides a helpful model.

- The existing national guidance on incident reporting and investigation needs to be reviewed and updated. Organisations should be required to follow it and monitored. There needs to be a uniform definition of "incident" for use nationally and locally. In the 2007 Mid Staffordshire adverse incident policy, "incident" is described as an "event," "occurrence" or "omission" (ESI00044757), leading to a risk of uncertainty. In addition, there is a grey area with respect to ongoing failures in care which may have adversely affected the patient but did not result from a single event, for example, failing to monitor fluid intake leading to dehydration, poor hygiene practices leading to infection or failing to take steps necessary to prevent bed sores from developing – the definition of incident needs to be clear whether such failure are to be include (and, if not, how they are to be monitored.

- Near-misses are as important to organisational learning as incidents leading to actual harm or death. Therefore, these should be included within local reporting policies.

External monitoring of incident reporting

103. "Safety First" recommended that

> "*PCTs should be accountable for ensuring that all providers used by their patients have effective patient safety reporting systems and are implementing technical solutions satisfactorily*,"

104. However, the South Staffordshire PCT formally only monitored SUIs as a tool for commissioning safer services in April 2009, before which time its ability to fulfil its responsibilities effectively appears to have been limited by lack of access to the relevant data. It did not have access to either adverse incidents or SUIs until 2006; and it was not until late 2007/early 2008 that it gained access to STEIS and adverse incidents started being provided to PCTs by trusts as part of their contract requirements. (LiveNote 30.03.11, 42 – 43). In addition to a possible lack of data, there has been a failure by PCTs that has been available –

> "*I would say that PCTs were 100% aware of what patient safety was and its importance but only about three quarters were really trying to address the issues and understand the patient safety data that was available*" (Statement of Suzette Wood, WS0000044963, paragraph 82).

105. The SHA also fell short in its role as "overseer making sure that other institutions do what they are supposed to do". Peter Blythin confirmed that by 2010, there were thousands of SUIs still open on the

system – mostly relating to MRSA – as the process in place of ensuring that the root cause analysis had been undertaken and the SUI closed was not happening in practice (LiveNote 12.04.11, 54 – 55, 62 and evidence of Eamon Kelly, LiveNote 20.04.11, 12 – 15).

106. Meanwhile, the NPSA, which had perhaps the best access to information, receiving both SUI information from STEIS as well as holding the dataset anonymous incidents reported to the National Reporting and Learning System (NRLS), considered its role to be confined to identifying learning across the system, rather than exposing the risks posed to patient safety within any particular organisation. The NPSA was able to identify whether a trust had a "healthy reporting pattern," which is characterised by a high number of low level reports (statement of Suzette Woodward, NPSA0000000001, paragraph 3.13) The NPSA produced feedback reports with respect to the Trust's incidents reporting on NRLS and identified that it "started slowly" and only made the expected number of reports from October 2007 and a lower level of no harm incidents and deaths with a high level of low, moderate and severe harm incidents (NPSA0000000001, paragraph 3.24 – 3.28).

107. It has also been acknowledged that monitoring SUI information across the NHS has been inhibited by the absence of a single consistent definition, with each SHA publishing its own policy. Sir Bruce Keogh explained that without a consistency in definition:

> *"if you're a small hospital and you have, let's say for argument's sake, 100 incidents a year, then you have the opportunity to look at a lot of those in quite a lot of detail. But a lot of hospitals will have tens of thousands -- you know, ten to 20,000 incidents reported, and some of those will be serious and some won't. And when you've got a lot, of course there's a tendency -- there's a risk that you will change the threshold in order that it would meet what you could physically deal with"* (LiveNote 20.09.11, 74:23).

108. The NPSA have now produced a definition in its National Framework for Reporting and Learning from Serious Incidents requiring Investigation including death and "serious harm". At the same time, mandatory reporting by organisations of incidents resulting in "moderate harm" and above has been introduced through paragraph 18 of the Care Quality Commission (Registration) Regulations 2009, with respect to the incidents which need to be reported to NPSA and the CQC.

Recommendations:

- As well as there being a uniform definition of what should be reported,. there should be, adopting Sir Bruce Keogh's view a single portal to "report once and use many times" (20.09.11, 73 – 82).

- It should be mandatory to inform and, where the patient / family wishes, involve the patient/their family

in SUI investigations.

- The requirement to report incidents causing moderate harm and above to the CQC contained in the CQC Registration Regulations should be accompanied by a corresponding requirement to share information with the patient / their family through the 'Being Open' process.

- The template used to report incidents both internally within trusts and to the national system should contain a mandatory field for the reporter to declare whether the 'Being Open' process has been implemented with the patient/family affected (some trusts are currently doing this of their own volition).

Patient Safety Alerts

109. One of the core functions of the NPSA is to monitor reported incidents in order to feed back lessons to be learnt by the system by way of Patient Safety Alerts, Safer Practice Notices and Rapid Response Reports (PSA). AvMA strongly supported this initiative, which should be a simple effective scheme that prevents harm and save lives. PSAs are the vitally important end product of all the NPSA's work. (see Donaldson LiveNote 19.09.11, 138:15 – 142:19 and Keogh 10.09.11, 156:20 – 159:18)

110. PSAs are not simply about "ticking boxes" but rather, highlight issues which trusts can address through review of their internal processes and procedures and implementing the required action in the alerts. An illustration was provided by Julie Hendry:

> *So, for example, I think within my first week, we had a -- a bulletin from the National Patient Safety Agency around training of staff to administer blood products. And so I immediately asked for the records of which staff had been trained, and I immediately found out there were no records. When I probed further, I found that there wasn't assurance that staff had been trained. (LiveNote 08.03.11, 34:11)*

111. Suzette Woodward confirmed that she had completed an analysis with respect to the Trust's compliance with PSAs and 519 alerts were sent to the trust from 1 January 2005 – 31 December 2009, of which four were outstanding, although 149 had not been signed off until after the deadline (WS0000044963, paragraph 139).

112. The Trust had a process for disseminating PSAs. Val Suarez, the Medical Director, confirmed that this fell within the realm of clinical governance, for which Helen Moss was responsible. She indicated that upon receipt, PSAs went through the divisional governance routes and would have been monitored through clinical quality and effectiveness group and ultimately the Executive Governance Group (LiveNote 22.03.11, 188). However, clinicians provided varying accounts of how this process worked

at a divisional level. Whilst Dr Nakash referred back to the process outlined by Val Suarez, Dr Turner indicated that he was only aware of PSAs through personally received email alerts and was not aware of a formal system (LiveNote 02.03.11, 49). Dr Durrans, the Clinical Lead for Surgery and Deputy Medical Director, confirmed that he had no intimate knowledge or recollection of the system (LiveNote 10.03.11, 43). Val Suarez, confirmed that she was aware of PSAs not being implemented as quickly as they should have been; as well simple lack of awareness, the system lacked support, resources of clear lines of responsibility (LiveNote 22.03.11, 188 – 190)

113. The position now is that the Trust says it is taking steps to ensure that they have implemented and recorded compliance with relevant PSAs (LiveNote 10.03.11, 93 – 94) but the same level of attention is not necessarily being given to PSAs throughout the NHS. This is demonstrated in three reports published by AvMA. In the most recent report "Too little, too late" (February 2011) it is shown that although there had been some improvement in PSA compliance since its last report six months earlier, 50% of trusts were still failing to comply with at least one alert and nearly 7% of trusts were failing to comply with more than five alerts.

114. There is currently no process for a single body to take responsibility for monitoring and enforcing PSAs. Neither the PCT nor the SHA did so (evidence of Yvonne Sawbridge, LiveNote 31.03.11, 12 and evidence of Peter Blythin, LiveNote 11.04.11, 156 – 159). Although HCC core standard C1B stated "Healthcare organisations protect patients through system that ensure that patient safety notices, alerts and other communications concerning patient safety which required action are acted upon within required time scales (CURE0005000542, 7), Heather Wood confirmed that despite relevant data probably being available, she did not think the HCC explored this (LiveNote 10.05.11, 166 – 167).

115. The CQC does not now consider monitoring or enforcement of PSAs to be part of its responsibilities. They commented upon the CQC's lack of relevant expertise and huge resource implications for the CQC. Andrea Gordon confirmed that whilst it was possible for non-compliance with a PSA to give rise to a responsive review, she was not aware of this having happened (LiveNote 23.05.11, 85 – 87). Amanda Sherlock explained in the following terms:

> *"We would have to demonstrate that non-compliance with a patient safety alert has a direct consequence of non-compliance with the essential standards. We do not have the power to enforce implementation of patient safety alerts."* (LiveNote 17.05.11, 83:7).

116. It seemed to be lost on the CQC that there are a range of responses possible short of a 'responsive review'. AvMA's evidence pointed out that in spite of the evidence of large scale non compliance by many trusts in its first report (February 2010), six months later the CQC had not established contact with a single trust, even by letter or a telephone call, to ascertain why the trust was non-compliant

and what their action plan for catching up was. Only upon AvMA's prompting was a letter sent to some of these trusts, and then only to those with 10 or more alerts outstanding. Neither was there any appetite for CQC discussing with PCTs and SHAs how the task of monitoring compliance could be shared. We do not believe that simply saying that these issues will be taken account of in the Quality and Risk Profile and that might prompt some action is good enough. If the regulator is aware of such serious failings as failing to implement patient safety alerts, that in itself should prompt a reaction.

117. Finally, the action taken by the NPSA with respect to compliance with PSAs is limited to identifying low compliance and issuing follow-up guidance. "It does not currently follow-up individual trusts in relation to their compliance with alerts. This is the role of the regulator, the strategic health authority and the primary care trust, all of whom have access to the central alerts system data" (NPSA0000000001, paragraph 3.34). Suzette Woodward commented that she would have expected compliance with PSAs to be a term of commissioning agreements with the PCT and was also surprised to discover that CQC did not in fact follow up on non-compliance (LiveNote 20.06.11, 85 – 87).

118. Despite the extensive resources dedicated to collecting and analysing the vast quantity of incident reports by the NPSA, giving rise to 75 current alerts (NPSA NRLS website). There has apparently been no serious action taken to ensure that these life saving directions are in fact implemented. AvMA consider that over time, the underlying priorities in patient safety have become blurred and the system has focussed unduly on information collection at the expense of action to prevent harm, or to intervene with organisations which do not properly comply. Suzette Woodward confirmed that one of the lessons learned by the NPSA is to review the process for following up PSAs (NPSA0000000001, paragraph 5.1).

119. AvMA believe that as well as implementation of PSAs being a vitally important issue in its own right, the approach to monitoring PSAs is indicative of wider issues with regard to monitoring and regulating the NHS, and the role of the CQC.

Recommendations:

- The forthcoming NHS Commissioning Board should assume responsibility for and prioritise the issuing of further PSAs. It should take on board any lessons about how the current system could be improved such as clarity about what is required by trusts and when they should declare compliance.

- It should be clarified what the respective responsibilities of different organisations are for monitoring trusts' compliance with alerts and intervening where there is not compliance. In the new system this will include CCGS, NHS Commissioning Board, and the CQC. Whilst priority should be given to chasing up trusts who have declared that they are not compliant, the monitoring system should be developed so that trusts

are assessed on their actual compliance with alerts even where they have declared compliance already. This should form part of a rolling programme.

- Timely compliance with PSAs should be made an explicit requirement in the CQC registration regulations. This will take away any doubt about their importance and the ability of the CQC to take action about non compliance;

- Particular attention should be paid to implementation of patient safety alerts in primary care. Currently PCTs simply pass on alerts to GPs, etc. There needs to be monitoring of implementation and CCGs may not be the appropriate body because they largely comprise of GPs themselves

- It should be made a requirement for every NHS body to declare their status with regard to each PSA applicable to them which is past the completion date, in an accessible way on their website, in their Quality Accounts and on a central website such as NHS Choices (see evidence of Sir Bruce Keogh, LiveNote 20.09.11, 159:11). This action on its own should be a powerful incentive for compliance..

- Trust boards should discuss status of alerts at each board meeting together with other patient safety items.

- The CQC must react to evidence of problems which come to its attention about potential lapses in patient safety when they become aware of it, rather than waiting for enough data to be collected to tip the Quality and Risk profile to 'red' and spark a full reactive review. Interventions short of a full reactive review such as seeking explanations / assurances from the trust concerned and liaisng with commissioners should be used.

C. INQUESTS

120. The inquest process can be one that provides opportunities to identify and address failings within hospitals and one which ensures that bereaved families can understand what has happened to their relative. The evidence received by the Inquiry shows that in relation to the Trust the inquest process fell far short of achieving either of these goals, and the reasons for that lay in the way the Trust handled the provision of information to the coroner, as well as shortcomings in the inquest system itself.

Reporting of deaths by the Trust to the coroner

121. Post mortems are undertaken and inquests held in circumstances where the death is "unnatural" or the cause of death is unknown. The information entered on the death certificate will determine

whether or not a full investigation will follow. At the Trust, the flow of information to the coroner was subject to a series of filters (imposed by the Trust) inhibiting the provision of clear and accurate information concerning deaths. Kath Fox expressed her concern that there was a lack of clear understanding of this process amongst junior doctors, including occasions when doctors did not know that deaths needed to be reported to the coroner at all. Discussions took place with the coroner's officer as to what should be entered as a cause of death on the certificate. There was pressure not to mention contributory factors, including infections (LiveNote 10.02.11 137-144, 153) difficult. Kath Fox's understanding of the reason for this approach to reporting causes of death was as follows:

> *"I say that the coroner's officer actually has a heart of gold and he believes someone should die with dignity, and should we putting the 90-year-old patient through -- and the family through the trauma of a post-mortem when a death certificate could be issued. But it doesn't necessarily mean to say that that cause of death is correct." (LiveNote 10.02.11, 158:12)*

122. Dr Valerie Suarez, a pathologist and the Medical Director at the time, was also aware on an anecdotal basis of pressure being placed upon doctors to complete death certificates with a cause of death, noting occasions when she had been concerned that a doctor did not have sufficient evidence to complete a death certificate accurately (LiveNote 22.03.11, 84-85). Dr Suarez's concerns were substantiated when an independent review of the quality of death certification in the Trust was undertaken in April-June 2008. It concluded:

> *"This demonstrated that in 22% of cases reviewed (just over 200) there was considered to be a significant difference in the cause of death with a further number in which the cause of death was unknown or unclear after the review. Also, 27% of cases should have been referred to the Coroner and accepted as Coroners' case. Some had been but had been issued as a "Part A")" (*WS0000012476, 259)

123. This issue can in the future be addressed through the introduction of independent Medical Examiners by the Coroners and Justice Act 2009 (CJA 2009), for the purposes of ensuring that deaths are reported to the coroner at the earliest opportunity and the "Medical Cause of Death Certificate" is as accurate as possible. Regulations to create a Medical Examiner service are before Parliament and if passed will come into force in the last quarter of 2012. Alan Fletcher, a Medical Examiner involved in pilots established under the CJA 2009, confirmed that whilst the same number of referrals have been made to the coroner in his area, "I am absolutely clear that there are more correct referrals than before" and less inappropriate contact with the coroner's officer for advice on the completion of the death certificate (WS0000002953, paragraph 3.11).

The role of the legal department in hospital

124. Inquests were dealt with by the legal department within the Trust, and one of the legal department's roles was to determine what information was supplied to the coroner on behalf of the Trust. The evidence given to the Inquiry by Kate Levy, the Trust Board Secretary and Head of Legal Services and by Stuart Knowles, the Trust solicitor, in relation to the inquest into the death of John Moore-Robinson, gives rise to serious concerns about the approach adopted. Ms Levy and Mr Knowles approached matters on the basis that their primary duty, in accordance with Solicitors' Code of Conduct, was to act in the best interests of their client, the Trust. The result was that an original report prepared by Mr Phair, a consultant in A&E, in which he expressed his opinion that Mr Moore-Robinson's death may have been avoided if he had been properly assessed on his initial attendance at the A&E Department of the Trust, was not provided to the coroner nor disclosed to Mr Moore-Robinson's family. (LiveNote 05.10.11)

125. The approach adopted gives rise to two serious concerns:

(a) Both Mr Knowles and Ms Levy maintained in evidence that the report, being the opinion of a consultant employed by the Trust who had not himself been involved in the care of John Moore-Robinson, was not admissible as either factual or expert evidence. Both also asserted that the opinion expressed was not relevant to the verdict to be considered by the coroner given that he was not concerned with civil liability or blame (LiveNote 05.10.11, 74-75, 184). The Inquiry should conclude that this was a far too restrictive approach to co-operation between the Trust and the coroner. It was for the coroner, not the Trust legal department, to determine what evidence the coroner would admit at an inquest and for the coroner and not the Trust legal department to determine what information was relevant to his inquest. The failure to ensure that the report was provided to the coroner meant that he was not in a position to carry out the fullest possible investigation into the circumstances leading to John Moore-Robinson's death.

(b) Neither Mr Knowles nor Ms Levy considered that this a matter upon which they needed to take express instructions (LiveNote 05.10.11, 86-87, 139-142). The Inquiry should conclude that this was an error. The result was that the Trust did not have the opportunity to consider and provide instructions on not just disclosure to the coroner but also, separately from the inquest process, whether its obligations of openness - under its own Being Open Policy - towards the Robinson family meant that a copy of the report should be provided to them. In addition it meant that nobody in a senior position in the Trust was aware of, and therefore able to take steps to address, a possible serious clinical failing in the A&E Department.

Involvement of patients' families within the inquest process

126. Inquests are intended to provide an opportunity for the families of patients to engage with the inquisitorial process of identifying the means by which the deceased came to their death. As with the complaints process, the families of patients should be considered central to this process in order to ensure that the full picture is seen by the coroner, and the family are able to fully participate in the inquest process, and their needs are met. As "properly interested persons", families are able to receive disclosure of key information prior to the hearing and have the opportunity to question witnesses at the hearing. Coroners have broad discretion in how they engage families of patients and practice varies. The coroner at Stafford, Andrew Haigh, confirmed that his approach was to only disclose information to families upon their request and that they would not know what information he had until they asked. He accepted that this would demand an understanding of the system on the part of a family and in particular detailed knowledge of what kind of documentation the coroner would obtain, and how to interpret those documents. (LiveNote 28.02.11, 71 – 72). He confirmed that he did not run a support service for families but he sent an information pack and his officer would speak with families before the inquest itself. However, he acknowledged that "in some cases it may not be, yes, the family may not know precisely what's going on, […] or yes, what is likely to happen at the inquest." (LiveNote 28.02.11, 76:7).

127. AvMA's wide experience of medical inquests, in particular through its Inquest Advocacy project, has shown us that patients' families need advice, support and representation in order to be effectively participate in the inquest proceedings. Even in cases where a more proactive and helpful approach is adopted by coroners than that described by Mr Haigh, the inherently complex nature of inquest into the deaths of patients who have been in the care of healthcare providers means that such inquests are particularly challenging for families. They have to find the resources and ability to interpret complex medical evidence and notes, against a background of grieving for the deceased, and generally in the absence of the coroner obtaining independent expert medical evidence. Within the NHS, resource has been allocated to provide patients and their families with support and advice through the course of complaints process. This should extend to inquests given such cases will by definition involve further investigation into serious and complex cases. This could form part of the specialist service, supplementary to ICAS, recommended earlier.

128. Equally, the difficulty which patients' families face in navigating the inquest process is compounded by the failure of trusts to voluntarily provide disclosure of the relevant medical records and other associated information concerning the death of their family member at the earliest opportunity, and to delay and obfuscate when those records are requested. In such cases, the inquest proceedings become the only means by which such information can be obtained. In circumstances where a trust acts in an open and transparent way with the family of a patient following death, the inquest process

becomes more manageable.

The effectiveness of "Rule 43" reports

129. Where a coroner hears evidence giving rise to a concern that circumstances creating risk of deaths will continue in the future and in their opinion, action should be taken to reduce this risk, Rule 43 of the Coroners Rules 1984 (the Rules) enables a coroner to report to a person the coroner believes may have power to take such action. Mr Haigh prepared at least 17 Rule 43 reports during the Inquiry period (WS0000005687, paragraph 38). Unfortunately, once received, it appears that these reports were not used to identify areas for improvement throughout the hospital but rather, dealt with by individual clinicians on a limited basis. Valerie Suarez, in her role as Medical Director, recalled responding to one and otherwise, not seeing "very many" (LiveNote 22.03.11, 93). Likewise, Stuart Knowles did not necessarily receive every Rule 43 received by the Trust on the basis that the coroner would write to individual clinicians (LiveNote 05.10.11, 108 - 110).

130. Since 17 July 2008, an amendment to the Rules has required that those who receive a Rule 43 report provide a written response within 56 days detailing any action that has or will be taken or an explanation as to why no action is proposed. The report and response are copied to the Ministry of Justice, which then publishes a bi-annual summary. This power is valuable in ensuring that lessons are learnt, which will often be the primary concern of families in inquest proceedings, and in introducing an element of transparency into the process. In response to the change of Rules in 2008, the Trust put in place a process to receive, respond and store these centrally and for the Head of Governance and legal department to retain oversight of resulting investigations and report to the Executive Governance Group.

131. A concern remains with respect to the inconsistent use of Rule 43 reports by coroners (see evidence of Andre Rebello, WS0003000058, paragraph 30). In light of their intended purpose to prevent further deaths and the oversight now provided by the Ministry of Justice, it would seem sensible to ensure that there is clear understanding amongst coroner as to whether and when Rule 43 reports are appropriate. This inconsistency of approach in relation to rule 43 reports reflects the broader and significant variation of the approach of coroners in the exercise of the range of their functions and powers.

Monitoring deaths within the NHS

132. Kate Levy confirmed that when she first joined the Trust, she noticed patterns with respect to repeated clinical negligence claims arising from an individual doctor's practice or inquests "raising similar issues where [she] had concerns that those issues shouldn't be arising so often." (LiveNote

05.10.11, 152-153). The Inquiry heard evidence from Kath Fox, Bereavement Officer, with respect to her observation that deaths increased when the consultants were off at bank holidays and weekends from 2003/2004 to 2008/2009. Although she spoke with senior managers, her concerns were dismissed (LiveNote 10.02.11, 144-148). Both examples demonstrate the importance of an organisation reviewing the pattern of deaths in order to identify whether these are associated by reason of factors such as time, service, individual clinician or procedure. Due to the weak risk management processes in place at the time, it appears that the Trust was not performing this basic analysis with respect to either deaths within the Trust or even, as explained above, Rule 43 reports received from the coroner.

133. In his evidence, Andrew Haigh, the coroner, distanced himself from any suggestion that he had responsibilities to provide oversight of the issues surrounding deaths within the trusts in his area. Andre Rebello said in his statement that coroners had limited resources and the Rules *"do not allow me to widen the scope of my statutory powers or to become an early warning system for general failure at NHS hospitals"* (WS0006000058, paragraph 61). Mr Haigh commented that if there had been an issue, he had no way of noticing given the large number of inquests he dealt with. In terms of his own records, he explained that these were not maintained in a manner which would enable him to go back and identify deaths within the Trust (LiveNote 28.02.11, 165-166). The Chairman himself was provided a telling description "Well, you're talking to someone who has personally viewed the coroner's filing cabinet and it wasn't a computer" (LiveNote 10.05.11, 165:24).

134. It is hoped that external oversight can be provided by Medical Examiners, who have the advantage of considering all deaths which occur within a Trust rather than deaths reported to the coroner. Alan Fletcher confirmed that in his opinion Medical Examiners would be able to spot trends through both formal means, such as maintaining and reviewing a database, and informal measures, recognising the importance of triangulating the information available to Medical Examiners, to coroners, and through the trusts' clinical governance systems (LiveNote 31.01.11, 108 – 109). Within this system, section 21 of the WA2009 provides for the appointment of a National Medical Examiner to issue guidance to ensure that Medical Examiners "carry out their function in an effective and proportionate manner," and any other function specified, which Alan Fletcher hoped would involved intervening with respect to problems encountered locally when concerns are raised (LiveNote 31.01.11, 107).

135. Dr Foster has also developed its own systems in monitoring deaths through analysis of mortality rates (Hospital Standardised Mortality Records). Although it has been recognised that such measures cannot be treated as a single reliable indicator of either good or bad care and treatment within a trust, AvMA hope that this work, including the development of SHMIs, will be co-ordinated with the work being undertaken by Medical Examiners and oversight provided by Ministry of Justice with respect to Rule 43 reports. Each body of information consider deaths from a different perspective and

should therefore be considered complementary, alongside other key indicators. If that data on deaths is thus triangulated it would be meaningful and a valuable tool in preventing further avoidable deaths and errors in care.

Recommendations:

- All coroners should be required to maintain a central database of deaths reported, inquests held, verdicts given and Rule 43 reports sent and received;

- Trusts should maintain a similar central recording system, to monitor the deaths, verdicts for purposes of identifying concerning patterns or trends and where Rule 43 reports are provided, that there is process by which their dissemination and implementation can be confirmed.

- There should be systematic external monitoring of Rule 43 recommendations and to what extent they have been responded to / put into place. This could be part of the patient safety function of the new NHS Commissioning Board. Information regarding trends or failure to respond appropriately should be reported to CQC.

- Steps should be taken to ensure support and where necessary representation is made available to families taking part in healthcare related Inquests; consideration should be given to including this in the specification for the specialist advice which it is recommended is commissioned to supplement the generic ICAS service.

- There should be a Chief Coroner, as provided for in the Coroners & Justice Act 2010, to lead reform of the coronial system and address the inconsistencies of approach of coroners.

D. RISK MANAGEMENT AND PATIENT SAFETY WITHIN THE NHS

Risk management within trusts

136. The evidence referred to above in relation to complaints, incident reporting and inquests demonstrates a real and very substantial failing in the effective management of risk within the Trust. Although there was evidence that information was beginning to be co-ordinated in 2007 onwards, it appears that responsibility for clinical risk management fell between a number of individuals, specifically the Medical Director, the Director of Nursing and the Head of Clinical Governance. Trudi Williams, who at that time was Head of Clinical Standards, refers to not wanting to challenge the decision made by the board to sign off on standards within the AHC on the as “I was literally the person that submitted on to the website” and did not feel that she had the experience or training to

challenge the board (LiveNote 07.10.11, 68, 73 - 74). The Head of Risk, Safety and Health appears to have dealt with broad range of corporate risk, including financial issues, compliance with targets, legal compliance and data management (see Corporate Risk Register Report, May 2007, TRU00010013654, for example).

137. The overall approach to risk internally at Mid Staffordshire is highlighted by two examples in which the Trust was slow to respond to evident concerns: the Royal College of Surgeons Report published 2007 which lead to two years of further "investigation" before effective steps were taken; and, the mortality alerts received in second half of 2007, which were initially explained by difficulties with coding and concerns only investigated thoroughly when the HCC commenced its investigation in March 2008.

138. It is also relevant to point out here that the National Health Service Litigation Authority (NHSLA) measured the effectiveness of risk management externally but that also failed to identify or effect positive change. This is addressed later in these submissions but it is important to recognise that there was no effective risk management nor monitoring of the effectiveness of risk management in place at the Trust.

139. Until 2008, complaints and incidents were dealt with separately to inquests and litigation, with information being held in separate locations (evidence of Sharon Llewellyn, LiveNote 18.01.11, 66). AvMA's experience is that this is a practice adopted in other Trusts and not unique to Mid Staffordshire. Until these four categories of information were incorporated within SafeGuard, the Trust was not able either to cross-reference incidents considered or to ensure that patients were informed and involved. Further, the legal department dealt with litigation and inquests independently both to the complaints management and incident reporting functions within the Trust. Up until the legal department joined the SafeGuard database in 2008, Sharon Llewellyn noted that she would not know whether an inquest was taking place and there was little co-ordination with the legal department with respect to the evidence gathered and "the right hand did not know what left hand doing" (LiveNote 18.01.11, 67:3).

140. This evidence demonstrates a fragmented and ad hoc approach to risk management. AvMA strongly believe that there needs to be strong central leadership and accountability with respect to this area of a trust's business, separate to the responsibilities of clinical governance or the Medical Director. Although it is important that trusts have central information systems capable of enabling easy access and analysis with respect to all information collating following incidents, AvMA considers that risk management should be clearly separated from the legal department. Rather than liability limitation, the process of risk management should involve creating a self-fulfilling cycle of risk reduction and quality improvement, whereby incident information produces learning which improve safety and

decrease risk. This is part of cultural change within trusts, which involves clear communication to and engagement of every level of staff within a hospital.

Recommendations:

- An executive member of the trust board should be specifically responsible for risk management. This individual's responsibilities would include monitoring and analysing the information available with respect to clinical incidents through the various sources available, including complaints, incident reports, litigation, and reporting to the board on a monthly basis. This individual would in turn receive monthly risk reports from the individual lead clinical risk managers of each department. Following clinical incidents, this individual would also be responsible for ensuring that relevant bodies are notified and the trust inform and involve patients and their families fully and appropriately and for liasing with the body responsible for central risk management.

Responsibility for risk management: The role of the NHSLA and NPSA

141. Responsibility for different aspects of risk management have been split up throughout the NHS. As part of its role in administering the risk pooling system, the Clinical Negligence Scheme for Trusts, the NHSLA assesses the risk management systems in place within a trust, with respect to a number of standards including governance, clinical care and "learning from experience." This last standard incorporates a number of elements which AvMA consider essential; incident reporting, raising concerns, complaints, investigations and "being open". (Exhibit AB/9 to Alison Bartholomew statement, LA0001000294, 30).

142. A robust assessment of risk management processes of this type could be very valuable in three different ways: firstly, as outlined above, an effective risk management systems provides an accurate picture of incidents both internally and externally; secondly, the absence of effective risk management systems highlights potential risk in terms of an organisation's ability to identify and learning from failings and thirdly, an absence of effective systems provides a warning that caution should be exercised in terms of reliance upon information from that organisation.

143. However, the nature of the current method of assessment means it does not accurately reflect the standards of risk management within a trust. Essentially, it is a snapshot taken every two or three years and relies largely on self-selected evidence of compliance. Steve Walker accepted the system could be subject to gaming (LiveNote 05.07.11,147). Trudi Williams accepted this was the case, indicating that policies would be prepared around the systems already in place:

So it was – so we demonstrated that there was a policy, and then we were able to take

examples which showed that that policy had actually even followed through. Again, you know, you can - you take your best examples. (LiveNote 07.10.11, 59:15)

144. Although the NHSLA Risk Management Standards expressly say that they are designed to "provide assurance to the organisation, other inspecting bodies and stakeholders, including patients" (Exhibit AB/9 LA0001000294, 6), Steve Walker confirmed that any other body which relied upon the ratings provided by NHSLA would be well aware of their limitations (LiveNote 05.07.11, 181). He emphasised that the assessment is intended to bring about improvements in the risk management within trusts by providing a financial incentive of allowing discounts linked to the CNST rating and was reliable "on its own terms" (LiveNote 05.07.11, 149 - 151). In other words the risk management was linked to driving down the number of litigation claims against a Trust. He said:

We're not offering a Good Housekeeping seal of approval. We are assuring anyone who's interested that trusts have met certain criteria, no more and no more less (LiveNote 05.07.11, 151:13).

145. The doubtful reliability of the assessment is demonstrated by the fact that the Trust received the highest rating of 3 in 2004. However, despite the limitations acknowledged by Steve Walker, both the CQC and Monitor do rely upon these assessments. CQC feed the ratings with respect to each standard into its QRP (evidence of Hamblin, LiveNote 18.05.11, 104-105) and Monitor relied upon the Trust's CNST rating in considering its application for Foundation Trust status (evidence of Hill, 24.05.11, 181 – 184). AvMA consider that the NHSLA's approach to risk management represents a missed opportunity.

146. The weakness in the approach to assessment is perhaps a reflection of the fact that the NHSLA will naturally be primarily concerned with the reduction in claim numbers throughout the NHS rather than the improvement of risk management overall. There are various ways in which the number of claims can be reduced. One way is to simply suppress information that would allow a patient to know of an adverse event, and another way is to improve patient safety. However the focus in improving patient safety by reference the claims numbers will of necessity focus on events that result in identifiable harm, and not near misses, or events where the care has been poor, unacceptable even, but has not been identified as the cause of injury in itself, usually because of co-morbidities.

147. AvMA believe that this function would be better placed within the CQC, responsible for quality within the NHS. This would provide the CQC with another area of key information to supplement the existing data it collates, remedying the weakness of self-assessment through ensuring that information can be cross-referenced. At the same time as ensuring that this information is given the attention it deserves within the regulatory framework, there is no reason it could not continue to be relied upon by the

NHSLA for risk pooling purposes.

148. Further, as with trusts' internal risk management systems, AvMA consider that it is conceptually important for risk management to be separated from the processes of litigation. Trusts approach their relationship with the NHSLA within the context of litigation arising from serious clinical incidents and it is reasonable to assume that in these circumstances, the natural inclination is toward protecting themselves against blame and liability. On the other hand, risk management should be approached as tool to be employed to protect patients, improve services and raise standards. This would be best housed with the CQC. Whilst this adds to the considerable responsibilities of the CQC, it is more logical and also reduces the number of 'regulators' with whom trusts have to relate, which has been a common theme.

Recommendations:

- Assessment of trusts' risk management processes and outcomes should be undertaken in the future by a risk management team in the CQC rather than the NHSLA. This added function would need to be appropriately resourced so that trusts would be assessed on an annual basis, involving both review of documents and inspection of processes by specially trained inspectors.

- The result of this assessment (and the subsequent CNST rating) for each trust should be made publicly available on trusts' websites and other appropriate sites eg NHS Choices

Analysis of NHSLA claims data

149. Instructed solicitors provide the NHSLA with a three monthly report on claims, which includes a section on risk management issues. As with all monitoring mechanisms, this can fulfil a number of functions; it can highlight concern with respect to a particular organisation (although it has been confirmed by Steve Walker that the profile with respect to Mid Staffordshire was "unremarkable" LA0000000001, paragraph 6) and it provides trusts with a reminder that it is being scrutinised, which in itself can be an incentive to improve standards.

150. However, importantly, this information provides the NHS with another perspective of areas of particular risk across the system. At present, it appears that this information is used by the NHSLA for the purposes of framing its risk management standards but again, AvMA's concern is that the NHSLA's natural focus will be on reducing claims. The information is provided to the NICE and NPSA, although it is not known how it is used, and its availability to the regulators, although "they have decided that they do not require the information but are aware that it is available for their use anytime." (Supplemental statement of Steve Walker, NHSLA0001000324, paragraphs 34).

151. Again, AvMA consider that this information should be used by the CQC for analysis given both this body's growing expertise in undertaking studies, reviews and producing reports with respect to themed areas (for example, stroke services, support for families with disabled children and the impact of the economic downturn) and the relevance of this information to its functions.

Recommendations:

- The NHSLA should analyse all claims received (including unsuccessful /withdrawn claims) for learning points for patient safety, and for trends with respect to individual trusts. This information should be shared with CQC.

Monitoring of information

152. The clear and continuing failings within the system to recognise the importance of monitoring the content of either complaints or incident reports, as outlined above in Part 1, indicates that there is still some way to go in terms of making best use of the information available. The National Quality Board has undertaken a review of "Early Warning Systems" in order to align the information available to the various bodies. However, this is an issue which needs to be continually reviewed and revised in the coming months and years as current bodies are reformed and re-created.

153. In particular, the NPSA is due to be abolished in 2012 and its functions replaced within the NHS Commissioning Board. It is understood that the details of this function are still being considered. Reassurance is sought that the wealth of information and the learning accumulated by the NPSA will not be lost in the transition of its function.

154. In the meantime, AvMA welcome the development of Indicators for Quality Improvement (IQI) as a central collation of data publicly available for use throughout the NHS. However, AvMA agrees with that emphasis needs to be placed on ensuring that primary care and secondary care sectors are both subject to the same requirements in terms of data quality, disclosure and sharing. It is also necessary to analyse the healthcare issues relating to particular groups of patients and in particular, patients who receive long term care through the NHS, including the large proportion of elderly patients. In order to assess the particular issues facing these patients, who may receive discrete episodes of care over a long period from both local GPs and local acute trust, this information needs to be shared. This would inform GPs in their commissioning role and as providers, the acute trust would be able to ascertain whether any failings within the hospital were being dealt with in primary care setting. For example, where a patient requires further care and treatment after a sub-standard hip replacement, this information will not be captured as either a complaint or an incident report.

155. CQC also needs to regularly monitor such information, with reference to the extensive body of data within its possession, in order to enable some triangulation to take place.

Recommendations:

- AvMA support the idea of an executive director being specifically responsible for information systems within a trust, as suggested within the information seminar.

Part Two: Being open with patients

There must be openness and transparency in everything which the NHS does.
(Bristol Royal Infirmary Report, HCC0015000235, 445)

The benefits and importance of being open

156. AvMA strongly believe that an organisation which is prepared to tolerate anything less than full openness with its patients will never have a truly learning culture. It is important to recognise that as well being a fundamental issue of principle, there are practical benefits to actively involving patients in the processes which follow clinical incidents or failings in care. As stated within the Trust's own "Policy on Being Open When Patients are Harmed", and reflecting AvMA's own experience:

> *Incidents can incur extra cost through litigation and further treatment; openness and honesty can help prevent such events becoming formal complaints and litigation claims. Many patients and / or their carers will often only make a litigation claim when they have not received any information or apology from the healthcare team following the incident (ES100042421)*

157. This is illustrated by the account provided by William Hudson to the Inquiry in relation to the care of his mother-in-law, in which he explained that he pursued a human rights claim on her behalf, noting "It was not our intention to seek financial compensation, however we felt that we had to take further action as the hospital complaints process failed to address all of our complaints. In particular, we have not received an apology from the Consultant" (WS0000001443, paragraph 42).

158. Julie Hendry recognised this important principle, commenting:

> *… the wholly [sic] philosophy of patient experience is, you know, "no decision about me without me"; that patients want to be consulted. They want to be kept informed. And – and in my experience, virtually every single complaint that you get, it's because patients or families have found something that's been a surprise to them that they didn't know about. (LiveNote 07.03.11, 176:3)*

159. There will also of course be circumstances in which the patient and their family will want to take further steps, including formal complaints, litigation and referrals to regulators. As emphasised with respect to complaints, the patient is central to the process of raising concerns and should be fully equipped with the relevant information concerning failings in their personal care in order to do so.

160. Meanwhile, sight should not be lost of the role of the staff involved in clinical incidents. Even staff committed to high standards of care and treatment can make mistakes and in these circumstances, the individuals responsible may be left with unanswered questions and concerns. AvMA believes that than a transparent and open investigation, in which patients are involved and informed, is also the interests of staff members involved.

161. Throughout the last decade, the importance of openness has been reiterated in various, guidance and policy documents, although with slightly different emphasis and application. These have included:

162. The GMC "Good Medical Practice" provides specific guidance for doctors:

> *If a patient under your care has suffered harm or distress, you must act immediately to put matters right, if that is possible. You should offer an apology and explain fully and promptly to the patient what has happened, and the likely short-term and long-term effects (GMC0003000028.*

163. The NHS Code for Managers states:

> *I will respect and treat with dignity and fairness the public, patients, relatives, carers, NHS staff and partners in other agencies … I will also seek to ensure that … patients are involved in and informed about their own care, their experience is valued and they are involved in decisions* (CURE00330017715).

164. The NHSLA Circular dated 15 August 2007 states:

> *It is both natural and desirable for clinicians who have provided treatment which produces an adverse result, for whatever reason, to sympathise with the patient or the patient's relatives; to express sorrow or regret at the outcome; and to apologise for shortcomings in treatment. We encourage this, and stress that apologies do not constitute an admission of liability. It's not our policy to dispute any payment, under any scheme, solely on the grounds of such an apology.*
>
> *Explanations: In this area, too, the NHSLA is keen to encourage both clinicians and NHS bodies to supply appropriate information whether informally, formally or through mediation. Explanations should not contain admissions of liability. For the avoidance of doubt, the NHSLA will not take a point against any NHS body or any clinician taking NHS indemnity, on the basis of a factual explanation offered in good faith before litigation is in train. (TRUST00030003735)*

165. The NPSA Safer Practice Notice of 15 September 2005 required all NHS organisations to develop a local policy consistent with the notice but adapted to local requirements by June 2006, and to raise awareness of the local policy amongst healthcare staff and provide appropriate information and support:

> *Being open simply means apologising and explain what happened to patients and / or their carers who have been involved in a patient safety incident.*

166. This policy explicitly does not apply to incidents in which harm is prevented, which was a matter to be decided in accordance with local policy. This is consistent with the NHSLA circular, with respect to apologies and explanations, and the GMC's "Good Medical Practice Guidelines" and the duty of candour proposals within Sir Liam Donaldson's consultation paper, *Making Amends*. This notice sets out the justification for the policy, stating:

> *Openness can also decrease the trauma felt by patients following a patient safety incident. Research has shown that patients will forgive medical errors when they are disclosed promptly, fully and compassionately. In England, a MORI survey, commissioned for the Department of Health's consultation document Making Amends (Department of Health, 2003) interviewed 400 people who had been harmed as a result of their healthcare treatment. Results showed that an apology (followed by investigation and support) was the most desired response to a patient safety incident, and this was considered more important than financial compensation and disciplinary action.*

167. The NPSA "Being Open" Patient Safety Alert 19 November 2009 issued "in response to changes in the healthcare environment and in order to strengthen Being Open throughout the NHS."

168. The NHS Constitution, at paragraph 8, says:

> *The NHS also commits:*
>
> - *to ensure you are treated with courtesy and you receive appropriate support throughout the handling of a complaint; and the fact that you have complained will not adversely affect your future treatment (pledge);*
> - *when mistakes happen, to acknowledge them, apologise, explain what went wrong and put things right quickly and effectively (pledge); and*
> - *to ensure that the organisation learns lessons from complaints and claims and uses these to improve NHS services (pledge).*

169. In spite of all these initiatives, there is consensus that there is insufficient openness with patients or their families when things go wrong and cause harm, as has been graphically demonstrated by evidence given to this inquiry.

The reality of openness and transparency within the Trust

170. In accordance with the NPSA Being Open notice, since 2005 the Trust had had a local policy in place.. However, little reassurance was provided in the course of the Inquiry that this had been implemented throughout the organisation in any meaningful way. Evidence has been provided with respect to various instances when disclosure of important information in relation to the care of patients was either delayed or withheld

171. Janet Robinson's response to the failures in the case of the death of her son is clear:

> *Q. We're going to look at what happened at the inquest in a moment but how open do you feel the trust was with you?*
> *A. They were not open at all.*
> *Q. And in terms of offering you the information which you felt that you needed early on in this horrible sequence of events, how do you feel they behaved in relation to that?*
> *A. I am absolutely appalled.* (LiveNote 23.11.10, 158:11)

172. Two patient relatives refer to lack of communication with respect to the failure of the Trust to inform them that their relative had clostridium difficile. Sandra Whitehouse (LiveNote 30.11.10, 85:22) and Elizabeth Cowie (LiveNote 30.11.10, 34:2)

173. At the time of producing a report of themes arising in June 2010 (MON00030009262), the ICNR had produced over 200 individual reports. In this document, it was confirmed:

- In a number of cases the families claimed that they were not fold that their relative had a HCAI and that they only found out when this was recorded on the death certificate.

- There were a few cases where families claimed that crucial information was not properly communicated to people with urgent need for cancer care (MON00030009262, 7).

- In a number of cases the notes contained no record of communication with patients / relatives (MON00030009262, 13).

174. It is also apparent that there was clear lack of understood practice with respect to the disclosure of SUI reports. This is starkly illustrated by the case of Gillian Astbury, where the SUI report concerning her death was only disclosed to her family more than a year after her death (second statement of Ron Street WS0000001352, paragraph 3). Despite being the named lead on the Trust Being Open policy, which specifically required SUI reports to be disclosed to patients and families, Helen Moss was not aware that it had not been practice to report SUIs to patients. Although it was confirmed that there had been some training provided on this policy (LiveNote 28.03.11, 115), those individuals who would be expected to know of such a policy with respect to SUIs seemed unaware of its existence. Sharon Llewellyn, PALS/Complaints manager, confirmed that despite not being aware of a particular policy in place, she would disclose SUI reports to patients if they made a complaint by cross-checking on Safeguard (LiveNote 17.01.11, 14–15 and 18.01.11, 33-35). Dr Turner understood his professional duties in this respect but when asked about the existence of a policy, indicated that "I made the assumption the trust would want to be open and honest to patients. I never heard anybody say otherwise" (LiveNote 02.03.11. 47-48). Kate Levy confirmed that there was no process in the trust in 2006 for notifying patients or families of every incident which occurred unless they "came forward and asked questions" (LiveNote 05.10.11, 154:1).

175. The extent to which patients have been left in the dark cannot, by definition, by quantified. Basic measures, such as incorporating a field on the incident reporting form to record that patient had been contacted and if not, the reasons for this, would have both provided a means of monitoring the extent to which the policy was being taken seriously in the Trust.

Openness within litigation

176. As demonstrated clearly through the case of John Moore-Robinson, the lawyers at the Trust considered themselves "walking a tightrope" in circumstances where litigation is threatened. On the one hand, the lawyer must consider the interests of the trust, supported by NHSLA, in admitting liability and the financial settlement which would follow. On the other hand, as Stuart Knowles clearly recognised, there are wider considerations, including openness and transparency. Likewise, Kate Levy expressed an awareness of the principles of openness and transparency but "may not have been aware" of the Being Open policy (LiveNote 05.10.11, 27-28, 144).

177. There is currently insufficient central guidance concerning complaints where litigation has commenced or is intended. Although the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009 (the complaints regulations) were changed deliberately so as to remove the previous bar on investigating complaints where litigation was taking place or intended, AvMA have discovered that some trusts are either unaware of or are flaunting the new system. In one instance, a trust is telling any complainant who is also seeking to make a clinical negligence claim that

their complaint will be put on hold until the litigation is closed. When challenged, the trust quoted as justification for this the advice issued by the DOH, that complaints could be put on hold if to investigate would 'prejudice' another process (even though the 'default' position should be to continue to deal with the complaint. The only explanation offered was that investigation of the complaint would 'prejudice' their defence of the claim. AvMA believe, and DOH officials have confirmed this was not the policy intention in devising the complaints regulations.

178. Although Sharon Llewellyn said that litigation had no bearing on providing a response to a complaint (LiveNote 17.01.11, 115), in practice the exclusion of a complaint where litigation was in contemplation (which exclusion was permissible under earlier complaints regulations) was considered by the legal department on a case-by-case basis. Stuart Knowles confirmed that Sharon Llewellyn would sometimes seek his advice where there was a potential threat to legal action; and he confirmed that "sometimes I would advise the Trust to carry on dealing with the complaint but I would make them aware that they had the right to "bring the shutter down" on the complaints process where a threat of legal action was made by the complainant." (WS0000074633, paragraph 31).

179. Julie Hendry commented that, currently, the indication of litigation would not prevent a complaint being investigated at the Trust (LiveNote 07.03.11, 169). Stuart Knowles noted "The situation on apologies in the NHS prior to the proceedings is changing but remains in a state of flux. In short, the position now is that when litigation is initiated a trust does not automatically close the complaints process…" (WS0000074633, paragraph 31). Accordingly, it appears that whilst there is no longer regulatory provision prohibiting trusts from considering complaints where litigation has been threatened, this remains a matter of judgment for individual trusts and their legal departments, depending on whether they consider the complaints process to be "prejudicial to the proper and effective conduct of the defence" of a legal claim. On behalf of the NHSLA, Steve Walker simply stated "that the litigation process would not interfere with the complaints process." (NHSLA0001000324).

180. There is no reasonable basis upon which it can be suggested that complaints process should not take place in circumstances in which litigation is threatened. A patient should not have to choose between seeking an apology and explanation through the NHS Complaints Process and financial redress for harm caused through clinical negligence litigation. If the complaints process is able to be curtailed in such circumstances, vital indicators of poor or dangerous practice may be missed, undermining an important function of the process. It may also be there are cases where litigation is avoided through provision of an apology, explanation and assurance that lessons have been learnt. Equally, the pursuit of litigation in serious and complex cases will focus the mind of the trust on ensuring that its investigation is full, transparent and independent.

181. Both of the Trust lawyers Kate Levy referred to the Being Open policy as being directed at clinicians rather than the legal department (LiveNote 05.10.11, 18-20 and 145), with Kate Levy commenting she did not consider herself to be within the class of people referred to in the policy (LiveNote 05.10.11, 188). AvMA are dismayed that this issue should be subject to interpretation of the strict wording of a guidance document or policy rather than a commitment to the principle underlying the policy to be applied by every member of an organisation with respect to their interactions with the patient. It is accepted that the primary responsibility must fall upon the clinicians to communicate fully and openly with the patients and families, both in line with their own professional duties and given their knowledge of the relevant clinical details. The lawyers' role is to provide robust advice to both senior management and clinicians alike with respect to their obligation to do so.

182. Further, trusts are of course subject to the NHSLA guidance on apologies and explanations, which has steadily developed over the years circulars have been issued; 1997, 2002, 2007 and 2009 in which it is made clear that an expression of sorrow or regret will not constitute an admission of liability and will indemnity under the CNST will not be disputed on this basis. It clarifies that the NHSLA will not "take a point" against any NHS body or any clinician on the basis of a "factual explanation offered in good faith." The stated aim of the circular is to encourage organisations and their employees to offer earlier and more information apologies and explanations. For many years the wording of the circular was at best unclear about whether being open with patients was more important than protecting the NHS from future litigation risks and could be interpreted as saying the opposite. Following pressure being brought to bear from patients the wording of NHSLA guidance has been changed and is now unequivocal. However, both Ms Levy and Mr Knowles believed that confirming that an individual had failed to diagnose a particular issue would be admission of liability. If this is the view taken, this would render provision of any explanations of an individual's actions impossible.

183. AvMA found the evidence of Mr Knowles and Ms Levy chilling in a number of respects, in particular, the unduly narrow approach to the assessment of the Trust's best interests which completely left out of account whether those interests included acting in accordance with NHS and the Trust's own policies and ensuring that the Trust was open and honest with patients and their families.

184. Following Mr Knowles' evidence, the NHSLA have confirmed "that they do not see any conflict between the need for openness (that is for appropriate factual explanation and if appropriate, apologies to be given) on the one hand and the requirement not to make any admissions of liability on the other."

Near misses

185. Particular attention has been paid in the evidence to those clinical incidents which may have potentially resulted in harm to a patient but in fact did not do so: the "near misses." These are not included within the Being Open policy, but Manjit Obhrai confirmed that the Trust would certainly consider this issue. Julie Hendry confirmed that it was her practice to inform patients of "near misses," and when asked whether this caused unnecessary anxiety for patients (LiveNote 07.03.11, 172 – 175), commented:

> *A. No, in fact the one I'm thinking of, the patient themself felt a bit uneasy about the incident. I don't think they quite knew why but they -- they didn't feel as if the clinical team -- they didn't have confidence that the event had gone as well it should be. So they were grateful for the call. But I haven't -- I haven't phoned anybody who's -- it's been absolutely news to them, no (LiveNote 07.03.11, 175:8).*

186. This confirms AvMA's view that patients will most commonly welcome this information. However, in circumstances where the disclosure may cause harm to the patient due to their physical or mental state, AvMA accept that there may be specific instances where the clinicians concerned should exercise their discretion, with reference to the best interests of the patient, and withhold the information. AvMA recommend that in making a decision as to whether or not to disclose information about a "near miss", a clinician should consult another clinical colleague or manager and record the decision in the patients notes.

External monitoring of Being Open

187. Suzette Woodward of the NPSA clearly recognised the difficulty in implementation of the Being Open guidance, explaining that the original Safer Practice Notice issued in 2005 was reissued as a Patient Safety Alert in 2009, after the effectiveness of the original notice had been assessed and it was determined that follow up was required to reinforce the issue and remind people of the requirement (LiveNote 20.06.11, 92:3). She further commented this issue was:

> *Much more cultural shift than a technical -- technical shift, and you -- you, the developer of that, need to do that very clearly and with a lot of help for that local organisation." (LiveNote 20.06.11, 83:17 – 83:22)*

188. Local "conversations", local audits and independent surveys provided an indication there was no means by which the NPSA would be aware that any specific incident had been disclosed to the patient or their families (LiveNote 20.06.11 93:09). The NPSA did not consider that it was responsible for

monitoring and enforcing any PSA and took no further steps in relation to enforcing this particular alert.

189. Steve Walker, the Chief Executive of the NHSLA, acknowledged that circulars were issued every 2 years partly in recognition of the fact that the message did not always filter down to the "front line" and the people are still reluctant, commenting:

> *The reasons for not doing it, I think, are in the individual and/or corporate psyche, where you find there is resistance or reluctance. But, you know, motorists have accidents and drive away, people cause accidents at work and if they don't think they're going to be caught they don't report it. (LiveNote 05.07.11, 171:19)*

190. The only organisation which did appear to assess the implementation of Being Open was the NHSLA, in its deeply flawed CNST assessment in October 2007 referred to above, which stated that "The trust was also able to demonstrate that its Being Open Policy is implemented throughout the organisation." (Bartholomew Exhibit AB/15, LA0001000677, 7)

A "Duty of Candour"

191. One means of supporting a shift to more openness with patients would be through the creation of a 'duty of candour' applicable to organisations. AvMA have long advocated such a duty being created. In his official report 'Making Amends' (2003 Sir Liam Donaldson, then Chief Medical Officer, specifically recommended the development of a statutory duty of candour. This recommendation has not yet been taken up by successive governments.

192. In his statement to the Inquiry, Sir Liam Donaldson said:

> *I have always personally agreed that there should be a statutory duty of candour. I have favoured it because I am of the view that professionals should be encouraged to take responsibility when they have done something wrong, rather than withhold instances of harm (WS0000070103, paragraph 181).*

193. It is clear that the measures taken to date have failed to bring about the organisational commitment to this principle and to achieve the fundamental change in culture with respect to the role of patients in a "patient centred" healthcare service which aspires to make "no decision about me, without me".

194. Whilst some argue that bringing about the desired cultural change and creation of statutory requirements are mutually exclusive, AvMA take the view that cultural change and statutory

enforcement are complementary. That view is shared by Cathryn James of Public Concern at Work:

> *We support this and see this as part of creating an open and transparent workplace culture, as it emphasis appears to be on encouraging health organisations to speak to patients. We see this as complimentary to good whistleblowing arrangements and quite separate from placing an additional duty on individual doctors and nurses to raise a concern about wrongdoing or malpractice in the workplace." (James statement, WS0000076467, paragraph 66)*

195. AvMA considers that although the emphasis upon being open in the NHS Constitution and the various guidance is helpful, it is not a substitute for an enforceable duty. By way of Freedom of Information Act request, AvMA established that the officials within the Department of Health were not aware of any instance when action had been taken with respect to failure to comply with the Constitution (Walsh Exhibit PW/2, WS0000002073, 20-21).

196. The NHS White Paper included commitment that the Government would "require hospitals to be open about mistakes and always tell patients if something has gone wrong" (DH0000000690). However, the current intention is to introduce only a 'contractual' duty of candour (which is currently the subject of a consultation by the Department of Health). This would in effect be a standard clause in hospitals contracts with the NHS. Hospitals would have to make a declaration about compliance annually as part of its contract.

197. The Health Committee report on 'Complaints & Litigation' (June 2011) specifically recommended that:
(a) "service agreements between NHS commissioners and their providers should include a contractual duty of candour to the commissioner", and
(b) "a duty of candour to patients from providers should also be part of the terms of authorisation from Monitor, and of licence by the Care Quality Commission". (Our emphasis)

198. AvMA agrees with the Health Committee that the duty of candour should form part of the terms of licence with the CQC (the CQC's Registration Regulations), giving them statutory force and giving the CQC the ability to enforce them.

199. The duty of candour should be one of the essential standards of quality and safety. Currently there are 28 existing essential standards of quality and safety which are terms of each organisation's registration with the CQC. The CQC monitors compliance with these essential standards and failure to comply with these standards is a breach, with respect to which the CQC are able to issue warning notices, penalty notices and ultimately, revoke the registration of an organisation. The CQC regulations already contain the statutory requirement to report incidents which have caused harm to

the CQC. This is done via anonymised reporting to the National Reporting and Learning System (NRLS). However, there is no statutory requirement to be open with the patient (or family of the patient) who has been affected by the same incidents. It would be wholly logical, practical and consistent to have a corresponding requirement to inform patients or the families of deceased patients fully about incidents. Further, that to require one but not the other sends out the clear message that being open with patients is not as important as communication with the regulator.

200. Currently, the importance of providing an apology and explanation is noted within the CQC's "Guidance about compliance: Essential standards of quality and safety" as one of various actions underpinning outcome 4 / regulation 9 concerning Care and Welfare. It's status within the CQC regulatory scheme is clearly inadequate given its importance. It does not provide the principle of being open with sufficient emphasis from the perspective of the organisation and does not represent an area of particular focus for the CQC in undertaking monitoring activities.

Recommendations:

- The 'Duty of Candour' should be part of the licensing conditions with the CQC as recommended by the Health Committee and others i.e. there should be a specific requirement within the CQC registration regulations

- The 'contractual' duty of candour should also be developed alongside the above, as an adjunct to it, not as a substitute

- It should be made explicit that anyone working for or acting on behalf of an NHS body, including lawyers, will only be acting in the interests of their client if they practice complete openness and honesty with patients of the NHS body and their relatives

- Central guidance on SUIs and other investigations should be revised to make explicit the requirement to be open with patients/families from the start and where possible to involve them in investigations;

- Clarification, backed up by clearly drafted guidance, that "near misses" should be reported to the patient or their family unless there are specific reasons not to. decision should be made by the treating clinician after consultation with a colleague or manager and both the decision and the reasons for it, should be recorded in the patients' notes.

- Clarification, backed up by clearly drafted guidance, that patients should be informed with respect to other events which may follow "things going wrong" including:
    - Reporting of death to the coroner and with reference to the "cause of death," the process

which will follow, including whether an inquest may be held and their involvement;
    - Decisions made in connection with disciplinary or regulatory proceedings with respect to individuals involved;

- With respect to individual trusts, the requirement to disclose information to patients needs to be backed up with:
    - A programme whereby staff are informed of its existence and trained with respect to its contents;
    - A process by which the communication with patients is recorded in a central location so that there is a clear audit trail;
    - Monitoring to ensure that it is being followed; and
    - Measures to enforce compliance where it is not being followed on individual or trust-wide basis.

- Clear guidance should be issued by the DOH on the operation of the NHS Complaints procedure to promote good practice and consistency in complaints handling. This should include making clear once and for all that the use of the argument that investigating and responding to a complaint would 'prejudice' the defence of a clinical negligence claim is totally unacceptable and define the very limited and exceptional circumstances where 'prejudice' of another process might be used as a reason for not investigating a complaint.

<u>Information / Transparency</u>

AvMA welcomes the increasing trend towards the open publication of more information about quality and safety in the NHS, and would like to see this expanded. For example the work on publishing success rates for cardiac surgeons could and should be replicated in other areas. Whilst publishing information will not on its own be sufficient to drive forward quality improvement, it can incentivise organisations and their staff. For example, if every trust had been required to publish its status with regard to Patient Safety Alerts on their websites it is likely that far fewer would have let themselves fall so far behind with implementation. Making such information would also empower the public and bodies such HealthWatch or the media to exert influence over NHS bodies. Rules about transparency should apply to every NHS body and there should be no concessions over this for Foundation Trusts

Recommendations:

- Every NHS body with a Governing board should be required to hold board meetings in public

- The NHS Commissioning Board should determine that NNS bodies should be required to publish a common set of data in an accessible way on their websites. This data should include:
    - The level of Risk Management / CNST Level attained under the NHSLA
    - The status of each Patient Safety Alert past the deadline for completion which is relevant to the NHS body, and an action plan for addressing any outstanding alert
    - Mortality rates, where these are available
    - Complaints information including outcomes and changes implemented as a result

Part Three: Raising concerns and "whistleblowing"

201. The term "whistleblowing" has been used within the Inquiry to describe both raising concerns internally on a day-to-day basis and to describe the process of making protected disclosures external bodies such as the HSE or CQC (as set out under the Public Interest Disclosure Act 1998 (PIDA)). However, in the case of the Trust, the evidence suggests that there was a deeply embedded culture that discouraged or prevented concerns being raised and addressed internally and, in most cases, the possibility of reporting externally was not even a consideration.

202. Upon publication of the HCC report, one of the immediate questions arising was why none of the staff had reported what was happening within the Trust. Helene Donnelly, one of few nurses who did formally register her concerns internally, provided a clear answer to this question. She told the Inquiry that, having raised serious concerns about the widespread falsification of A&E data, she was subject to a campaign of bullying and harassment. Crucially, at the end of a long investigation during which she was subject to verbal abuse and physical threats and provided with little information or support, the two sisters she had reported were reinstated without any formal disciplinary finding. In her view, other staff members, having observed this process, were fearful to speak out (LiveNote, 07.10.11, 139).

203. Sue Adams, local RCN steward, was aware of two other instances in which nurses tried, unsuccessfully, to raise concerns:

> *There was a nurse in -- in the A&E department, for instance, who was concerned about what was happening and contacted the RCN, as in outside the organisation, because she didn't feel that it would -- anything would be done by reporting it internally. And the RCN were involved and she was severely reprimanded by the managerial staff, and the team in the A&E department made her feel excluded, and as a result she -- she left. She was told off for contacting the RCN.*
>
> *Another nurse contacted the NMC to -- to voice concerns and was told that unless she named names and gave her name, they weren't prepared to -- to listen to the concerns being raised. And I think when that sort of information goes around and the staff hear about it, it makes them feel that they -- they can't or feel fearful of raising concerns. And a term that I frequently heard from some of the staff was that you had to put up and shut up, or shut up and put up, if you valued your job, because people were being told to stop moaning and whingeing.* (LiveNote 03.03.11, 52-53)

204. The Inquiry also heard evidence from doctors within the Trust with respect to ongoing under-staffing.

Every doctor is subject to professional requirements, in accordance with Good Medical Practice , to raise concerns with respect to potential or actual compromise to patient safety; and if no adequate action is taken, to take independent advice (GMC0003000028, paragraph 6). However, the doctors who provided evidence to the Inquiry explained how they persisted in voicing their concerns through the internal channels available to them, without success, rather than seeking such advice. Dr Dagget confirmed that he was not aware of anyone taking independent advice (LiveNote 16.02.11, 26-27) and although he raised his concerns in relation to staffing with the Nursing Director, Medical Director and Chief Executive, he did not take this further, commenting:

> *… it is a very big step to say 'Look, an entire hospital and its management structure is wrong.' It didn't occur to me that that could be done (LiveNote 16.02.11, 31:19).*

205. Union representatives at the Trust provided a similar account with respect to the willingness of staff to raise issues externally. Kath Fox, Unison Branch secretary and bereavement officer employed by the Trust for 16 – 17 years, confirmed that members had wanted to raise concerns but "none of them felt able to take that route." (LiveNote 10.02.11, 109 – 110, 123). Mark Young of Unite, a fulltime union officer with responsibility for approximately 250 members within Trust from 2001 onwards, confirmed that none of his members came to him wanting to "whistleblow." (LiveNote 08.02.11, 143 – 144). Denise Breeze, a nurse within the Trust since 1983 and RCN representative since 1980, confirmed that she was aware of only one instance of whistleblowing in 2005 – 2009, which did not relate to patient safety (LiveNote 09.2.11, 33 – 34).

206. Although the Trust did have a whistleblowing policy in place, it appears that the introduction of the policy was not accompanied measures to increase awareness amongst staff or training. Dr Singh was only "vaguely aware" of a whistleblowing policy (LiveNote 16.02.11, 144) and neither Dr Nakash (LiveNote 01.03.11, 64) Dr Turner (LiveNote 02.03.11, 24) knew of it. Kath Fox, a long term employee, confirmed that she received no training in whistleblowing (LiveNote 10.02.2011, 108).

207. It is surprising that in at least one instance, union representatives themselves were a barrier to reporting. Helene Donnelly highlighted concerns about the role of Mr Legan, the full time RCN officer and her local representative at the Trust, whom she consulted for support and advice having first raised her concerns with respect to the A&E department. Unaware, at this time, that he was representing one of the two sisters concerned, she described his response as follows:

> *Ultimately, he said that -- he was basically very dismissive of the whole situation and basically said that these things happen, there are personality clashes and that sort of thing. And when I tried to explain further and said, "Well, this isn't about a personality clash, this is much more fundamental than that and isn't just necessarily one individual, it is happening to lots of*

different people and obviously affecting patient care", he was just -- he was just very dismissive and basically said that -- once obviously we'd discussed the fact that the two sisters had been suspended and I was very fearful of the outcome of the investigation and should they return -- should they be returning, he informed me that they were going to be coming back, that they were going to have a slap on their wrists and that there would be team building exercises to help everybody resolve issues and obviously get on more productively, I suppose…. He was very dismissive and just told me to basically keep my head down, not raise concerns further, not cause any more trouble, because it would ultimately be worse for me, rather than them, i.e. the sisters concerned. (LiveNote 07.10.11, 143:1).

208. Those within senior management positions at the Trust appeared to dismiss concerns expressed about the ability of staff to raise concerns internally. At the same time, the Trust management fail to have registered the alarm bells concerning the culture within the Trust within the staff surveys – in particular, the fact that 13 – 23% of staff reported experiencing harassment, bullying and abuse from staff throughout the years 2003 – 2007 (HCC0026000478, HCC0026000504, TRU00010001645, ESI00047981).

209. It is clear that this culture extends beyond the Trust. Dr Mark Whitehouse, both a local GP and the son of a patient, stated that he had been told to be careful about what he said to the Inquiry on the basis that he could potentially be sacrificing his career by speaking out (LiveNote 29.11.10, 111–112). Dr Kim Holt, who has provided a statement to the Inquiry, is just one of a number of high profile whistleblowers whose careers have been effected or even lost as a result of acting upon their concerns (WS0000002929). As with the issue of patients not being informed of incidents which cause harm, it is hard to quantify the number of potential whistleblowers who do not raise their concerns as a result of bullying, intimidation or the fear thereof.

Reform and recommendations

210. On 9 June 2010, the Government's response to the concerns arising with respect to Mid Staffordshire was to announce a range of measures "to give teeth to the current safeguards for whistleblowers in the Public Interest Disclosure Act 1998":

- Reinforcing the NHS constitution to make clear the rights and responsibilities of NHS staff and their employers in respect of whistleblowing;

- Seeking through negotiations with NHS trade unions to amend terms and conditions of service for NHS staff to include a contractual right to raise concerns in the public interest;

- Issuing unequivocal guidance to NHS organisations that all their contracts of employment should cover staff whistleblowing rights;

- Issuing new guidance to the NHS about supporting and taking action on concerns raised by staff in the public interest; and

- Exploring with NHS staff further measures to provide a safe and independent authority to which they can turn when their own organisation is not listening or acting on concerns.

211. AvMA welcome these steps and agree that primarily steps need to be taken to create organisations in which there is a culture in which staff can be open with patients and confident in raising concerns with management. However, AvMA believes that these measures fail do deal with problems which arise for would-be whistleblowers well before any formal employment dispute. Where intimidation or bullying of would be whistleblowers takes place, it is likely that the majority feel forced to "back off". The support and protection of, and responding to whistleblowers' concerns as an essential part of patient safety. AvMA has heard from several health professionals that they have been warned off disclosing information about incidents which have harmed patients by management. This puts staff who want to do the right thing and be open with patients in an impossible position. Not to be open means they are in breach of their professional code, but to do so puts their career at risk. Far too much emphasis is put on PIDA which only applies when matters get to an employment dispute.

212. AvMA recommends that a suitable clause is introduced to the CQC Registration regulations requiring healthcare providers to take all reasonable steps to support, protect, and listen to whistleblowers (or staff raising concerns). Where the CQC becomes aware of registered organisations acting inappropriately towards staff raising concerns or whistleblowing, they should intervene and take action. The evidence of Dr Kim Holt suggests that this is not the case currently.

213. AvMA supports the introduction of new guidance with respect to supporting and taking action on concerns raised by staff. This should include clear and unequivocal guidance with respect to practical measures to be taken by trusts to ensure that staff are fully informed and understand the options available to them and, essentially, are informed of the channels available to access confidential and independent support and advice.

214. Within this context, account needs to be given to the current sources of such advice and support. Significant steps have been taken by the RCN [and NMC] in terms of issuing guidance and provision of a helpline (see statement of Adrian Legan WS00000039999, paragraph 33). John Black, the President of the Royal College of Surgeons, confirmed that they sometimes received whistleblowing calls from

surgeons in trouble, which is encouraged (LiveNote 27.06.11, 211). Dr John Heyworth, the President of the College of Emergency Medicine, confirmed that they had become more open and accessible and members were raising concerns more readily than in the past (LiveNote 07.07.11, 46). The GMC also have a contact centre . However, it is hoped that BMA and relevant royal colleges will further publicise and strengthen the support available for doctors seeking confidential advice concerning raising concerns. AvMA supports the continuing provision of an independent and confidential support and advice by Public Concern at Work.

215. With reference to Helene Donnelly's experience of support provided by her local RCN representative, clear guidance and training must be provided to individuals representing staff members given the potential for conflicts of interest to arise

216. The Government has also suggested the introduction of "a safe and independent authority to which they can turn when their own organisation is not listening or acting on concerns" AvMA recommend that consideration is given to establishing a specialist service in the UK similar to the National Whistlblower Centre in the US (http://www.whistleblowers.org/). This is a safe place where whistleblowers can turn to when they need to with confidence that they will be supported.

The impact of "gagging" clauses

217. AvMA believe that more effective action needs to be taken to prevent the use of clauses which have the effect of dissuading or preventing potential whistleblowers from raising their concerns externally. There has been concern for some time that the use of "gagging clauses" has persisted within compromise agreements, despite the provisions of section 43J of the Employment Rights Act 1996 (as amended by section 1 of PIDA), which render any provision within any agreement between a worker and his employer void "in so far as it purports to preclude the worker from making a protected disclosure".

218. The Inquiry has received evidence that the CQC, has engaged in the practice of including "non-disparagement" clauses within compromise agreements. Heather Woods and Roger Davidson, former CQC employees, confirmed that such clauses were included in their compromise agreements (LiveNote 10.05.11, 170 – 171 and LiveNote 16.05.11, 86 - 87). Cynthia Bower was asked about this clause, which reads as follows:

That Dr Wood will not at any time hereafter make or repeat any statement which disparages or is intended to disparage the goodwill or reputation of the CQC, or any specified person

219. Ms Bower asserted that these were standard clauses in compromise agreements when people left the

organisation and suggested that it was made plain that Dr Woods could give evidence to an Inquiry. She accepted that although there was a "public interest override" in other circumstances, this was not clear from the agreement (LiveNote 19.05.11, 102 – 103).

220. Whilst "gagging clauses" which contravene section 43J are contractually void, the fact that both Heather Woods and Roger Davidson were sufficiently concerned with respect to their contractual obligations to obtain direction from the Chairman demonstrates that even "void" clauses can have a powerful influence.

221. Although direction was provided within a Health Service Circular dated 27 August 1998 that every NHS Trust and health authority "should prohibit" such clauses (WS00000076467, CJ/12, 275), this has not been effective. It does not help if bodies such as the HCC/CQC charged with regulating the NHS themselves indulge in such practices. It is not enough to tell NHS bodies themselves that they "should prohibit" gagging clauses. More serious action is required with actual consequences for employers who introduce or try to introduce them. Gagging clauses are another form of cover up preventing transparency and system wide learning to protect patients.

Recommendations

- The use of gagging clauses should be robustly prohibited and action taken against employers who seek to introduce them

- A suitable clause is introduced to the CQC Registration regulations requiring healthcare providers to take all reasonable steps to support, protect, and listen to whistleblowers (or staff raising concerns).

Part Four: Professionalism and professional responsibility and accountability

Healthcare professionals

222. Like everyone who has looked in some depth at what happened at the Trust, AvMA has been continually asking itself how so many individual health professionals could have let their own standards of care to patients fall so low, and how the poor practice of colleagues was not reported or acted upon. In short, what happened to professionalism and the caring element of healthcare professionalism.

223. AvMA agree with Sir Bruce Keogh's statement concerning the failings within the Trust:

> *… in terms of delivering quality, it wasn't the CQC, it wasn't the PCT, it wasn't the SHA who treated patients badly in Mid Staffs, it was individual clinicians, largely, and therefore for me, in terms of really developing quality in the NHS, there needs to be a significant focus on professionalism… And, therefore, when you get organisational failure it reflects, I think, or it is a reflection of failure of professionalism and clinical leadership at a clinical team and clinical individual level. So if we want to improve quality, the first area that we need to focus on, I believe, is improving professionalism and focus on quality among individual clinicians* (LiveNote 20.09.11, 199:13).

224. This is not to say that systems of management, regulation and commissioning do not have a vitally important role to play in promoting and supporting good professionalism and preventing or detecting and intervening where there are lapses. To state the obvious, prevention is better than cure and one has to start with healthcare professionals on the frontline of patient care.

Health professional recruitment, selection and training

225. The inquiry has heard in some detail from various witnesses on these topics. However, what particularly impressed AvMA was the degree of consensus arrived at the workshop on "Patient Experience". Particularly with regard to nursing, there was a strong opinion that the way we recruit, select and train nurses needs to be revolutionalised. In selecting people for training as nurses more regard should be given to people's motivation and caring qualities. The training of nurses should be less academic based and much more time allocated to training on wards. More emphasis on basic nursing care and interaction with patients is needed. Emphasis should be placed on 'basic' tasks such as helping patients eat, attending to toileting needs, and patients' comfort and cleanliness. These should not be seen as something below a nurse or something that Healthcare Assistants are there to do instead, but an integral part of the job. And somehow, the image of caring for elderly people

should be changed so that nurses are proud of working on elderly care wards and it has status. Investment of resources into basic elderly care should be made a priority with guaranteed minimum nurse number levels. It is accepted that resources are not unlimited and that prioritisation of guaranteeing good standards of care for elderly people, even at the expense of access to certain other treatments or the benefit of more choice is justified.

226. With doctors as well as nurses, more attention should be paid to applicants' motivation and caring qualities, and communication skills. These should be better developed in the training of health professionals with more emphasis on communication skills; ethical issues in healthcare; and on patient safety.

Audit and appraisal

227. The Inquiry heard evidence about widespread acknowledgement within the Trust of individual staff failings, set against little evidence that these were formally addressed. Upon reviewing the staffing records of individuals whom Julie Hendry knew had been investigated in the past, she commented "you wouldn't know that from the individual staff records all," although with respect to her experience of conducting an investigation, it seemed to be "common knowledge" (LiveNote 07.03.11, 192).

228. The lengthy history of concerns within the general surgical department provides a stark illustration of the failure to take immediate and appropriate action to address individual failings. Again, there was evidence of general awareness of problems within the department, with Valerie Suarez commenting:

> *Of all the issues facing me when I started [September 2006], this was one that had been well known throughout the consultant body for some years. (LiveNote 22.03.11, 95:21)*

229. Against a background of intense inter-personal difficulties between two particular consultants, she explained that her immediate concern was to identify whether there was any underlying evidence with respect to patient safety being compromised, leading to production of the first Royal College of Surgeons report in June 2007. Despite this describing a "dysfunctional department" in which a lack of cohesion "makes it very difficult for members of the team to function in a satisfactory way," where "discussion and decision making are compromised by disagreement," and there was a lack of key protocols (HCC0021000238), her conclusion was that "they didn't indicate that there was a capability problem. They indicated that there were – as we were already aware of, there were serious interpersonal issues and they said that there was no evidence for concern of one surgeon over another" (LiveNote 22.03.11, 108:24). At the time, this was dealt with through a combination of audit, producing protocols, recruitment and training (Executive Governance Group review of Action Plan

21.07.08, ESI00239681). However, concerns persisted, and a second Royal College of Surgeons report was produced in October 2009, detailing a catalogue of appalling failures causing serious harm to patients (RCS00000000178). On any view, this report highlights that over a period of at least 4 years, the Trust failed to protect patients from increased risk associated with the practice of these clinicians.

230. It is not surprising that these events occurred within a trust which had a poor record of clinical audit and appraising staff. In relation to audits, Dr Singh said that in his experience, individual clinicians would undertake audits on their own initiative, but there was no formal "audit meeting" to discuss outcomes (LiveNote 16.02.11, 140 – 141). This is supported by Dr Durrans, who confirmed that individual doctors complied with their duties to audit their own results (LiveNote 03.03.11, 141-142). Dr Turner confirmed that although audits took place in the A&E department upon his arrival, clinical governance within the department was "immature" and he said that "it was audit without the final step where you say "Well, this is -- this is how we have performed and these are the changes we could make in order to improve this for the next time this particular item is audited"" (LiveNote 02.03.11, 37:18).

231. Helene Donnelly, who worked within the Trust for more than five years, had never had an appraisal (LiveNote 07.11.10, 162:10). According to the NHS National Staff Survey in relation to the Trust for the years 2005 - 2008, only 20 – 29% of staff had a structured appraisal in the previous 12 months (HCC0026000504, TRU00010001645, ESI00047981, HCC0032014684). Further, it is clear that the Trust failed to maintain either proper staff records or collate performance-related evidence of the practice of individual clinicians, such as the number of complaints. Dr Durrans commented that "I would have liked to have done is pressed a button and have all the detail about colleagues delivered to me. That has never existed." (LiveNote 03.03.11, 169:21). Such information should have enabled failings to be identified and addressed immediately – whether through training, performance management or suspension of practice – thereby protecting patients from avoidable and unnecessary harm.

<u>Accountability</u>

232. "Accountability" is a term commonly used but often poorly defined. AvMA believe that establishing accountability should be seen as a process to avoid failings rather than simply ensuring that there is someone to blame when things do go wrong. This process consists of five important elements:

1. Clear identification of individual responsibility;
2. Provision of training, support and guidance to the individual;
3. Availability of transparent information with respect to fulfilment of that responsibility and established methods of monitoring this information;
4. Providing an appropriate acknowledgement and explanation with respect to failings;

5. Where necessary and appropriate, pursuit of necessary restrictions or sanction with respect to that individual, including disciplinary / employment proceedings or regulatory investigation.

233. Julie Hendry commented on the absence of accountability throughout the Trust on her arrival:

> *I think one of my overriding perceptions when I came to the trust was that there wasn't a very clear level of accountability throughout the organisation, because there'd never been any sort of sanction for people who didn't take accountability. So if it was easier to do something outside a process, and then that failed, there was a -- historically no monitoring of it, but also there was no sanction for the individual (LiveNote 07.03.11, 180:13).*

234. Within these circumstances, the level of denial encountered within the Trust upon publication of the HCC report is perhaps more explicable (LiveNote 16.03.11, 64). This was an issue highlighted in the evidence of the Chairman, Toni Brisby, who said that although some patients received poor care, she believed that:

> *The reason a huge number of people didn't find anything uniquely dreadful is that there was nothing uniquely dreadful to find out. (LiveNote 03.10.11, 47:22)*

235. Without clarity concerning accountability, there is a danger that an organisation is unable to distinguish between individual and organisational failures and therefore, where responsibility truly lies. AvMA support the development of an "open and fair" culture in which there is less emphahsis in trying to apportion individual blame but where individuals are held to account, where appropriate, and systemic problems are properly addressed.

<u>Disciplinary proceedings</u>

236. AvMA recognise that errors happen and will continue to happen but the accounts provided with respect to individual staff in Mid Staffordshire demonstrate that there will remain a need for disciplinary and regulatory action where staff members show callous and uncaring disregard for the safe care and treatment of patients, serious dishonesty or dangerous levels of competence.

237. The evidence heard by the Inquiry suggests that when disciplinary action was taken, it was half-hearted at best. Helene Donnelly provided a compelling account of how two sisters she reported as involved in falsification of records in order to meet A&E targets were reinstated after a conversation between Adrian Legan (the RCN representative) and Martin Yeates (LiveNote 07.10.11, 148-149).

Health Professional regulatory bodies

238. Both the NMC and the GMC have important roles in considering the fitness to practice of individual practitioners and ensuring that appropriate steps are taken "in the public interest," including interim suspensions where warranted and ultimately, imposing sanctions limiting or preventing further practice. Unlike disciplinary proceedings, both bodies have the prime function of preventing further unsafe practice causing harm to patients.

239. The potential for professional regulation in effecting cultural change has been demonstrated within the field of obtaining effective consent, identified as a principle failing in the Bristol Royal Infirmary Inquiry. After the recommendations emphasising the importance of the substance rather than the form of consent, the GMC re-issued its earlier 1998 guidance with respect to consent with a new title "Consent guidance: patients and doctors making decisions together." Alongside this, the full range of measures has been implemented including training, protocols and reliance upon ethics committees. Importantly, the GMC have also been prepared to take regulatory action against individuals in connection with this issue. In AvMA's view, these actions together have brought about a change in the attitude of doctors to these issues.

240. Evidence submitted by AvMA following a Freedom of Information Act request showed that according to the Trust's records only one referral was made to the NMC and two to the GMC in the period 1 April 2005 – 17 June 2009 (exhibit PW/1, AVMA0001000228). Niall Dickson, Chief Executive of the GMC, confirmed that 14 doctors came to its attention prior to the HCC report being issued, although of the 17 complaints, 10 were made by patients and only three were made by the Trust (WS0000048792, paragraph 173). Given the extent of seriously unprofessional and uncaring treatment at the trust, AvMA find such low levels of referrals astonishing.

241. It is accepted that referrals need to be considered on a case-by-case basis, but again, a reluctance to report may have been a consequence of the lack of clarity within the Trust as to individual responsibility. Karen Jennings commented on her experience that it was difficult to raise complaints with the NMC without very clear evidence (WS0000004454, paragraph 14) and Helen Moss highlighted the difficulty which was posed by extricating organisational failures from individual failures when considering whether to report a nurse to the NMC for failing to report a SUI (LiveNote 28.03.11, 107).

242. AvMA were also worried by the apparent absence of any action with respect to the failings of clinical professionals to report concerns about other health professionals in compliance with their professional duties. Subsequently, in the Health Committee's July 2011 reports of the annual accountability hearings with the GMC and NMC, both confirmed that a number of doctors and nurses

were under investigation in connection with their work at the Trust "purely for failure to raise concerns" about other registrants. (Health Committee "Annual accountability hearing with the Nurses and Midwifery Council: Seventh Report of Session 2010 – 12," 19 July 2011, paragraphs 18 and 19 and "Annual accountability hearing with the General Medical Council: Eighth Report of Session 2010 – 12," 19 July 2011, paragraphs 43 and 44). Whilst AvMA agree with the Health Committee that the professional duty on doctors and nurses to report concerns about fellow health professionals, and about patient safety generally is important to uphold, it is also mindful how difficult it can be for an individual. This is why its recommendations about supporting and protecting whistleblowers are so vital.

Gaps in Regualtion of staff: Healthcare Assistants and Clinical Support Workers

243. In its recent report following the accountability hearing with the NMC, the Health Committee endorsed "mandatory statutory regulation of healthcare assistants and support workers" on the grounds of public protection, although noting that the NMC would need to make significant progress with respect to conduct of its core functions before taking on this extra responsibility (Health Committee "Annual accountability hearing with the Nurses and Midwifery Council: Seventh Report of Session 2010 – 12," 19 July 2011, paragraphs 25 and 26).

244. AvMA strongly support these proposals concerning the regulation of Health Care Assistants (HCAs) and Clinical Support Workers (CSW). At the Trust, the same duties would be shared between qualified nurses and HCAs and both were responsible for delivering poor standards of day to day care in terms of feeding, drinking, cleaning, toileting, cleanliness and dignity. There can be no justification for nurses being answerable to an external body responsible for protecting the public and HCAs who fail in providing basic standards of care not being so answerable. AvMA is alarmed that current Government thinking seems to be against introducing such regulation, and hope they can be persuaded otherwise.

245. One clear advantage of regulation would be the introduction of unequivocal standards, which would provide both a template for providing care and a yardstick against which that care could be assessed. It is acknowledged that the standards to which an HCA would need to adhere should take into account the differing level of their training and the more circumscribed nature of their role .

Recommendations:

- AvMA recommends a concerted drive to invest in care of the elderly, with guaranteed minimum nursing levels and investment in the image and status of caring for elderly patients

- Changes to the recruitment selection of trainee nurses and doctors, with more emphasis on motivation, communication skills and caring qualities.

- Training of nurses to be less academic and more focussed on basic nursing and caring skills, with more time spent training on wards

- more standardisation and more emphasis on providing training for all clinical professionals, from HCAs to consultants, with respect to the following areas, with regular refresher training:
  - An individual's personal responsibilities to provide safe care and protect patients from harm within the context of their professional ethics;
  - Communication and openness with patients
  - Care of the elderly given they represent such a high and increasing proportion of patients.

- Introduction of the regulation of HCAs by the NMC as soon as possible. It is recognised that establishing training, qualification and regulation will take time. Therefore, in the interim, it is suggested that a set of standards are agreed for the purposes of ensuring understanding about the essential quality of care being provided;

NHS trust boards

246. The Inquiry has heard repeatedly that the trust board is the "first line of defence" for patients. In the case of the Trust, this line of defence was weak and ineffective. It is clear that the Board only received limited information concerning the day to complaints and incidents, after being filtered through a complex system of audit and governance committees. Without these details, the reports received throughout the relevant period appear to have been dismissed as being unrepresentative of a wider problem. It is apparent from the experience of the Inquiry, that boards can only truly be the "first line of defence" and be held accountable for doing so, if they know exactly what is happening in the organisation. Considerable progress has been made at the Trust since the HCC report, including such simple steps such as "walking the wards" and the hard lessons learnt by Mid Staffordshire should be taken into account by other trust boards nationally.

247. The failings of the board are not for want of guidance and protocols, including the Nolan Principles of Public Life, the 2002 "Code of Conduct for Managers" (CURE00330017715) and the 2003 NHS Appointments Commission's "Governing the NHS: A Guide for NHS Boards" (CURE00330012693). The Bristol Royal Infirmary Inquiry report recommended that managers as healthcare professionals should be subject to the same obligations as other healthcare managers, including being subject to a regulatory body and professional code of practice (HCC0015000235, recommendation 92, 458). Although regulation of NHS managers was rejected, a Code of Conduct for Managers was introduced

as a means of identifying common standards. The Code is incorporated within the employment contracts of senior NHS managers, but the evidence suggests that it has had limited impact in relation to raising standards across the board. It is further limited in its application, only explicitly applying to managers at executive board level and not to non-executive directors and senior managers who do not have place on the board. Nor does it apply to those in NHS Foundation trusts, rendering it useless with regard to huge swathes of the NHS.

248. AvMA note with interest the initial steps taken with respect to regulation of NHS manager by the Advisory Group headed by Ian Dalton. In its report dated February 2010, "Assuring the Quality of Senior NHS Managers" (NPSA0006000001), it is confirmed that this group agreed that the current standards were out of date within the current NHS environment and therefore, should be reviewed and renewed. Importantly, it considered that the new standards should apply across the board to both executive and non-executive directors. To this, AvMA would add that consideration should be given to extending the application of the standards to all senior management positions.

249. AvMA understand that Sir David Nicholson has provided instructions to the CHRE to commence drafting standards for NHS Managers. Further to the Government's command paper "Enabling Excellence: Autonomy and Accountability for Healthcare workers, social workers and social care workers".

250. Further, there was consensus within the Advisory Group that the National Leadership Council should assist with the initiation of an independent system of voluntary professional accreditation, whether as the first prelude to statutory regulation or an end in itself. AvMA support this development as a means of requiring NHS managers to make public commitment to the core values of public service within the NHS, against which their professional conduct can then be assessed. In common with clinical professionals, the actions and behaviour of NHS managers directly affects the health and wellbeing of patients and for this reason alone, AvMA consider that it would be appropriate to hold NHS managers to account through statutory regulation.

251. Another new means of bringing about board accountability to the public is the introduction of Quality Accounts. Sir Bruce Keogh explained that trusts were given free reign with respect to the content of Quality Accounts initially, but having considered the first batch of these produced, "I looked at them, and they looked nice. And then I thought, "Could Mid Staffs have produced a good quality account?" And the answer was "Yes"." He described these as appearing like advertising brochures focussing on particular successful areas within the trust. The response to this was to require trust boards to sign off on each service line in order to force trusts to consider the data available with respect to quality. (LiveNote 20.09.11, 123 – 125). Quality Accounts are potentially a useful tool for accountability and quality improvement, but it is as yet too early to assess their efficacy.

252. There is concern that non-executive element of the Trust Board were reluctant to take responsibility with respect to operational issues. Toni Brisby made it clear in her evidence that even where it was apparent that processes were failing within the Trust, for example with respect to the A&E department, she considered that the Chair and Non-Executive Directors should not get involved in operational issues (LiveNote 03.10.11, 49:10).

Recommendations:

- In terms of individual managers and leaders at all levels, as a minimum compliance with the revised Code of Conduct for NHS Managers should be a requirement of every employment contract, to be reviewed within the context of a robust system of internal supervision and appraisal;

- The revised Code of Conduct for NHS Managers should apply across the whole of the NHS, including executive and non-executive directors, senior managers and partners / practice managers of GP practices. It should apply to both NHS trusts and Foundation Trusts;

- Consideration should be given as to how breaches of the Code should be dealt with. To be consistent with healthcare professionals, managers should both be accountable to their employer but also to a professional body with whom they are registered and who can withdraw their registration.

- All board meetings, whether trusts or Foundation Trusts, should be required to be held in public, (with the exception of legitimately confidential matters such as individual performance issues and disciplinary proceedings). These need to be held at a time when members of the public can attend, and publicised sufficiently so that they are aware of the details, including the way in which they can participate;

Foundation Trusts

253. Overall AvMA see little evidence that the development of NHS Foundation Trusts has provided significant benefits to patients and in fact may have damaged patient safety in the NHS. It is clear to us from evidence seen and heard by the inquiry that Mid Staffordshire took its eye off the ball of patient safety having been distracted by a perceived need to achieve Foundation Trust status.

254. Upon achieving Foundation Trust status, a Council of Governors was established with powers to appoint and remove the Chairman and Non-Executive Directors and approve the appointment of the Chief Executive. They had specific responsibility for "holding the Board of Directors to account in relation to the Trust's performance in accordance with its terms of authorisation" (Mid Staffordshire Trust "Information for Prospective Governors" ES100219581).

255. The evidence of witnesses who served on this council was that the ability of governors to fulfil this role was limited. Rod Hammerton provided the following account:

> *I think it was because of my experience with the hospital and the PPIF that I was asked to join the foundation trust as a public governor. However, in my view the word 'governor' does not really seem appropriate to the role and I now feel frustrated to have been given that title. In reality I was merely a member of the public outside looking into the operations of the board without any real power… I was frustrated from the very start at the impossibility of actually getting anything done as a public governor. If I could have been allowed to take on responsibility or effected change I would have done, but I was generally just lectured at. We just made recommendations and the hospital agreed do things in a certain timescale. We had no power to make them do it* (LiveNote 14.12.10, 114:14).

256. He noted with respect to his attendance to committee meetings in his role as public governor that "there was an overriding feeling that nothing was really being achieved and my presence on the committee was just part of 'going through the motions' as far as the public was concerned" and commented the hospital management kept a tight rein on visits which we made to the hospital as public governors. "We only saw what they wanted us to see" (LiveNote 14.12.10, 115:22).

257. Sandra Barrington was appointed as a staff governor and had a similar experience, stating:

> *I felt very much from the beginning, although I knew what my responsibilities were, I didn't actually know how to carry them out. (LiveNote 17.02.11, 71:17).*

The Chairman and Chief Executive

258. Martin Yeates was appointed as Chief Executive of the Trust in 2005 when it was clear that the quality of care at the Trust was suffering due to a combination of severe financial pressure and a lack of clinical governance systems. The measures he took to deal with these issues were slow to be applied with clinical governance systems only becoming embedded in the Trust after Helen Moss was appointed in 2007 and staffing levels only being adequately reviewed in 2008. In the accounts provided by both Martin Yeates, he maintains that the SHA and PCT provided little support in terms of breaking even and in the circumstances, it was considered that application for Foundation Trust status would assist the Trust in achieving financial stability and improving the quality of services. Instead, this proved to be a breaking point for the Trust given the focus upon financial savings at the cost of service provision. By increasing pressure upon the Trust without also providing adequate support to the Trust leadership, it seemed inevitable that poor decisions would be made.

259. After the publication of the HCC report, both the Chief Executive and the Chair were allowed to resign, leaving patients and families who suffered in the Trust and the public at large questioning whether there ever would be circumstances in which individual NHS leaders would face personal consequences for the failings of their organisations. The problem was defined in the course of David Flory's evidence, in which various competing public interests were identified within the three options open to a trust: (1) suspending and disciplining the Chief Executive, thereby preventing a new person from being appointed, (2) summarily dismissing an individual, thus swiftly cauterising the problem, but precipitating litigation and the potential for substantial pay-outs, or (3) allowing the Chief Executive to resign, allowing the trust to move on with a new manager, but again forfeiting personal accountability . It appears that the last option was seen as the least unattractive option. Stephen Moss confirmed the importance of introducing permanent new leadership given the limited impact that interim Chair and Chief Executive were able to have (LiveNote 16.03.11, 150). As a result, it has taken three years and two inquiries before Martin Yeates himself has provided his own account of what happened.

260. This account provides clear illustration of the relationship between weak Trust boards and lack of stability at leadership level. Nigel Edwards and Ruth Ellis cited research of Hoggett Bowers in their seminar paper which found that just over 50% of NHS Chief Executives and Director of Finance had been in their post for less than two years, whilst just over 10% had been in post for over seven years. In order to establish strong and effective trust boards, AvMA support the work of the National Leadership Council in developing leaders.

Responsibility of the Secretary of State

261. On a broader level, as the first Foundation trust to fail, the Inquiry into Mid Staffordshire has highlighted the confusion surrounding the relationship of "independent" Foundation trusts to the Government. Originally intended to be accountable to the local population and to Parliament, the realities of Mid Staffordshire have made it clear that both bodies have limited remit and the only body with any real powers to take instant action, for example, in removing Chief Executive and the Board, is Monitor.

262. As accepted by David Flory, there will still be instances when the Secretary of State must intervene (LiveNote 15.09.11, 80). In light of the weakness disclosed in the approval process and the continuing development of both Foundation trusts and the role of Monitor, it seems that the Secretary of State's ultimate responsibility for all NHS trusts, whether or not Foundation trusts, should be expressly acknowledged. Andy Burnham confirmed that there was an underestimation of how new Monitor and CQC were at the time, and with time, the relationship between the two bodies would mature.

263. AvMA are pleased that the potential de-authorise of trusts has been provided for within the Health Act 2009.

Recommendation

- Changes to regulations should be made as soon as possible to ensure consistent requirements between foundation and non-foundation trusts with regard to meeting in public, reporting complaints information

Part Five: Commissioning, performance management and regulation

264. The evidence heard by the Inquiry has confirmed that whilst strong trusts may be able to cope with financial pressure and the imposition of targets, these simply make matters worse for trusts which are struggling.

> *"It gets easier to do things that regulators want as the organisation becomes more successful, success leads onto success. If you're an unsuccessful Trust with a financial problem that you focus on that and your eye goes off the ball on other things. But if you are a financial sound Trust and you've got your staffing levels about right then it's fairly easy and you can absorb new requirements. However, if you have something flagged in your Trust the whole world comes down on you which is a big distraction." (Seminar paper "Balancing external requirements and a positive internal culture" by Nigel Edwards and Ruth Lewis, interview transcript 2).*

> *"Financial pressures are a focus of the Board, but we are a stable successful organisation and so can absorb a lot more challenges than most." (Seminar paper "Balancing external requirements and a positive internal culture" by Nigel Edwards and Ruth Lewis, interview transcript 5).*

265. Two separate issues arise; firstly, how can the system of commissioning respond to trusts which are facing day to day difficulties in their finances, leadership and organisational culture in a way that reduces the risk of failings occurring and secondly, how can regulatory systems respond to these trusts in a way to both reassure the public there is a safety net in place whilst enabling services to be improved rather than undermined.

Commissioning and performance management

266. During the relevant period, commissioners were in a state of development and were focussed on achievement of financial and national targets to the exclusion of considering quality (see evidence of Griffiths – LiveNote 29.03.11, 28-29). The SHA acknowledged that it had a similar focus (evidence of Morrey, LiveNote 27.03.11, 6). From the perspective of the Trust, there was no support at the time available from either the PCT or the SHA with respect to the persistent problems being faced (Statement of Yeates, WS0000074921).

267. The negative effect of the commissioning arrangements appears to have been experienced elsewhere in the NHS:

"We had a disastrous PCT, they didn't seem to be pursuing world class commissioning to make services better, and they just wanted to cut costs. For example, the PCT in our area played us off against other organisations and didn't have a structured approach to improving service delivery. During one process of trying to improve our successful Stroke Service, we approached the PCT to obtain funding for another consultant. They blocked the services development, and this had a significant impact on where the Trust was going and affected a whole range of other services. Their focus was on cutting costs and would not engage in discussions about improving services." (Seminar paper "Balancing external requirements and a positive internal culture" by Nigel Edwards and Ruth Lewis, interview transcript 2).

268. The failures of PCTs to deliver quality services has been widely recognised and therefore, given the reliance upon commissioning within the NHS reforms to deliver efficient and effective healthcare services, this is an area which demands very careful consideration in the future. In particular, consideration has been given to the ways in which commissioners have and will incentivise the provision of good quality care, through both financial sanctions for poor care, for example, "never events" and bonus payment for good care.

269. It is clear that commissioners can and should receive considerable data concerning their providers, and will be engaged on a regular basis with acute trusts with respect to both finances and provision of services. They therefore should be able to identify problems ahead of any regulator and must therefore, work closely with regulators in sharing information and agreeing on priorities with respect to areas of risk. One suggestion would be for CQC and commissioners, along with HealthWatch, to have regular meetings to consider "early warnings" with respect to relevant trusts.

The role of systems regulation

270. The regulator must work alongside the commissioners in order to ensure that basic standards are being met, recognising that in terms of identifying and remedying risk, the CQC cannot supplant a robust and effective board or the potential for the day to day contact between commissioner and provider to identify problems. It is also recognised that once a regulator identifies problems, it has limited means available to assist the trust in solving these problems.

"In the end how effective is this in ensuring your local hospital is a safe and well-run organisation, no amount of regulation will get at that. What matters most is the quality of Board leadership and leadership in the wider organisation, that's a cultural thing. Ultimately external focus is intermittent… The machinery isn't there to support a failing Trust, but to manage external reputations. At the time when I was in a failing Trust the whole focus of the system was on financial turnaround, and most people externally were interested in the

backwash effect to them… External regulation has a value but will not guard against failure." (Seminar paper "Balancing external requirements and a positive internal culture" by Nigel Edwards and Ruth Lewis, interview transcript 8).

271. Whilst steps are being taken to improve services through commissioning and performance management, AvMA are concerned that sufficient emphasis is given to the important role of regulation. It is apparent that whilst the levers in place to improve services will be effective in enhancing services or improving processes within an already successful organisation, these same mechanisms may have a damaging effect on organisations struggling. It is important that the robust regulation takes place, especially during the anticipated period of transition, in order to provide reassurance to the public that basic standards continue to be met. In particular, regulators must remain alert to all indicators of poor care rather than relying upon information provided by trusts. They must also be resourced sufficiently to ensure that action is taken before it becomes necessary to consider closing down services.

272. Regulatory burden is a very real concern for many organisations, given the recognition throughout the system that resources should be not be diverted to compliance at the cost of providing front line services. However, this is not a reason to expect less from organisation but rather, to ensure that the monitoring system is co-ordinated in order to ensure that information is provided once and used many times. Antony Sumara commented very forcefully upon the regulatory attention the Trust was receiving, which was frustrating as "each is asking for similar sort of information in a slightly different format." (LiveNote 16.03.11, 98:13).

Provision of assistance and support

273. It is clear that during the relevant period, the Trust lacked any real support from any external body, as described by John Newsham:

"Q. Mr Newsham, we're all trying to get an understanding of how things really work. You're being told that you have to cut your budget. You're being told there's a cost improvement plan of 10 million, et cetera. Part of that is not filling vacant posts. Part of it is reducing posts. But if there comes a point where the squeeze is so hard that you feel, as a trust, you can't deliver appropriate patient care, what are your alternatives? What can you do?

A. We could do that. The answer was -- was no. We got no extra support.

Q. So what do you have to do? Do you just carry on?

A. We have to do the best we can with the resources we've got. We have to redirect resources. And we have to, as was highlighted here, go through improvement programmes." (LiveNote 23.03.11, 156:1)

274. At the time, the PCT and SHA were primarily concerned with finances and compliance with targets and the HCC precluded itself from this role by reason of the investigation carried out. It is clear that there is a need within the system for provision of external expert assistance to trusts which are struggling but at present, it remains unclear where this responsibility lies. Common sense suggests the essential element of preventing another failing like Mid Staffordshire is to ensure that there is support available to assist in immediate resolving problems before failings become entrenched and difficult to remedy. This runs counter to the current trend of enabling trusts to develop independently of central government yet it must be acknowledged that different trusts are at very different stages of development.

275. When asked whether he felt that a regulatory organisation should provide assistance to troubled organisations, Stephen Moss stated:

> *"A. Yeah. Yeah. I have a lot of sympathy with that view. To some extent that was the model that the Commission for Health Improvement worked to, where the inevitable action plan following a review would be something that the Commission for Health Improvement facilitated the development of. So they could actually put in a challenge at that stage to the development of any action that results from the publication of the report. Now, I found that on the receiving end, from being in my own trust, as well as being a member of CHI to be a particularly helpful process, because, in other words, you're not walking away as a regulator from a message that's quite a hard message that you're delivering. What's you're saying is "This is where we feel you've failed but in our view - but we will work with you to produce whatever action you need to take to make things better". (LiveNote 16.03.11, 160:27)*

276. However, the focus of the CQC in discharging its statutory requirement to "perform its functions for the general purpose of encouraging the improvement of health and social care services" under section 3 Health and Social Care Act 2008 is on bringing about systemic improvement through its regulatory activities rather than providing particular assistance to individual trusts. As stated by Baroness Young:

> *We were both there to look at poor quality care and help -- make sure that that improved and didn't recur, but also to draw a general lessons from other standards of care across the country, to encourage the -- the adoption of good practice, right across the system, and to highlight issues where generally the system was either doing rather well or doing rather badly, so that we could really prioritise our work on areas where there were clearly problems that weren't just germane to one particular trust or provider but - but could well be also*

needing to be tackled in other places. So we - we - we didn't see ourselves and I indeed was very clear that we shouldn't be the care failure commission, we were the Care Quality Commission, and we were about promoting good practice as well as stamping out poor practice (LiveNote, 04.07.11, 4:6).

277. Meanwhile, Sir Bruce Keogh confirmed that the clinical governance support team within the DOH, which had provided support for struggling organisations, was abolished in 2008 at a time it was believed that clinical governance was understood and had been "widely taken up through the service." He believed that the NHS Institute for Innovation and Improvement offers a very similar supportive service. (LiveNote, 20.09.11, 93-94)

278. It is also noted that in the National Quality Board's (NQB) report on Early Warning Systems in February 2011, it is noted that in the event of failure, the responsibility for securing rapid improvements in the quality of care at the failing organisation rests with Monitor in the case of Foundation trusts. (SHA0017000205, 49).

Recommendations:

- A specific NHS body should be charged with the responsibility for providing advice and assistance to trust boards which consider that they are unable to provide service which meets the CQC essential standards of safety and quality within the finances they have available. It is recognised that this service should be separated from the regulatory function of the CQC;

- Commissioners should meanwhile be focussed upon both building in "levers" for quality within commission arrangements as well as providing expert advice with respect to using resources efficiently whilst maintaining safe services.

The status of Foundation Trusts and the role of Monitor

279. The Inquiry has heard extensive evidence with respect to the weaknesses in the authorisation process for Foundation trusts. Although corporate governance was carefully considered, clinical governance was not and the only measures of quality which were considered were compliance with targets, which it is acknowledged do not reflect standards of care within the organisation (see for example evidence of Mike Gill, LiveNote 14.03.11, 15). There was complete lack of communication with between the HCC and Monitor (see for example evidence of David Hill, 24.05.11, 194). Further, the lack of co-ordination between the SHA, DOH and Monitor created the real risk that each relied upon the others' assessment rather than acting as a check in the process. This is an area where those involved in the three stage authorisation process took immediate steps to remedy the deficiencies in

the authorisation process, a similar process was applied with respect to the 87 other trusts who had been authorised prior to Mid Staffordshire. Therefore, there is very real concern that the autonomy associated with being a Foundation trust has not necessarily been warranted in every case given the weak mechanisms.

280. Accordingly, AvMA believes that there needs to be some honesty within the system, and with the public, about the implications of becoming a Foundation trust. Authorisation is given on the basis that well governed, financially robust and legally constituted. It is essential that any notion that this signifies some kind of "gold standard" in quality of care or patient safety must be dispelled. In recognition that Foundation trusts are simply a means by which trusts can be financially independent, it is important to ensure that the framework for regulating quality must be consistently applied to all trusts across the NHS.

281. With respect to mechanisms to measure and encourage high quality care, there must be consistency in application between NHS trusts and Foundation trusts. This is not proving to the case to date. The DOH, PHSO and CQC were working together to improve learning from complaints information, leading to a joint statement being signed in March 2011 by regulators and the NHS, along with the PHSO and DOH, to "strengthen the use of complaints data, better enabling benchmarking across organisations, making it easier to identify poor performers" (WS0000056086, paragraph 67). Meanwhile, at present, submission of basic KO41 information is voluntary for Foundation trusts, with 1 in 7 choosing not do to so in 2010 – 2011 (statement of Bostock, WS0000056086, paragraph 62).

282. Further, despite having public membership, Foundation Trust boards are not required to meet in public. There can be no justification for this within a system concerned to ensure transparency and accountability at every level.

283. Further, careful consideration needs to be given to ensuring that there are clearly understood regulatory procedures between CQC and Monitor which follow identification of problems with quality of care. At present, the situation is unclear. As stated in the NQB report "Review of early warning systems in the NHS" published February 2010:

> *Governance of clinical quality and patient safety are included as one of the seven elements of Monitor Compliance Framework. Specifically, boards of NHS foundation trusts are asked to certify that they have and will keep in place effective arrangements to monitor and improve the quality of healthcare provided to patients; and that they are currently, and have sufficient plans in place to continue to be registered with the CQC […]*
>
> *Where Monitor sees evidence of material service underperformance, or wider governance or*

financial problems, it will act swiftly to identify the underlying cause and ensure that action is taken effectively and promptly. If Monitor is concerned that a trust is not taking appropriate action to address significant concerns, it can use its formal powers to safeguard patients […] Monitor looks to the CQC for advice in respect to NHS foundation trusts compliance with registration requirements (SHA0017000205, 44 - 45).

284. The position is not made very much clearer in Monitor's own Compliance Framework in which it is stated:

> *In the case of an NHS foundation trust failing to meet these standards, the Care Quality Commission will liaise with Monitor, and taking account of their respective powers, Monitor and the Care Quality Commission will work together to ensure these requirements are met (MON00030000267, 4)*

285. It is unknown whether the CQC take a different approach to monitoring Foundation Trusts on the basis that Monitor have responsibility for overseeing that Foundation Trusts comply with authorisation.

286. It is understood that proposed NHS reform will lead to Monitor being developed as an economic regulator, to complement CQC as the quality regulator (DOH "Liberating the NHS: Regulating healthcare providers: A consultation on proposals", 9). AvMA emphasise the importance of clear delineation between the ongoing responsibilities of Monitor and CQC concerning the quality of services. For the sake of consistency and in order to ensure that clinical quality is assessed by those with appropriate expertise, AvMA believe that this area should rest solely with the CQC. At present, there continues to be the risk that responsibilities overlap between Monitor and CQC, and history has shown that this can lead to neither body taking responsibility. Again, care needs to be taken to ensure that a clear and coherent message is provided to the public concerning the role of Monitor.

Part Six: The future of public and patient involvement

The significance of patient and public involvement

287. "Patient and public involvement" (PPI) refers to the structures and systems which enable both service users and members of the community to provide oversight of the healthcare services and to provide their views and a system which is able to listen and respond. Although various specific bodies have been established over the years enabling PPI, it consists of many and various measures, both formal and informal, internal to and independent to trusts. For example, it includes involving patients in key decision making concerning their care and importantly, the processes which follow "when things go wrong" in their care and as set out by Sir Liam Donaldson, ensuring that patients are represented within decision making structures concerning service provision, design and improvement (LiveNote, 19.09.11, 167 – 168). The following section deals solely with the development of PPI bodies, as separate entities within the NHS, and the proposed establishment of HealthWatch.

288. PPI organisations are vital - effective public and patient oversight and involvement in Mid Staffordshire might have meant that the failings within the Trust would have been identified and acted upon despite the gaps in the system of commissioners, performance managers and regulators at the time. Malcolm Alexander describes the hole left by CHCs in the local community:

> *The absence of an effective local body to monitor services from a patients point of view, walking through wards and clinics, talking to patients, carers and staff, watching, smelling hearing and producing reports and recommendations of their finding, and following these through to see service improvement, was in my view a disaster for patient and public involvement in the NHS. Similarly the absence of a high street PPI body meant that LINKs and Patients Forums were invisible to the public. Julie Bailey has symbolically addressed this issue by making her café into a "one stop shop" for people with complaints about the NHS (WS0000077913, paragraph 19)*

289. Establishing a strong and effective HealthWatch should be considered an absolute priority within the context of impending NHS reforms. AvMA is greatly concerned that the Government's current proposals for HealthWatch are deeply flawed and fail to draw on the lessons from the past. AvMA hope that the Inquiry will make significant recommendations about this which will help change the Government's mind. In order to do so, it is imperative that the Inquiry carefully considers the strengths and weaknesses of the three different forms of PPI organisation in existence in the last decade. Although PPI within the NHS over the last decade has been undermined by poor central support, a lack of resources and frequent structural change, there are many clear lessons for the future development of PPI.

The strengths, weaknesses and abolition of Community Health Councils

290. Peter Walsh, Chief Executive of AvMA, served as Chief Officer of the local CHC for Croydon from 1994 – 2001 and thereafter as National Director of the Association of Community health Councils from 2001 until 2002. In his experience, CHCs were strong and effective bodies well designed to fulfil their role. Described as "one stop shops," patients and the public could to attend for a range of reasons, including:

- Advice about patient's rights within the NHS
- Help with making complaints to the relevant bodies within the NHS
- Raising general issues of concern for CHC to follow up in its monitoring role.

291. By being accessible and available, CHCs were well equipped to be able to fulfil their role monitoring local services and raising issues identified with the trust concerned or the relevant authorities. The CHCs were independent to the local NHS, enabling them to raise concerns identified. They were also part of a national body, which was able to provide overview of the work of individual CHCs and press for change nationally. Importantly, CHCs had their own paid staff, who were able to provide structure and support for the CHC's members within the context of the national CHC movement. Ken Lownds referred to the strength of the CHC being that the members "really got to know and respect and trust those people over many years." (LiveNote 08.12.10, 94:2). CHCs had a presence on the local high street and were widely known about and understood. Finally, having been in place from 1974 – 2003, CHCs were a "stable and consistent platform." (Professor Newdick EXP0000000129, 1).

292. CHCs were abolished in 2004 as a result of controversial plans announced within the 2001 NHS Plan. The actual reasons for abolition have been subject to fierce debate ever since but some suspect that the CHC's had become a "watchdog with too much bite." Little rationale was provided for the reform, although the Government at the time maintained that the reform would strengthen rather than weaken the patient voice (statement of Peter Walsh, AVMA0001000005, paragraph 31 – 34).

293. Whereas most evidence has pointed to the relative strength of CHCs, criticisms that have been levelled at CHCs are that they were un-representative, under-resourced and "ineffective." No evidence has been provided to substantiate this view and this does not tally with the accounts given by witnesses to the Inquiry:

294. David Kidney MP was asked whether the current view of CHCs was coloured by nostalgia and commented on the strength of those running the CHCs and the robust action taken, including media coverage:

A. What did I think was good about our CHC? I think they were -- the people there were savvy, in terms of the subjects that they investigated were the ones that mattered, that they seemed to investigate quite thoroughly and robustly and independently of managers, and they published reports which sometimes were quite strong, and because they were savvy on the subjects they investigated, they attracted media attention too. So they got more coverage, and therefore more attention.

Q. You talk about people being savvy, that's all to do with the quality of the person you have on the committee, isn't it?

A. Sometimes it does come down to the quality of the people in organisations, yes (LiveNote 03.02.11, 171:7)

295. Philip Jones, member of Stafford Borough Council and representative of the Trust's Board of Governors, commented in his statement that Community Health Councils were "very good," commenting that it published reports and became a "embarrassment to the government." (WS0000001783, paragraph 39).

296. At paragraph 47 of his statement, Andy Burnham MP acknowledged that:

> *"The abolition of Community Health Councils ("CHCs") was not the Government's finest moment, and we did not have the greatest degree of support for this change. This was not due to a lack of will, as the Government wanted, and believed, in public involvement. However it seems that we failed to come up with something to replace CHCs that did the job well." (WS0000063400, 47)*

297. No explanation has been provided with respect to the failure to ensure that the strengths of CHCs were carried through to the next incarnation of PPI. Although section 16 of National Health Service Reform and Health Care Professions Act 2002 specified that Patient Forum for the local PCT had the function of providing independent complaints advocacy services as part of a local 'one stop shop', the PPI system was implemented in a very different way, with the functions of ICAS being contracted to different organisations. Further, although section 20(2)(d) of the 2002 Act envisaged the CPPIH providing staff to Patient Forums, "hosting" arrangements were developed. This set the new system of PPI up to fail in the way that it seems to have done in its various guises in respect to the Trust.

Patient & Public Involvement Forums and Local Involvement Networks

298. The overwhelming concern with respect to the function of PPIFs was that they were insufficiently robust to properly scrutinise their local trusts. This is perhaps best summed up by Terry Deighton with respect to whether he considered the body to be independent:

"No, there was reluctance to make any statement to the press anyway, because it was thought that the hospital was doing a grand job and they didn't want to aggravate the sort of problems that they may have – it was very woolly […] I don't think they were particularly interested in what was going on at the hospital, other than to go along and have a cup of tea with the various members." (LiveNote 01.12.10, 91:12).

299. This concern was shared by others who had been involved in the local PPIF, including Wendy Wintle, who resigned after one meeting after it was unwilling to address real issues of patient safety, such as MRSA (LiveNote 13.12.10, 4–5). Professor Newdick indicated that this was not an isolated problem, commenting "There was a concern, I think, that they might have been simply too close to the institutions in which they were located, and perhaps lost a sense of objectivity of ability to represent patients properly (LiveNote 16.11.10, 154:12).

300. The reasons for the lack of effectiveness were explained by lack of expertise and lack of information. Robin Bastin commented upon the ability of individuals within PPIF to undertake the job of "going into a hospital and giving a valid opinion at the end of the day how that hospital is doing" (LiveNote 02.12.10, 30-31). Further, he specifically addressed the lost opportunity to PPIF due to inability to consider complaints information:

"A. Well, it wasn't really rocket science in the sense that to improve the hospital you need to pay very careful attention to complaints, for the simple reason that you are dealing here with the symptom rather than the cause of what is going wrong. So I was very anxious to ensure that one moved back from simply logging complaints to ensure that the cause of those complaints were dealt with as far as possible on a once-and-for-all basis, and I thought that the PPI should take a really prominent part in looking at whether or not this process was functioning." (Livenote 02.12.10, 80:15)

301. He also commented that the PPIF "the PPI forum wasn't concerned at all with what PALS was getting up to…" (LiveNote 02.12.10, 85:23) and during his involvement with LINks, noted "As far as I know, ICAS wasn't one of the organisations that was involved in any shape or form with LINk (LiveNote 06.12.10, 111:3)

302. The inherent weakness of hosting arrangements were demonstrated by the operation of LINKs in Stafford, which replaced PPIF. The local authority commissioned hosting arrangements from Stafford University who had little experience in this complex area (see evidence of Wendy Wintle, LiveNote 13.12.10, 1 – 13) Linda Seru was provided little handover and no guidance. She effectively commenced her role with "blank sheets of paper" (LiveNote 11.1.11, 0). By this time, funding for

national body had been withdrawn, leaving both the host and the LINks members without any guidance or support.

303. Immediate concern arose with respect to constitution and structure of LINKs. The body had no clear sense of purpose or direction and without structural support, individual members pulled in different directions to each other and importantly, to the host. Robin Bastin expressed his particular concern that the agenda was being set by the host:

> *"A. Yes, but I would repeat what I said a little while ago that the whole purpose of LINk was that the ordinary people of Staffordshire should decide what LINk did and how it operated, and here we have the host deciding that for us." (LiveNote 02.10.11, 171:3)*

304. The nature of this relationship was evidently unclear, which was not assisted by the fact that the host were benefiting financially from the arrangements. Matthew Snowden confirmed that the University was provided with £70,000 from the £300,000 budget *"for renting office premises, the staff, a small amount for training, provision of computer equipment, those kinds of things" (LiveNote,* 10.01.11, 106:17) In addition, the way that the council decided to keep back resources for itself has ominous implications for the Government's proposals that HealthWatch and ICAS funding will be determined by local authorities.

305. With respect to both PPIF and LINKs, there was also a widespread lack of clarity with respect to the role of PPIF and LINKs in the community, undermining its ability to attract volunteers with range of backgrounds, expertise and experience. Chris Welch, PPI Forum Administrator, also commented upon the expectations placed upon voluntary members:

> *"I can't see how a voluntary model where it's voluntary-led will ever be as focused as a professional paid organisation. I mean, it is - it is a fact of life that volunteers have got a whole lot of priorities in their lives and, you know, they don't wake -- most volunteers don't wake up everything morning thinking "I've got to go and do that today for that particular objective". Whereas generally speaking, hopefully, most paid staff do wake up every morning and say "I've got that job to do, I'm going to go and do it". So there is a real distinction there between voluntary labour -- I'm not just talking about LINks, I'm talking about voluntary labour generally and professional labour, and to - you know, you've got to be very careful when you start to put the responsibilities of paid professional staff on to voluntary workers, voluntary people. That may be a rather controversial thing to say, and it's my own - I must stress, it is my own opinion, having worked in the private sector for 30 years and having worked in the voluntary sector for six years."* (Livenote 13.12.10, 197:14).

306. Further, although meetings were in public, they were rarely attended by the public – partly because they were held in the early afternoon or evening (LiveNote 01.12.10, 176). Robin Bastin further commented upon the lack of community representation and involvement:

> *Well, you come back to the basic fact, don't you, that the main users of hospitals are the elderly and the frail? And young people, very often working people, have no experience of hospitals. They have busy lives and they're not able to get to the meetings, which are often at difficult times. So the support from the general public for such organisations tends to be fairly limited (Livenote 02.12.10, 24:6.*

307. This lack of clarity extended to the local community in Stafford. Julie Bailey confirmed that until she had been in contact with Terry Deighton and Robin Bastin, she did not know about PPIF / LINKs (LiveNote 22.11.10 129:18). Terry Deighton and Robin Basin did not know about the organisation until someone suggested that they join (LiveNote 01.12.10 and 02.12.10, 22).

308. Throughout this period of transition, it is also clear that there was ineffective handover from one body to the next, (evidence of Ken Lownds, LiveNote 08.12.10, 92, Rod Hammerton 14.12.10, 113) with Matthew Snowden describing that the lack of gradual evolution as being “disastrous” (LiveNote 10.01.11, 83).

309. Again, LINks in Stafford was not necessarily an isolated example of failure. Malcolm Alexander commented:

> *"I have mentioned above Ben Bradshaw’s comment that he thought the poor performance of the LINk in Stafford was exceptional. I do not think this particular LINk was exceptional. My view is that there are many LINKs in the country which would not have performed better. To be clear, some LINks do perform extremely well and I would be proud to be part of them. However, many seem to be in the formation stage even now. Much of the blame for this must rest with the government for establishing a new model of PPI in 2008 without properly consulting and listening to the lay people who would be running LINks, and imposing an organisational model that was often unworkable." (WS0005000021, paragraph 82)*

Applying lessons from the past

310. HealthWatch has been presented as an essential part of the new system, placed between local authorities, CCGS, local providers and the CQC. At present, the detailed proposals with respect to HealthWatch are still emerging, with a five page briefing paper having been produced by the DOH near the conclusion of the Inquiry (DH00000004590) and the provisions for HealthWatch in the Health

& Social Care Bill being the subject of debate in Parliament. A recurrent theme in the evidence to the Inquiry and again at the seminar on 'patient experience' is that a stronger voice for local patients might have raised the alarm earlier about problems experienced at the Trust and have supported individual patients and the community better. Also, that to be effective, the new system of PPI / HealthWatch needs to incorporate some of the best aspects of CHCs, their role as an independent local 'one stop shop' and 'patients watchdog', whilst also moving with the times. AvMA concurs with that general view and offers the following recommendations:

Consistency

311. Ironically, one of the few valid criticisms of CHCs had been that there was a degree of inconsistency between them. However, the proposed arrangements for HealthWatch would seem to guarantee huge inconsistency, because local authorities will be responsible for determining the funding levels and choice of provider of local HealthWatch. AvMA recommends that:

- Local HealthWatch organisations' budgets are ring fenced and calculated using a consistent formula
- Like CHCs, HealthWatch organisations are established in each area with the same constitution and status rather than leaving it to the 'market' to throw up suitable tenders for local authorities to choose from

312. AvMA has already outlined its concerns with respect to the provision of ICAS by independent providers in. The same concerns apply with respect to the provision of local HealthWatch organisations by local authorities. Although the details are not clear, DOH HealthWatch Transition Plan makes it clear that local authorities will commission local HealthWatch "with freedom to decide how to do this." Annex A to the paper sets out examples of organisations forms and structures including Community Interest Companies, Industrial and Provident Societies, Companies Limited by Guarantee and Charitable status (DOH HealthWatch Transition Plan, March 2011, 15)

313. The evidence with respect to PPIF and LINks in Stafford has clearly shown the link between the standards and effectiveness of a PPI organisation and the individual "host." As noted by Robin Bastin:

> *Q. Let me just ask you a couple of things arising from what you've just said. Do you have doubts about the capacity of the local authority to run such an organisation?*
> *A. Grave doubts.*
> *Q. Is that because of the experience that you've had with the lack of control of LINk?*
> *A. Yes, definitely. (LiveNote 06.12.10, 104:15)*

314. Matthew Snowden commented that he considered that HealthWatch needed to be constituted in a

similar way throughout the country, although taking into account different ideas, priorities and problems (LiveNote 10.01.11, 86–87).

315. It is intended that HealthWatch England will "provide leadership, support and advice to local HealthWatch organisations, reducing variation across the country." Further clarification is needed in this respect, given the emphasis upon local bodies developing local solutions. If local HealthWatch are created as individual and unconnected bodies, linked only to local authorities, the role of HealthWatch England in providing national leadership will be vital. Clear guidance must be provided to local bodies in order to create a strong and consistent national network of local HealthWatch bodies.

Cohesive

316. The importance of providing local PPI organisations with its own paid staff has been highlighted above. By doing so, it is possible to develop a body of knowledge and experience to enable members to discharge their functions effectively and for the staff themselves to be part of a vibrant movement – not just 'hired help' in the form of 'host organisation' staff as we have seen the arrangements in Stafford were. The benefits of developing an organisation with its own trained staff are clearly set out by Malcolm Alexander:

> *In order to work effectively a public involvement organisation needs a cadre of staff across the country who understand how the health and social care sectors operate, understand how to monitor hospitals and social care services, knows how to influence change and be unafraid to publish the findings and blow the whistle when necessary. (WS0005000021, paragraph 99)*

317. AvMA recommends:

- Local HealthWatch are allocated their own staff rather than the arrangements for hosting organisation contracts being repeated.
- Either National HealthWatch or the CQC (if National HealthWatch is to be part of CQC) could hold the contracts of employment for the staff and deal with payroll and other human resource functions (similar to the arrangement for CHCS and what should have happened with CPPIH and PPI Forums)

Real and demonstrable independence

- National HealthWatch should be independent of CQC, as CQC is one of the bodies which National HealthWatch will want to monitor and potentially criticise. At the very least, more rigorous

arrangements for protecting its independence within CQC need to be developed

- Local HealthWatch organisation's independence should be protected by the funding not coming from local authorities or at least being strictly ringfenced and guaranteed if channelled through local authorities. National HealthWatch could be a suitable conduit for funding.

318. At present, it is intended for HealthWatch England is to be established as a committee of the CQC. The DOH have also confirmed that given the importance of independence, and the varying understanding of what this means, this "is an area for further work and this is being taken forward now." AvMA shares the concern of Malcolm Alexander and agrees with the proposed solution:

> *"I am concerned that this will mean that HealthWatch England will not be sufficiently independent, and there is also a danger that being part of the CQC will make it too far removed from the local communities, calling into question its ability to effectively be informed about performance of the local healthcare sector. It is possible that this hurdle may be overcome if the members of HealthWatch England are elected from the Local* HealthWatch. " (WS0005000021, paragraph 96)

319. With respect to local HealthWatch, AvMA suggest that local authorities should not be the funders of local HealthWatch. There is a clear conflict of interest to if local HealthWatch are responsible for scrutinising social care services provided by the same body upon which it relies for funding.

320. It has been clarified that it is the intention that funding for local HealthWatch will be made available to local authorities through the "formula grant which is a non-ring fenced grant," as with LINks currently. It is intended that local authorities will be held accountable for the effectiveness of their local HealthWatch through "their local community, through their health and wellbeing board and their overview and scrutiny function." (DH00000004590, 3). However, at the same time that the responsibilities of local authorities are being extended, funding has decreased and is likely to decrease further. Given the reliance which is being placed upon HealthWatch within the NHS reform AvMA consider it is essential for adequate funding be ring fenced. Malcolm Alexander commented

> *"In my opinion this funding structure is very damaging as the money that will be provided to the local authorities and earmarked for HealthWatch will inevitably be affected by the budget constraints being faced by local authorities leading to a funding gap. The funding arrangement could also be the source of tensions in relations between the local authority and Local HealthWatch and could easily sour relationships between the two bodies which ought to work together."* (WS0005000021, paragraphs 94-95)

> *"In addition I wish to states that since 2008, the removal of ring fencing from funding for*

LINks has had a catastrophic effect on public involvement in health and social care. Some LINks have had a budget cut of up to 75%." (WS0000077913, paragraph 23)

"One stop shop"

321. HealthWatch should be given the responsibility for providing ICAS.

322. In the foreword to the "HealthWatch Transition Plan," Lord Howe, Parliamentary Under Secretary for Quality, states:

> *"Our plans for HealthWatch will provide people with a single point of contact. They can put people in touch with the right advocacy organisations, or help them find information about the choices they have; they can support people to speak out and they can give those who want to get more involved the opportunity to do so."*

323. However, as outlined above, the current intention is for complaints advocacy to be provided through one of three means; by HealthWatch, by third party provider or through HealthWatch by a third party provider. By doing so, this undermines the principle of HealthWatch being the single port of call for patients and the public with concerns and the clear benefits of CHCs in this regard will not be realised in any consistent way.

324. One of the benefits of having a local one stop shop is that information indicative of things going wrong in the local NHS can seamlessly be passed on to HealthWatch for it to use its monitoring and intervention powers, rather than having tortuous arrangement s for sharing information.

325. Should ICAS remain outside the local HealthWatch, careful co-ordination will be required to ensure firstly, the two bodies provide consistent message to public and patients. Secondly, both will be recipients of vital information from patients and the public with respect to day to day concerns in relation to service provision. This information would need to be consolidated to ensure that it provides a comprehensive picture to HealthWatch and the other relevant monitoring bodies.

326. Since 2003, PPI has been subject to repeated trial and error. AvMA emphasise the importance of committing sufficient resource and expertise to ensuring the success of HealthWatch from the start. As stated by Professor Newdick, the challenge is "to give it some time to put some roots down and become responsive." (LiveNote 16.11.10, 182:7).

Part Seven: Dealing with the aftermath to incidents

327. AvMA are concerned to ensure that the lessons learnt through this Inquiry include how the system should respond to such incidents in the future. Although AvMA hope that such events will never be repeated, given the ongoing concerns of poor care within the NHS highlighted in recent reports, the wisest approach in future must be to hope for the best but plan for the worst. The response must include providing immediate support and advice to patients and their families as well as providing reassurance that failings would be scrutinised and those involved would be required to account for their actions. By responding quickly to failings, it should be possible to enable the trusts in this difficult position to focus on the process of improving services and re-building trust with patients and the wider community. This was clearly not the experience in Mid Staffordshire, where the Trust remains under intense scrutiny to this day after substantial delays in undertaking a full inquiry into the failings.

Responding to patients and their families affected by the failings

328. On publication of the HCC report in March 2009, the Secretary of State for Health, Alan Johnson, immediately announced that an Independent Case Note Review (ICNR) would be established, through which any patient or family who considered that they had been affected by poor care at the Trust could have their case notes reviewed by an independent team of clinicians. This project was unprecedented. It seems apparent that those responsible did not appreciate the challenges it involved from the outset but rather, the process developed in response to problems as they arose. Whilst the initiative was clearly well intended, it has become clear through the Inquiry that no contingency plans existed for how a large scale problem within the NHS like this should be handled.

329. An immediate concern related to the independence of the ICNR given it was originally announced that the Trust itself would provide the review. Given the obvious conflict this presented in terms of the criticisms of the Trust and the pressing need for the Trust to focus its resources and attention on improving its services, this was clearly inappropriate. Initial steps undertaken by the Trust reinforced this concern. Dr Laker, the lead clinician appointed to undertake the ICNR, commented upon the perception of his independence being compromised after being appointed by the new Chairman of the Trust, rather than the SHA or PCT (WS0000002471, paragraph 5). Further, in the early stages of the review process, Dr Laker had to intervene when he discovered that reports were being provided to the Trust prior to the being shared with the patients and families (LiveNote 14.02.11, 27).

330. Responsibility for the ICNR was only handed over to the PCT in August / September 2009. This was a significant improvement. Even still, although one step removed from the Trust, there continued to be concern with respect to the PCT's involvement given their own role in the failings at the Trust (see

David Kidney MP LiveNote, 03.02.11, 163:19).

331. When the Trust considered the plans for ICNR in April 2009, there is no mention in the relevant board paper of providing independent advice and assistance to families through the process (other than counselling for bereaved families) (Laker Exhibit ML/1, WS0000002471, 29). Having written number of letters, Helen Moss only confirmed to AvMA on 21 July 2009 that she would include information within letters being sent to patients concerning ICAS and AvMA being available as sources of advice and support through the process. Even still, Julie Bailey confirmed that nobody she had spoken to was aware that they could seek the assistance of an "independent advocate" and therefore, Cure the NHS distributed the contact details for AvMA amongst the group itself (LiveNote 23.11.10, 109). Although the PCT recognised the need to arrange independent advice and support, this was unfortunately so late in the process many families were denied this opportunity.

332. In these circumstances, AvMA were surprised that their offer to both the DOH and Trust both to provide input into the planning for the review and support for patients and their families was not taken up (AVMA0001000005, paragraph 62). In light of its unique experience and expertise of dealing with patients with similar experiences to those in Mid Staffordshire, it may have been possible to avoid some of the difficulties and consequences encountered. Having suffered appalling standards of care and treatment at the Trust, followed by the failures of the wider system to adequately acknowledge and address these failings, this should have been the first priority. David Kidney MP, who had a role in "funnelling" patients into the review process confirmed that those involved should have had independent support available (LiveNote 03.02.11, 163:8). In particular, AvMA believe that since case note reviews will inevitably involve consideration of medical or clinical issues, patients and families will be better able to identify concerns and frame questions to be answered with expert assistance.

333. The experience of some patients who provided evidence underlines the importance of support and advice. Although some appeared satisfied with the report provided, others indicated that the reports provided were inaccurate or missing key information (statement of Patient Relative C WS0000000797, paragraphs 24, 28 and Patricia Meadon WS0000001407, paragraphs 30-32) or in some cases, delayed (statement of Janet Robinson WS0000000041, paragraph 60) or never received (statement of Patient Relative B WS0002000163, paragraph 35, 41 – 45).

334. In addition to the concerns above, it appears that the process of undertaking the reviews was poorly thought through from the initial stages and inadequately resourced. Dr Laker described delays caused by contacting, and agreeing contracts, with further independent nurses and clinicians after the number of reviews continued to increase from an original pool of 60 to 217 in total. In his report concerning the process in August 2009, he noted:

"This document clearly indicates that these individuals had not been appointed and that there had been little done prior to this point regarding putting systems in place and appointing appropriate individuals to ensure that the processes ran smoothly." (WS0000002471, paragraph 101).

335. He also commented that there had been inadequate resource available and in some cases, "expediency was prioritised over thoroughness," referring to some review reports as "appalling." (WS0000002471, 23 – 28). A review of this nature will always be a resource intensive exercise and therefore, realistic financial accommodation should be allowed at the off-set. However, through both being prepared before the event and undertaking a realistic planning exercise, and taking up advice and help from organisations such as AvMA with relevant expertise, many of the costs associated with delay, both financial and personal, may have been avoided.

336. The NQB addressed this issue to some extent in its report "Review of early warning systems in the NHS" produced in February 2010 (SHA0017000205, 49 - 50) in which it stated that when failings happened, as they inevitably would given that no system is 100% failsafe, the system must be able to respond in a co-ordinated and aligned way in order to safeguard patients, ensure continued provision of services to the population and secure rapid improvements in the quality of care at the failing organisations. Given there was no existing mechanism in place to ensure that the management and regulatory responses were aligned, it recommended that SHA, alongside the independent regulators, takes responsibility for "providing clear leadership and ongoing co-ordination and pace of action." This is only part of the answer and in any case SHAs are to be abolished. Below we make some practical recommendations about how the system could better react when there is a large scale failure.

Recommendations:

- A contingency plan is developed by agreement between the DOH, NHS bodies, independent regulators and relevant patient groups with respect to the process of responding to large scale problems in the NHS, including the division of responsibility and resourcing. This would involve ensuring that patients and their families had immediate access to independent and expert support, advice and representation and a co-ordinated rather than ad hoc approach.

- A careful review of the Mid Staffordshire ICNR process itself is undertaken in order to identify strengths and weaknesses and guidance is prepared for future ICNRs or similar processes

- In a similar way to ensuring that a trust has access to independent clinicians to undertake reviews of

internal investigations, a standing pool of nurses, consultants and other relevant medical staff is established who would be willing and able to undertake reviews within an ICNR, with whom terms of their engagement had already been agreed. This could be the same group of individual clinicians available to undertake investigations, as suggested with respect to complaints in part 1A.

The difficulties in determining whether to hold a public inquiry

337. The decision making process to hold a full public inquiry concerning the wider issues concerning Mid Staffordshire has been long and difficult, and ultimately determined on political rather than practical grounds after a change of Government. Having campaigned with others for a full public inquiry since 2009, it seemed inconceivable to AvMA that there should not be a public inquiry given the seriousness and scale of the failures at Mid Staffordshire. The obvious question which arose for AvMA and the public at large was "if this does not justify a public inquiry, what on earth would have to happen within the NHS to justify one?"

338. AvMA believes that the delay caused by the decisions to commission a series of smaller investigations, with the terms of reference and authors determined by the DOH, has hindered the Trust's ability to move on and damaged public confidence. It has also caused needless extra suffering both to the families and the staff affected by these appalling events and has wasted valuable resources. For the avoidance of any doubt, AvMA is not suggesting that the very first priority should not have been to ensure that patients were being protected at the Trust and the Trust being helped get back on track. Quite the opposite. However it was clear at the outset that retrospective system wide lessons needed to be learnt and that this warranted a public inquiry.

339. The value of the current Inquiry cannot be underestimated. It has enabled proper and public scrutiny of the entire structure of supervision and monitoring surrounding the Trust can account for the failure to identify the problems earlier and more effective. This is both important process for those who suffered the consequences of this failure but also, it is clear that this focus has triggered immediate improvements to practice and procedure within some of the organisations involved . AvMA also remain confident that the Chairman's recommendations will have real and identifiable impact upon the current systems and planned NHS reform provided the Government is prepared to revisit measures it is already putting into legislation, as it says it is.

340. Currently, under section 1 of the Inquiries Act 2005, the relevant Minister has a discretion to hold a statutory public inquiry if (a) particular events have caused, or are capable of causing, public concern, or (b) there is public concern that particular events may have occurred. Given the broad nature of this discretion, the possibility of successful challenging a Minister's decision are slim.

341. The Inquiry has heard evidence with respect to the issues which were considered relevant by those advising the Secretary of State at the time, which demonstrated a clear unwillingness to allow a full systemic review to take place. In a note prepared by David Flory, Director General of Performance and Finance to the Secretary of State/Minister for Health dated 22 June 2009, the reasons not to hold an inquiry included "is arguable unnecessary given that there has already been thorough investigation of both the Trust's failures, and those of the commissioners and performance managers," referring to Dr Colin Thome's 32 page report and Dr Alberti's 21 page report, both published on 29 April 2009, only a short period of time after the HCC report was published. As this Inquiry amply demonstrates, these reports were hardly "thorough". AvMA and others with so much to offer the subject matter being covered by Dr Alberti and Dr Thomé were not even involved. Further, in the same note, he commented "It is likely to be used as an opportunity for opposition parties to make political capital in criticising Government policy." (DH00170000150, 2-3). The potential self interest and party political influence on a Secretary of State's decision whether or not to hold a public inquiry are obvious.

Recommendations:

- To avoid the danger of party politics having too much to do with a decision on whether or not to hold a Public Inquiry, rather than the Secretary of State having sole say on this, alternatives such as the decision resting with the Health Select Committee or Privy Council should be considered;

- AvMA also recommends that consideration is given to how public inquiries like this are run in the future. As well as political self interest, another powerful disincentive for calling a Public Inquiry has been cited as being the cost. It is possible to argue that a Public Inquiry could be made considerably less expensive and quicker if the process was not so reliant on lawyers

- Finally, consideration should be given as to how the findings and recommendations of a public inquiry can be made more effective. We hope that it will not be the case with this inquiry, but there have been inquiries in the past where some of the main the findings and recommendations have been allowed to gather dust on the shelf. Having called for a Public Inquiry concerning the Trust, AvMA note with concern that legislation is currently going through parliament which commits the Government to courses of action in areas on which the Inquiry is likely to be making recommendations;

- Importantly, in view of the changes which will be occurring over the next months and years, AvMA asks that the Chairman seeks an opportunity to review the substance of his concerns identified within his report and the implementation of his recommendations after a fixed period, for example, 12 months.

NHS Reforms / Re-structuring of the NHS

- It is not for AvMA to comment on the best way to manage or structure the NHS but something AvMA is well placed to comment on is the extent to which patient safety is considered in any structural changes both local and national. It is generally accepted that any re-organisation increases risk. AvMA believes it is not unreasonable therefore that any significant reorganisation should be subject to a risk assessment specifically considering the implications for patient safety and that a transition plan ensuring continuity for patient safety and risk management work be produced. The current set of reforms going through parliament, whether good or bad for the NHS in the long term, cannot be said to have been designed with patient safety as a key guiding principle. Rather, patient safety appears to have been an afterthought and in fact is afforded significantly less prominence in the reformed system. We are disappointed, for example, that there will no longer be a NPSA and that its role, such as it continues at all, will apparently be subsumed into the new NHS Commissioning Board with a fraction of the resources currently dedicated to it. The NPSA was not perfect but its pure focus on patient safety was an asset which won admiration from around the world. Further, even if it is accepted that the new system will be as good as or better than the existing one in promoting patient safety, AvMA is gravely concerned about the lack of a robust transition plan. Bodies such as PCTs and SHAs which have been so much the subject of the Inquiry are set to disappear and have already been losing staff at an alarming rate. The NPSA is about to shut up shop in March 2012 but is already barely functioning. Whereas the Health & Social Care Bill is still going though parliament. There is clearly going to be a long period of transition before the new system is fully up and running and there is no proper transition plan for maintaining patient safety in the interim. We hope we are wrong, but the direct period we are entering into seems to be the perfect breeding ground for all that went wrong at the Trust rather than a new era of improved patient safety.

CONCLUSIONS AND RECOMMENDATIONS

There will be people who say that many of the findings and recommendations of this Inquiry are more or less irrelevant because steps have already been taken or are in the process of being taken to address the issues. Some will say that Stafford was a one off special case and the problems seen there are unique to it. On both counts they are wrong. AvMA's experience from around the country and the continuing stream of fresh evidence tells us that the problems can be found, to varying degrees, across the whole country. Some will say that the programme of reforms currently before Parliament will make things better and safer and help avert another scandal like the one at Stafford. AvMA's view is that, based on the evidence that has come before the Inquiry and its own experience and analysis, that is not necessarily the case. In some respects what many consider to be the unnecessary upheaval and even the specific direction of travel of some of the current reforms could make things worse. If the Chairman agrees with even some of the most central of our recommendations, then the Government will need to consider changing track if the learning from this tragedy is really going to inform the future and help avert recurrence.

There will also be those who say that the problems experienced at the Trust can all be rectified by building good leadership within NHS organisations and changing the culture from within. That imposition of monitoring, rules, targets and regulation is at best a distraction and even a hindrance to good leadership and culture change. AvMA agree that there can be no argument about the need to change culture, nurture better leadership, and that what is most important are the qualities of health professionals directly providing care to patients and of local ward and board leadership. However, it would be a huge mistake to think that these things can develop organically in a consistent way that is acceptable in what is still claimed to be a National Health Service. The role of regulation is to set out the framework and context in which the service must operate. To set out what standards and principles must be adhered to. To give direction and purpose to the leadership, professionalism and culture that all agree is crucial. Regulation should also be the safety net that all rely on in the event there are, as inevitably there will be in such a big and diverse service, problems with meeting those standards. In AvMA's view, the failure of the system to recognise what was going wrong at the Trust and to intervene earlier was in part due to an over reliance on local leadership and freedom and a cultural reluctance to regulate or intervene. This was not helped, but in fact made worse, by the political drive to bring in reforms in the shape of Foundation Trusts built around the mantra that more freedom and localism was an end in itself. Patient safety was not the key priority around which those reforms were designed. It is not, in AvMA's opinion, a key priority around which the current reforms were designed either. It should be.

Over simplistic and ideologically driven positions should be resisted. Whilst regulation on its own cannot put all the problems right, it is vitally important. The situation where regulation and intervention is seen as 'politically incorrect' must be avoided. There has to be a balance between avoiding the stifling of local leadership with over regulation, bureaucracy and targets and the undeniable need for a system of regulation that is sensitive enough to see a problem before it becomes a disaster and proactive enough to intervene. There is a danger in

trying to be over sophisticated about this. Some warning signals need to be taken seriously and acted upon in their own right. Unusually high mortality rates are a prime example which have had much attention in the Inquiry. The example of the NPSA's Patient Safety Alerts is a graphic illustration of how a system which sounds good on paper becomes almost meaningless unless there is a robust joined up system of monitoring compliance and intervening where there is not compliance. Commonsense surely dictates that something pretty serious should happen when trusts fail to declare compliance with so-called "required" actions which are designed to save lives and unnecessary harm based on the human tragedy and best efforts of the patient safety system which have led to them. Yet, the Inquiry has heard that this did not happen with Stafford and it does not necessarily happen elsewhere. It is not enough for the CQC to say that non-compliance *might* affect the "Quality and Risk Profile" and that depending on what else feeds into the profile that this *might* trigger some kind of response. The Quality and Risk Profile is a very clever and potentially useful tool. However, if the system cannot respond more appropriately in the face of so obvious a signal that patient safety is not being properly prioritised, then there is a serious problem.

It is over simplistic to label targets as 'bad'. It is only right and proper that any professional or organisation is set targets or objectives. They are an important and useful part of the system, if chosen wisely (with clinical / safety issues trumping anything else) and managed with common sense and wisdom. If a target is not met and there is a credible justification for it, it should not be deemed a failure. Commissioning processes and bodies have a vital role to play also in the monitoring and upholding of quality. They will be even more important in the reformed system. However, there is a danger in over reliance on a commissioning process, however rooted in local clinical knowledge, to uphold quality and safety. There needs to be a clear understanding about the respective roles of commissioners and regulators. There was clearly a disconnect in the case of Stafford. AvMA perceive a continuing and growing confusion about the role of each. This is illustrated by the evidence of some of the witnesses and current debates about how a 'Duty of Candour' with patients can be made real. The Government says that this is an issue best dealt with through the commissioning process. However, any other key standard of principle, which it is considered that every healthcare provider should meet, is contained in the essential standards incorporated in the CQC's Registration Regulations. This both sends a clear signal about how seriously the issue is taken and puts it in a regulatory context where a provider (a) has to demonstrate that it is taking the issue seriously, has appropriate policies and procedures in place and is taking appropriate measures in order to be registered and continue to be registered, and, (b) means that the CQC has the power, set out in statute, to take regulatory action where this is not the case. AvMA believe that the appropriate balance between commissioning and regulation can be struck if regulation is about setting out the fundamental essential standards and principles which underpin good quality, safe care and which need to be adhered to; and, the regulator is equipped to step in and take action where there are breaches. Commissioning is more about monitoring that the standards are being met and feeding information to the regulator and instigating improvement locally where action short of regulatory action is needed. Commissioners inevitably have other issues they need to consider beyond supporting the regulatory function, such as responding to local need and pressures, and value for money. There needs to be more of a connection

between commissioners and CQC so that there is mutual understanding of the respective roles and what needs to be monitored. AvMA are dismayed that something as fundamental as a Duty of Candour could be considered primarily an issue for the commissioning/contracting process as opposed to regulation. If this were the case, a logical conclusion might be that the CQC registration regulations are unnecessary and anything that is currently an essential standard in them could simply be reproduced in standard NHS contracts and Clinical Commissioning Groups could be left to monitor and enforce them. That, AvMA believes, is a highly dangerous prospect. Simplistic and ideologically driven resistance to regulation and over reliance on the power of commissioning and competition should be resisted.

It is well established that insight, openness, transparency and fairness are key components of a patient safety culture. No one has given evidence to the contrary. However the current position within the NHS, as it was within the Trust, is that whilst cover-ups are certainly not condoned they are in effect tolerated. If the opportunity is not taken to make clear that a Duty of Candour - openness and honesty with patients and their families when things go wrong - is as essential a standard as anything else that is set out in statutory CQC regulations and that breaches will not be tolerated, there is little chance of changing that culture. Whilst regulation on its own cannot change culture, regulation is needed to underpin and give priority to the culture change that is required. It would underpin good leadership, training and support which are also needed. Support and protection of health professionals who may need to raise concerns and 'whistleblowers' is an equally important factor that AvMA argue is not being given sufficient priority.

In all of its evidence, conclusions and recommendations AvMA is bringing a patient perspective informed by almost 30 years of directly supporting thousands of people each year affected by medical accidents. The patient, carer and public perspective needs to be strengthened throughout the NHS. There is consensus about that. It is truly scandalous that the voice of patients and their families were not heard or were ignored. AvMA makes a number of recommendations about how to address this. From its position as a national patient charity it has a unique insight into how the different structures / organisations for patient and public involvement have operated over three decades. AvMA believes that whilst Community Health Councils were not perfect they were far more effective than anything that has followed or that is planned. Plans for the new Healthwatch need to be changed so that they incorporate what was best about CHCs whilst addressing where they could be improved. NHS bodies need a 'critical friend' in the form of a local and national 'patients' watchdog' to help them see things from the patient perspective and to provide a 'reality check' and challenge them when needed. Patients and the public need their own easily identifiable local 'one stop shop' to whom they can turn for independent help and advice and rely upon to be their local watchdog and collective voice in the system. That local body needs to bring together the richness of its members and its own staff as part of a strong national movement that can challenge and influence at the national level.

The complaints process in Stafford let people and patient safety down. It continues to be inadequate around the country in spite of a number of attempts at reform. AvMA make a number of recommendations with a

view to making it more robust, particularly by adding independence to the process and by empowering patients or their families in the process.

In its submissions AvMA has discussed the nature of 'professionalism' both in terms of clinical staff and managers and has made a number of recommendations on improving the selection and training as well as regulation of healthcare professionals and managers. From the evidence received by this Inquiry, it seems that something very worrying has happened to the way our healthcare professionals see themselves and their role. One of, if not the most important, things AvMA wants to see come from all of this is a strengthening and embedding of 'caring' and professionalism throughout the professions, as opposed to just the vast majority of them which is the present case. There should be a particular drive to invest in elderly care services and make sure that all elderly patients receive good standards of care – even if that means re-prioritising where money is spent. Caring for elderly patients should be given the status it deserves.

Finally whilst we all hope not to see another system failure of the gravity and scale as we did at Mid Satffordshire, there will from time to time continue to be some serious failings affecting large numbers of patients. In the interests of learning for patient safety and in order to best support people affected by these failures there should be a contingency plan and some resource allocated to allow a consistent and adequate response. Systems for investigating and learning from such incidents should be improved.

We would encourage the Chairman to carefully consider our recommendations and incorporate as many of them as he can into his own.

ANNEX A

AvMA Recommendations

PART ONE: IDENTIFYING AND RESPONDING "WHEN THINGS GO WRONG"

A. The complaints process

PALS

- *PALS should be clearly defined as an internal customer care or 'trouble shooting' service, quite distinct from the formal complaints process. PALS role in formal complaints should be restricted to explaining the procedure and signposting to appropriate staff and sources of independent advice. There should be no suggestion that in order to make a complaint people have to go through PALS first. It should be clearly explained that PALS staff are not independent but a service provided by the Trust itself.*

- *There should be provided clear minimum standards with respect to the provision of PALS (including opening hours, information to be provided to patients) and clear central support and guidance with respect to best way to provide effective PALS, based on the experience throughout the country;*

- *Trusts should ensure that there is understanding throughout the organisation in relation to the importance of role of PALS, in particular understanding by those senior medical staff who may be the first point of contact for PALS staff.*

- *PALS must have clear channels of communication and information sharing agreements with the local HealthWatch. As set out below, AvMA considers that independent complaints advocacy should be provided by local HealthWatch but in the event that it is provided by third party providers, this communication should extend to these bodies in addition to Healthwatch itself.*

- *Patients must be informed of basic information in a clear and consistent manner, including:*
    - *Clarification of the role of PALS as an internal "customer care" service – separate from complaints;*
    - *Information on the availability of independent advice and support with complaints (ICAS and more specialist advice agencies such as AvMA);*
    - *The difference between raising a concern and making a complaint and how to do the latter;*
    - *The system of local complaints resolution within the NHS complaints system, including how to make a complaint and what to expect thereafter;*
    - *Possibility of Parliamentary and Health Service Ombudsman reviewing the complaint, how and*

when to do this and what to expect thereafter;

- *Role of other bodies including CQC and (in the future) Clinical Commissioning Groups*

- *The PALS should be monitored by the relevant commissioning body. The quality of the service lends itself to be simply and easily measured through patient feedback.*

Quality of local investigation and resolution of complaints

- *Patients should be involved throughout the course of the complaint investigation, including the offer of an initial meeting with relevant clinical staff.*

- *Trusts must ensure that there is integrated system for patients to obtain copies of their medical notes, within the required time limit. From the patient perspective, it should not matter whether the request is made to PALS, through the complaints process or the Trust solicitors. All requests, made to any part of the Trust, should be dealt with centrally*

- *Consideration should be given to model person specifications and grading for complaints staff; training and development needs of complaints staff should be addressed*

- *Consideration should be given to the creation of an independent investigation unit either within an existing body (for example, the CQC) if not a new body entirely devoted to investigating cases where death or serious injury has occurred, or where it is determined that internal investigation is not appropriate or possible.*

- *At the very least, there should be a more co-ordinated approach to providing for a more arms' length/independent element in complaints investigations concerning serious injury or death. This could draw on existing examples of good practice (for example in Devon & Cornwall) and guidance be issued to ensure consistency of approach.*

- *A central database of clinical staff with the willingness and ability to conduct investigations of this nature should be developed. (On occasions AvMA has been asked to recommend such people from its existing database of medico-legal experts. This can help ensure that the investigation is as independent as it can be and perceived as such)*

- *Patients making complaints should be informed from the outset of the circumstances in which the local investigation may be conducted by an independent investigator, including what this means in practice ie. whether independent to service, site or trust. This information, which should be set out on the website, and written material provided to complaints, will ensure that expectations are clear*

Second and third tier complaints process

- *Clear guidance should be provided to trusts to encourage them to reconsider an investigation once a response is issued should the patient have concerns with respect to the findings. This should involve clear communication as to the area of dispute and the option of independent review. It should, however, remain the complainant's choice whether it is re-opened by the trust or is taken by the PHSO/independent review body.*

- *Consideration should be given either to returning to a three stage complaints procedure with more access to independent reviews and a link to the regulatory role OR changes in the remit and capacity of the PHSO so that she can take on many more cases for investigation. In the meantime, the PHSO guidance on a "worthwhile outcome" should be redefined to explicitly include:*
    - *Where the trust's conclusions are disputed by the complainant and an investigation by the Ombudsman may arrive at different conclusions;*
    - *Resolving disputes over facts;*
    - *Where the NHS body's investigation or response is inadequate;*
    - *Where there is an unfair refusal to investigate certain issues.*

The role of other bodies in considering complaints

- *The CQC's role in dealing with individuals' concerns about a registered healthcare provider should be clarified and better publicised, including how individuals (or organisations for that matter) can alert the CQC to a possible need for a reactive review of a registered provider;*

- *The HSE's statutory responsibilities with respect to investigating health and safety failings need to be revised to ensure that there is absolute clarity with respect to when they will and will not become involved;*

- *Comprehensive guidance for patients should be issued which covers the respective roles of MPs, the Department of Health, NHS and other public bodies and what each can and should do with complaints or concerns received about health services*

The availability of independent complaints advocacy, support and advice

- *There should be a requirement on trusts to provide consistent, appropriate information about how to access independent advice to potential complainants and in any case where there has been a patient safety incident resulting in harm, a case is notified to the coroner, or a serious untoward incident or other investigation is carried out. It should include information about ICAS and how to access its services. There*

should be no suggestion that potential complainants should have to go through PALS first. Information should also be provided on sources of specialist advice such as AvMA.

- *ICAS services in the future should be provided by local HealthWatch organisations through staff specifically working with HealthWatch for that purpose.*

- *National HealthWatch should set and monitor standards for the service and collect lessons centrally from this work.*

- *Resources should be allocated to local HealthWatch for ICAS provision according to an agreed formula, and not directly from local authorities, the NHS or Department of Health.*

- *As well as the generic ICAS type support with NHS complaints, available through HealthWatch, provision should be made for the more specialist advice referred to above including help with making complaints (referrals) to the GMC and NMC, but also potentially helping members of the public understand clinical, regulatory and medico-legal aspects of their case so as to make informed decisions about which processes to follow. This could include support with inquests into healthcare related deaths. National HealthWatch could be given the role of commissioning such a specialist service from suitably experienced and specialist organisations.*

<u>Trust learning from complaints and other concerns</u>

- *Independent lay representatives from local HealthWatch (and possibly other organisations) should be invited to take part in reviewing complaints within a group within trusts with responsibility for complaints review. The role could include consideration of actual complaints (within protocols covering patient confidentiality etc) but also retrospective review of complaints and consideration of issues arising of them and monitoring of implementation of recommendations.*

- *Annual surveys of all complainants should be conducted by trusts, in conjunction with local HealthWatch and commisioners to elicit feedback on the experience of and satisfaction with the process and outcome*

<u>External monitoring of complaints processes</u>

- *Clear guidance should be provided on who should be monitoring what in terms of complaints handling – not just in terms of process but also content including any worrying trends or serious failings in care – and how to escalate any concerns. Ultimately, the CQC should be informed of and take action about any potential breaches of its standards.*

- *In order to make monitoring possible all trusts (including Foundation trusts) should be required to share data from PALS as well as formal complaints with commissioners and with HealthWatch. This must contain qualitative as well as quantitative information, including results of surveys of complainants.*

- *Representatives of commissioners should also be members of the internal trust groups to monitor complaints and implementation of actions resulting from complaints.*

B. Incident reporting

Failure in Trust processes

- *There should be, at Board level, an individual who is accountable for the accuracy, completeness and appropriate analysis of the information arising from "when things go wrong", including the consistency and co-ordination of investigation processes. The approach described by Professor Elliott in his seminar presentation provides a helpful model.*

- *The existing national guidance on incident reporting and investigation needs to be reviewed and updated. Organisations should be required to follow it and monitored. There needs to be a uniform definition of "incident" for use nationally and locally. In the 2007 Mid Staffordshire adverse incident policy, "incident" is described as an "event," "occurrence" or "omission" (ESI00044757), leading to a risk of uncertainty. In addition, there is a grey area with respect to ongoing failures in care which may have adversely affected the patient but did not result from a single event, for example, failing to monitor fluid intake leading to dehydration, poor hygiene practices leading to infection or failing to take steps necessary to prevent bed sores from developing – the definition of incident needs to be clear whether such failure are to be include (and, if not, how they are to be monitored.*

- *Near-misses are as important to organisational learning as incidents leading to actual harm or death. Therefore, these should be included within local reporting policies.*

External monitoring of incident reporting

- *As well as there being a uniform definition of what should be reported, there should be, adopting Sir Bruce Keogh's view a single portal to "report once and use many times".*

- *It should be mandatory to inform and, where the patient / family wishes, involve the patient/their family in SUI investigations.*

- *The requirement to report incidents causing moderate harm and above to the CQC contained in the CQC*

Registration Regulations should be accompanied by a corresponding requirement to share information with the patient / their family through the 'Being Open' process

- *The template used to report incidents both internally within trusts and to the national system should contain a mandatory field for the reporter to declare whether the 'Being Open' process has been implemented with the patient/family affected (some trusts are currently doing this of their own volition).*

Patient Safety Alerts

- *The forthcoming NHS Commissioning Board should assume responsibility for and prioritise the issuing of further PSAs. It should take on board any lessons about how the current system could be improved such as clarity about what is required by trusts and when they should declare compliance.*

- *It should be clarified what the respective responsibilities of different organisations are for monitoring trusts' compliance with alerts and intervening where there is not compliance. In the new system this will include Clinical Commissioning Groups, NHS Commissioning Board, and the CQC. Whilst priority should be given to chasing up trusts who have declared that they are not compliant, the monitoring system should be developed so that trusts are assessed on their actual compliance with alerts even where they have declared compliance already. This should form part of a rolling programme.*

- *Timely compliance with PSAs should be made an explicit requirement in the CQC registration regulations. This will take away any doubt about their importance and the ability of the CQC to take action about non compliance;*

- *Particular attention should be paid to implementation of patient safety alerts in primary care. Currently PCTs simply pass on alerts to GPs, etc. There needs to be monitoring of implementation and CCGs may not be the appropriate body because they largely comprise of GPs themselves*

- *It should be made a requirement for every NHS body to declare their status with regard to each PSA applicable to them which is past the completion date, in an accessible way on their website, in their Quality Accounts and on a central website such as NHS Choices (see evidence of Sir Bruce Keogh, LiveNote 20.09.11, 159:11). This action on its own should be a powerful incentive for compliance..*

- *Trust boards should discuss status of alerts at each board meeting together with other patient safety items.*

- *The CQC must react to evidence of problems which come to its attention about potential lapses in patient safety when they become aware of it, rather than waiting for enough data to be collected to tip the Quality*

and Risk profile to 'red' and spark a full reactive review. Interventions short of a full reactive review such as seeking explanations / assurances from the trust concerned and liaisng with commissioners should be used.

C. Inquests

- *All coroners should be required to maintain central database of deaths reported, inquests held, verdicts given and Rule 43 reports sent and received;*

- *Trusts should maintain a similar central recording system, to monitor the deaths, verdicts for purposes of identifying concerning patterns or trends and where Rule 43 reports are provided, that there is process by which their dissemination and implementation can be confirmed.*

- *There should be systematic external monitoring of Rule 43 recommendations and to what extent they have been responded to / put into place. This could be part of the patient safety function of the new NHS Commissioning Board. Information regarding trends or failure to respond appropriately should be reported to CQC.*

- *Steps should be taken to ensure support and where necessary representation is made available to families taking part in healthcare related Inquests; consideration should be given to including this in the specification for the specialist advice which it is recommended is commissioned to supplement the generic ICAS service*

- *There should be a Chief Coroner, as provided for in the Coroners and Justice Act 2010, to lead reform of the coronial system and address the inconsistencies of approach of coroners*

D. Risk management and patient safety within the NHS

<u>Risk management within Trusts</u>

- *An executive member of the trust board should be specifically responsible for risk management. This individual's responsibilities would include monitoring and analysing the information available with respect to clinical incidents through the various sources available, including complaints, incident reports, litigation, and reporting to the board on a monthly basis. Following clinical incidents, this individual would also be responsible for ensuring that relevant bodies are notified and the trust inform and involve patients and their families fully and appropriately;*

Responsibility for risk management: the role of the NHSLA and NPSA

- *Assessment of trusts' risk management processes and outcomes should be undertaken in the future by CQC rather than the NHSLA. This added function would need to be appropriately resourced so that trust would be assessed on an annual basis, involving both review of documents and inspection of processes by specially trained inspectors.*

- *The result of this assessment (and the subsequent CNST rating) for each trust should be made publicly available on the trust's website and other appropriate sites eg NHS Choices*

Analysis of NHSLA claims data

- *The NHSLA should analyse all claims received (including unsuccessful /withdrawn claims) for learning points for patient safety, and for trends with respect to individual trusts. This information should be shared with CQC.*

Monitoring of information

- *AvMA support the idea of an executive director being specifically responsible for information systems within a trust, as suggested within the information seminar.*

PART TWO: BEING OPEN WITH PATIENTS

A Duty of Candour

- *The 'Duty of Candour' should be part of the licensing conditions with the CQC as recommended by the Health Committee and others i.e. there should be a specific requirement within the CQC registration regulations*

- *The 'contractual' duty of candour should also be developed alongside the above, as an adjunct to it, not as a substitute*

- *It should be made explicit that anyone working for or acting on behalf of an NHS body, including lawyers, will only be acting in the interests of their client if they practice complete openness and honesty with patients of the NHS body and their relatives*

- *Central guidance on SUIs and other investigations should be revised to make explicit the requirement to be*

open with patients/families from the start and where possible to involve them in investigations;

- *Clarification, backed up by clearly drafted guidance, that "near misses" should be reported to the patient or their family unless there are specific reasons not to. The decision should be made by the treating clinician after consultation with a clinical colleague or manager and both the decision and the reasons for it, should be recorded in the patient's notes*

- *Clarification, backed up by clearly drafted guidance, that patients should be informed with respect to other events which may follow "things going wrong" including:*
    - *Reporting of death to the coroner and with reference to the "cause of death," the process which will follow, including whether an inquest may be held and their involvement;*
    - *Decisions made in connection with disciplinary or regulatory proceedings with respect to individuals involved;*

- *With respect to individual trusts, the requirement to disclose information to patients needs to be backed up with:*
    - *A programme whereby staff are informed of its existence and trained with respect to its contents;*
    - *A process by which the communication with patients is recorded in a central location so that there is a clear audit trail;*
    - *Monitoring to ensure that it is being followed; and*
    - *Measures to enforce compliance where it is not being followed on individual or trust-wide basis.*

- *Clear guidance should be issued by the DoH on the operation of the NHS Complaints procedure to promote good practice and consistency in complaints handling. This should include making clear once and for all that the use of the argument that investigating and responding to a complaint would 'prejudice' the defence of a clinical negligence claim is totally unacceptable and define the very limited and exceptional circumstances where 'prejudice' of another process might be used as a reason for not investigating a complaint.*

<u>Publication of Information</u>

- Every NHS body with a Governing board should be required to hold board meetings in public

- The NHS Commissioning Board should determine that NNS bodies should be required to publish a common set of data in an accessible way on their websites. This data should include:
    - The level of Risk MAngement / CNST Level attained under the NHSLA
    - The status of each Patient Safety Alert past the deadline for completion which is relevant to the NHS body, and an action plan for addressing any outstanding alert

- Mortality rates, where these are available
- Complaints information including outcomes and changes implemented as a result

PART THREE: RASING CONCERNS AND WHISTLEBLOWING

Whistleblowing reform

- *A suitable clause should be introduced to the CQC Registration regulations requiring healthcare providers to take all reasonable steps to support, protect, and listen to whistleblowers (or staff raising concerns). Where the CQC becomes aware of registered organisations acting inappropriately towards staff raising concerns or whistleblowing, they should intervene and take action*

- *New guidance with respect to supporting and taking action on concerns raised by staff should be intorduced. This should include clear and unequivocal guidance with respect to practical measures to be taken by trusts to ensure that staff are fully informed and understand the options available to them and, essentially, are informed of the channels available to access confidential and independent support and advice.*

- *AvMA supports the continuing provision of an independent and confidential support and advice by Public Concern at Work.*

- *clear guidance and training must be provided to individuals representing staff members given the potential for conflicts of interest to arise.*

- *Consideration should be given to establishing a specialist service in the UK similar to the National Whistlblower Centre in the US (http://www.whistleblowers.org/).*

The impact of gagging clauses

- The use of gagging clauses should be robustly prohibited and action taken against employers who seek to introduce them

PART FOUR – PROFESSIONALISM AND PROFESSIONAL RESPONSIBILITY AND ACCOUNTABILITY

- *There should be a concerted drive to invest in care of the elderly, with guaranteed minimum nursing levels and investment in the image and status of caring for elderly patients*

- *Changes to the recruitment selection of trainee nurses and doctors, with more emphasis on motivation,*

communication skills and caring qualities.

- *Training of nurses to be less academic and more focussed on basic nursing and caring skills, with more time spent training on wards*

- *More standardisation and more emphasis on providing training for all clinical professionals, from HCAs to consultants, with respect to the following areas, with regular refresher training:*
    - *An individual's personal responsibilities to provide safe care and protect patients from harm within the context of their professional ethics;*
    - *Communication and openness with patients*
    - *Care of the elderly given they represent such a high and increasing proportion of patients.*

- *Introduction of the regulation of HCAs by the NMC as soon as possible. It is recognised that establishing training, qualification and regulation will take time. Therefore, in the interim, it is suggested that a set of standards are agreed for the purposes of ensuring understanding about the essential quality of care being provided;*

NHS Trust Boards

- *In terms of individual managers and leaders at all levels, as a minimum compliance with the revised Code of Conduct for NHS Managers should be a requirement of every employment contract, to be reviewed within the context of a robust system of internal supervision and appraisal;*

- *The revised Code of Conduct for NHS Managers should apply across the whole of the NHS, including executive and non-executive directors, senior managers and partners / practice managers of GP practices. It should apply to both NHS trusts and Foundation Trusts;*

- *Consideration should be given as to how breaches of the Code should be dealt with. To be consistent with healthcare professionals, managers should both be accountable to their employer but also to a professional body with whom they are registered and who can withdraw their registration.*

- *All board meetings, whether trusts or Foundation Trusts, should be required to be held in public, (with the exception of legitimately confidential matters such as individual performance issues and disciplinary proceedings). These need to be held at a time when members of the public can attend, and publicised sufficiently so that they are aware of the details, including the way in which they can participate;*

Foundation Trusts

- *Changes to regulations should be made as soon as possible to ensure consistent requirements between Foundation and non-foundation trusts with regard to meeting in public and reporting complaints information*

PART FIVE; COMMISSIONING,PERFORMANCE MANAGEMENT AND REGULATION

Provision of assistance and support

- *A specific NHS body should be charged with the responsibility for providing advice and assistance to trust boards which consider that they are unable to provide service which meets the CQC essential standards of safety and quality within the finances they have available. It is recognised that this service should be separated from the regulatory function of the CQC;*

- *Commissioners should meanwhile be focussed upon both building in "levers" for quality within commission arrangements as well as providing expert advice with respect to using resources efficiently whilst maintaining safe services.*

PART SIX: THE FUTURE OF PATIENT AND PUBLIC INVOLVEMENT

Applying the lessons from the past

- The development of PPI must take full account if the principles of consistency, cohesion, real and demonstrable independence and creating a one stop shop. In particular:

- Local Healthwatch organisations should all be established using a consistent model

- Funding for local HealthWatch should be guaranteed and allocated to each Healthwatch body. If funding is provided by local authorities, it should be ring fenced

- Local HealthWatch should be allocated their own staff, (with contracts and human resource functions dealt with by National HealthWatch)

- HealthWatch should should be the designated provider of ICAS

- National HealthWatch should be independent of the CQC . If it is based within CQC, there should be robust safeguards to protect its independence

PART SEVEN: DEALING WITH THE AFTERMATH OF INCIDENTS

- *A contingency plan is developed by agreement between the DOH, NHS bodies, independent regulators and relevant patient groups with respect to the process of responding to large scale problems in the NHS, including the division of responsibility and resourcing. This would involve ensuring that patients and their families had immediate access to independent and expert support, advice and representation and a co-ordinated rather than ad hoc approach.*

- *A careful review of the Mid Staffordshire ICNR process itself is undertaken in order to identify strengths and weaknesses and guidance is prepared for future ICNRs or similar processes*

- *In a similar way to ensuring that a trust has access to independent clinicians to undertake reviews of internal investigations, a standing pool of nurses, consultants and other relevant medical staff is established who would be willing and able to undertake reviews within an ICNR, with whom terms of their engagement had already been agreed.*

<u>Public inquiries</u>

- *To avoid the danger of party politics having too much to do with a decision on whether or not to hold a public inquiry, rather than the Secretary of State having sole say on this, alternatives such as the decision resting with the Health Select Committee or Privy Council should be considered;*

- *Consideration should given to how public inquiries like this are run in the future. As well as political self interest, another powerful disincentive for calling a public inquiry has been cited as being the cost. It is possible to argue that a public inquiry could be made considerably less expensive and quicker if the process was not so reliant on lawyers*

- *Consideration should be given as to how the findings and recommendations of a public inquiry can be made more effective - to avoid the findings and recommendations gathering dust*

- *In view of the changes which will be occurring in the NHS over the next months and years, AvMA asks that the Chairman seeks an opportunity to review the substance of his concerns identified within his report and the implementation of his recommendations after a fixed period, for example, 12 months.*