Monday, 8 November 2010

(10.30 am)

(Proceedings delayed)

(11.50 am)

THE CHAIRMAN: First, might I apologise for the late start today. I hope that this will not be repeated, but there was a procedural matter in relation to one member of the public I've had to deal with, and I hope I have. It took longer than expected.

I am now going to make some opening remarks, following which Mr Kark will make an opening statement.

Opening remarks by THE CHAIRMAN

THE CHAIRMAN: It is a pleasure to be able to open the formal hearings of this inquiry. I appreciate that there are many present who have campaigned for it to take place, and for them too it must be a significant milestone. I am sure they are, as I am, pleased that it has proved possible to hold these hearings in Stafford so that those most closely affected by what has happened in their local hospital can hear the evidence for themselves with a minimum of inconvenience.

I would liked to thank Stafford Borough Council and its officers for their very considerable assistance in making this possible at the cost, it has to be said, of considerable inconvenience to themselves.



We are all here because of the terrible standard of service inflicted on so many of the patients who went to Stafford Hospital for treatment and their families. Last year in my first inquiry I sat and listened to many stories of appalling care. As I did so, the questions that went constantly through my mind were: why did none of the many organisations charged with the supervision and regulation of our hospitals detect that something so serious was going on, and why was nothing done about it? That question was one which many patients and their families and, it is fair to say, healthcare professionals as well wanted to be answered.

While we are not here to reinvestigate what went wrong in Stafford Hospital, I think it is important, as we consider the actions and inactions of various management and organisational structures in what will inevitably be some dry detail, that we keep at the forefront of our minds the terrible effect of the systems failings of those it was meant to serve.

I would like to pay tribute to the determination and courage of those who have campaigned for this inquiry and the helpful way in which they conducted themselves at my first inquiry. The distress that must be provoked by having to revisit such unpleasant experiences and memories cannot be underestimated, particularly when, as



in too many cases, these concerned the loss of a loved one.

The public should be very grateful to all those in this position who contributed to my last inquiry and have offered to come forward again this time. I would like to pay particular tribute to Julie Bailey, without whose tenacity many of the issues which have been exposed would not have seen the light of day. I would like to offer her and her family my particular sympathy today at the opening of this inquiry, which by sad coincidence is the third anniversary of the death of her mother, whose case it was which propelled her into starting her campaign.

I will say a word now about the scope of the inquiry. We know what went wrong in Stafford. The Healthcare Commission report, Professor Alberti, Dr Colin-Thome and my own earlier report disclosed that.

This inquiry is required to build on those findings, not to revisit them. In order to do this, I have to do a number of things. I have to find out and tell the story of what these organisations knew, and what, if any, actions they took. To do this I must ask relevant persons responsible for these organisations to give their account of what happened. I must look at why the system of NHS management and regulations external to the



trust did not detect or act on the deficiencies before the intervention of the Healthcare Commission in 2008/9. There was clearly cause for concern before that action was taken.

I must then identify the lessons to be learnt from the Stafford experience and suggest how they might be applied to the system as it is today, taking account of the changes that have taken place since then and also the reforms that are now being proposed. In order to do this, I will have to consider a large amount of documentary evidence and other material and to take oral evidence from a wide range of witnesses.

I should make it clear that the fact that a person is asked to give oral evidence before me does not mean that I have decided that either they or the organisation in which they worked should be the subject of any criticism, still less that the individuals in question should be blamed in any way for what happened here. They will be invited to give oral evidence, because it is thought that will help the inquiry achieve its purpose.

We will hear details of at least some of the cases of poor care which demonstrated the breakdown of systems at Stafford, as it will be necessary to see the context in which the regulators and others were working. Some

of these stories I will have heard before and indeed I summarised them in my earlier report. However, others may not have heard them. I ask them to bear in mind two things.

Firstly, it is not the role of this inquiry to investigate each complaint and decide whether it is well-founded, although many may be. My job this time is to look at how the system dealt with the complaints and concerns arising out of such experiences and the people who suffered and reported them.

The second point is that such experiences are not necessarily representative of what it is like at Stafford Hospital today under its new management. It is inevitable there will continue to be incidents giving cause for concern, both there and in other hospitals as well.

Such incidents do not of themselves show that there has been no improvement, any more than that the absence of such incidents would prove everything has been put right. It is not part of my task in this inquiry to judge whether the trust has changed and improved since the events I considered at the last inquiry, but I do know it from evidence I heard then that this new management team set about the daunting task of changing the culture and standards with energy and enthusiasm and



I myself have seen examples of good practice there.

How long will this inquiry take? The size of its task is formidable. A large number of organisations and individuals have been approached for information and evidence. My inquiry team has identified over 150 potential people to approach. Even if not all of these are called to give oral evidence, and it is highly unlikely that all will be required to do so, others will emerge as witnesses as their involvement and significance becomes more clear.

We have received what is estimated to be nearly 1 million pages of documentation, much of which has not been subjected to any meaningful analysis by the parties providing it. In short, the task I have been set is truly formidable and complex. Nonetheless, it is I believe a very worthwhile and important task. At a time of change in the National Health Service, it is essential that the lessons to be learnt from the Stafford disaster are incorporated into its governance. That requires the story to be told and those responsible for various parts of the system to explain what their organisations did and to identify where their roles might have been performed better. It then requires an analysis of that evidence so that I can consider what safeguards, monitoring and other measures should be put



in place to provide better assurance that minimum standards of quality and safety of care will be provided to all who seek healthcare.

The terms of reference require me to use my best endeavours to provide the Secretary of State with a report of the inquiry by the end of March next year. Given the huge volume of material the inquiry team will now have to examine, it is clear to me that realistically the hearings and the production of my report cannot be completed by the end of March. Therefore, I have discussed this with the Secretary of State. We have agreed that the importance of my examining the material being made available and the added lessons that are likely to be provided justifies the inquiry taking longer than originally envisaged. It would be wrong and misleading to set a new deadline but it remains important for this inquiry to be concluded as quickly as possible in order to provide assistance in relation to the reforms currently under consideration.

It is clearly in the public interest that I should conduct this inquiry with that requirement in mind and I intend to do. Therefore, I hope to conclude most if all not the formal oral hearings before the middle of next year. It will inevitably take some time after that to complete the analysis of the evidence and produce the



report. However, it is emphatically in the interests of the patient groups, Stafford Hospital and its staff as well as the National Health Service and the public generally that the lessons to be learnt from this inquiry are identified in the shortest possible timescale and I urge all those involved to recall that in the weeks to come.

There are many interested parties represented here today, and I am pleased to see their readiness to participate in this inquiry. No doubt they and the public will understand and accept that these are not proceedings involving adversarial litigation or conclusions about criminal and civil liability. I am not here to try claims made by one party against another. The role of the interested parties is to assist the inquiry to get at the truth of the matter and to assure its effectiveness in fulfilling its terms of reference. They will largely do that by facilitating the production of information and evidential material and by ensuring that counsel to the inquiry is aware of the issues which the parties believe ought to be raised so that he can pursue the relevant lines of inquiry.

Today, we're going to hear the opening statement of Mr Tom Kark QC, counsel to the inquiry. I understand this is likely to last at least into tomorrow, if not

into the day after that. I will then hear opening statements from those core participants who have indicated a wish to make such a statement.

Finally, may I describe some of the general arrangements that will be followed during these hearings.

Sitting times, on Monday we will sit between 10.30 and 5.00. Tuesday to Thursdays 10.00 am to 4.30 pm. We will break for lunch between as near 1 o'clock and 2 o'clock as is practicable, and normally I will take a short 15-minute break at some convenient point in each of the two sessions of the day. Generally, there will be no public hearings on Fridays.

A list of the witnesses to be called in any week will, to the extent this is possible, be published two weeks in advance. A transcript of the day's proceedings will be posted on the inquiry's website as soon as practicable after their conclusion.

I would remind everyone that filming, photography and recording are not permitted in the hearing room or the press room, mobile phones must be switched off in the hearing room and switched to silent in the press and public section.

Can I, please, remind members of the press that they should respect the privacy of members of the public



attending the hearings. Entry to the inquiry premises of both media representatives and the public is solely for the purpose of attending the hearing. Therefore, I must ask the reporters not to approach individuals for interviews or quotes whilst in the inquiry building. If any member of the press or the public has any question about the inquiry, they should not hesitate to contact the secretary to the inquiry, Mr Alan Robson, sitting to my left, or the solicitor to the inquiry, Mr Peter Watkins Jones, he is just behind counsel there. And contact details for them, if you do not wish to approach them personally, or cannot, are available on the inquiry website. That concludes my opening statement, and I now invite Mr Tom Kark to commence his.

Opening statement by MR KARK

MR KARK: Sir, this public inquiry arises out of the events at Mid Staffordshire Hospital Trust between January 2005 and March 2009. As everyone present knows, there has already been one inquiry into those events chaired by you. The purpose of this second and now public inquiry is to focus not on what went wrong, but how it was allowed to go on for so long without appropriate remedial action.

Why did no one act to correct the serious errors that were undoubtedly taking place? Why did the



healthcare system as a whole tolerate what were clearly unacceptable standards of care? Why did those who should have been in the right position to take steps not do so?

There were numerous national and local agencies which might have been thought to carry some responsibility for the lack of care and the failures which are identified in the first inquiry. Despite the existence of national and local agencies concerned with the regulation of the NHS and the delivery of primary, secondary and acute care services, the appalling lack of care was allowed to continue with little effective intervention.

The purpose of this inquiry ultimately is to bring to the attention of the Secretary of State for Health a clear explanation of why the commissioners of healthcare services and the regulators of the trust failed the people of Staffordshire, and how the same sequence of events might be prevented from ever happening again, not only in Staffordshire but in any other part of the United Kingdom.

In commenting upon the role of external organisations you wrote in your first report:

"Local confidence in the trust and the NHS is unlikely to be restored without some form of independent



scrutiny of the actions and inactions of the various (external) organisations to search for an explanation of why the appalling standards of care were not picked up. It is accepted that a public inquiry would be a way of conducting that investigation."

The 16th recommendation of your report was as follows:

"The Department of Health should consider instigating an independent examination of the operation of commissioning supervisory and regulatory bodies in relation to their monitoring role at Stafford Hospital with the objective of learning lessons about how failing hospitals are identified."

In your open letter to the Secretary of State dated 5 February of this year, which introduced your report, you said this:

"The inquiry heard and has reported the many concerns expressed about the role that external agencies play in the oversight of the provision of healthcare. There is undoubtedly further work to be done, not only at the trust but elsewhere before public confidence can be assured."

And further, at page 415 of your report, you concluded that there was a need for an independent examination of the operation of each commissioning,

supervisory and regulatory body with respect to their monitoring function and capacity and identify hospitals failing to provide safe care, in particular:

(1) what the commissioners, supervisory and regulatory bodies did or did not do at Stafford.

(2) the methods of monitoring used, including the efficacy of the benchmarks used, the auditing of information relied upon and whether there is a requirement for a greater emphasis on actual inspection rather than self-reporting.

(3) whether recent changes, including the memorandum of understanding between Monitor and the Care Quality Commission, quality accounts and the registration of trusts by the CQC will improve the process by which failing hospitals are identified.

(4) what improvements are required to local scrutiny and public engagement arrangements; and.

(5) the resourcing and support of foundation trust governors.

On 9 June 2010 Andrew Lansley, the Secretary of State for Health under the current coalition government, wrote to you inviting you to chair a public inquiry and setting out the terms of reference. They are as follows:

(1) to examine the operation of the commissioning,



supervisory and regulatory organisations and other agencies, including the culture and systems of those organisations in relation to their monitoring role at Mid Staffordshire NHS Foundation Trust between January of 2005 and March 2009, and to examine why problems at the trust were not identified sooner and appropriate action taken. This includes, but is not limited to, examining the actions of the Department of Health, the local strategic health authority, the local primary care trust, the independent regulator of the NHS foundation trust, Monitor, the Care Quality Commission, the Health and Safety Executive, local scrutiny and public engagement bodies and the local coroner.

(2) where appropriate to build on the evidence given to the first inquiry and its conclusions, without duplicating the investigation already carried out and to conduct the inquiry in a manner which minimises interference with the Mid Staffordshire NHS Foundation Trust's work in improving its services to patients.

(3) to identify the lessons to be drawn from that examination as to how in the future the NHS and the bodies which regulate it can ensure that failing and potentially failing hospitals or their services are identified as soon as is practicable.

(4) in identifying the relevant lessons to have



regard to the fact that the commissioning, supervisory and regulatory systems differ significantly from those in place previously and the need to consider the situation both then and now.

(5) to make recommendations to the Secretary of State for Health, based on the lessons learnt from the events at Mid Staffordshire and to use best endeavours to issue a report to him by March 2011.

In your opening remarks you have dealt with the timing issue already.

Although this inquiry was requested by the Secretary of State for Health and has been set up under the auspices and funding of the Department of Health, it is totally independent of that department. The process of this inquiry, as with any public inquiry, is your sole responsibility applying the relevant inquiry rules.

The calling of relevant evidence before this inquiry is my responsibility and that of my team. My role is to assist the inquiry, which means assisting you to meet the terms of reference. To that end, I am supported by an experienced team. To my right, my juniors Mr Ben FitzGerald and Ms Jo Hughes. We are also fortunate to have secure the services of Eversheds Solicitors who are acting as solicitors to the inquiry under the leadership of Peter Watkins Jones has who has



already been introduced.

I also introduce the other counsel on behalf of core participants, some of whom are present today.

On behalf of Cure the NHS Mr Matthias Kelly QC is leading Mr Jeremy Hyam, who I understand is present, as is Kate Beattie.

On behalf of AvMa and the Patient Association, Ms Shaheen Rahman appears.

On behalf of the foundation trust, Mr Nick Mullany is here, together with Ms Katie Price.

On behalf of the PCT Rachel Langdale QC and Mr Rob Harland.

On behalf of the West Midlands SHA Ms Sally Smith QC and Mr Christopher Mellor.

On behalf of the Department of Health Mr Tom Richards.

On behalf of Monitor Karon Monaghan QC and Ms Amelia Walker.

On behalf of CQC we have Debra Powell and Ms Eleanor Grey.

On behalf of the HPA Ms Fiona Addison.

On behalf of the NPSA, I don't think she is here, we have Ms Diane Barber, who will be appearing.

And on behalf of the NHSLA Mr Owain Thomas.

The Royal College of Physicians who are core

participants are apparently not attending for a few days and I am afraid we don't know who at the moment represents them.

In leading the inquiry team I have sought to ensure that we will explore every relevant nook and cranny of the health service. We as a team will do our utmost not to leave a pebble unturned which might reveal material of interest and relevance within the terms of reference.

As part of the work done by the inquiry team, we have approached over 170 individuals organisations and agencies, and the inquiry team has written to 114 GP surgeries. We have invited the core participants to make suggestions for the witness list so that we obtain different perspectives and such suggestions as have been submitted have been carefully considered, and that request still holds good.

We have tried hard to think widely, focusing both within the NHS and outside the NHS, and to that end you will also have as assessors to assist you the following individuals.

Professor David Black, a consultant physician in geriatric medicine and Queen Mary's hospital in Sidcup.

Ms Tricia Hart who is the deputy chief executive and director of nursing and patient safety at South Tees Hospital NHS Foundation Trust.



Professor Peter Hutton a consultant anaesthetist at University Hospital Birmingham NHS Foundation Trust and honorary professor at the University of Birmingham.

And Sir Adrian Montague, now chairman of the 3I Group and who previously held the post, among many others, of chairman of British Energy when he would have had a close interest in the safety of the UK's nuclear energy programme.

They will be available to give advice to you as needed and will, we understand, on occasions attend the hearing. We also propose to call expert witnesses both in relation to the structure of the healthcare system and its regulation, as well as from other public bodies responsible for civilian safety.

We do not hope by this inquiry alone to bring about changes which will ensure no repeat of the Stafford debacle. But we can assist you, sir, in coming to conclusions and recommendations which will assist the government to do so, by bringing as much relevant and helpful information as possible before the inquiry from every quarter.

The inquiry team will, we hope, be assisted by representations from the core participants, all of whom have an intricate knowledge of their specific area of interest. That specialisation, which is not one which



the inquiry team can match, will we hope prove to be a valuable assistance to help me and my team formulate appropriate questions for witnesses and identify areas of inquiry.

As you have already remarked, this is an inquiry and not a trial. It is important that we all bear that in mind throughout these proceedings.

Section 2 of the Inquiries Act specifically provides that the inquiry panel is not to rule on and has no power to determine any person's criminal or civil liability. However, the panel is not to be inhibited in the discharge of its functions by any likelihood of liability being inferred from facts that it determines or recommendations that it makes.

We are likely to get better information and cooperation from witnesses who feel inclined to cooperate voluntarily and who do not feel themselves under attack or that they are here simply to be vilified. However, there may be some witnesses who do not volunteer information which they should, either through lack of understanding of the process or -- and we hope this is less likely -- because they are wilfully uncooperative. Equally, there will be witnesses who with the best will in the world unconsciously fail to reveal relevant information which could assist the



inquiry.

My purpose and that of my team is to get as much pertinent information out of witnesses as possible and our examinations of witnesses will be conducted throughout with that purpose well in mind.

Can I say something about what I call the patient voice. This inquiry will not hear from individual patients who were mistreated, nor from their relatives, except insofar as they have relevant evidence to give within the terms of reference. Examining individual cases and giving patients and their relatives the opportunity of revealing their own stories was part of the role of the first inquiry. We will be calling a number of patient relatives to deal specifically with the complaint system and how it worked or failed to work for them.

That is a topic within the terms of reference and an important one to help us discover where mistakes were made and where the fault lines lay. We have also been in touch with a number of patient groups which represents the patient's voice, and we will be calling a number of witnesses from such groups to provide us with their perspective and their assistance, and there is, as you have already mentioned, of course, a specific patient group, Cure the NHS, who have applied for core

participant status and have been granted it and so are here represented and we will come their participation.

No one should think that we do not have the patients who were failed by the trust at the forefront of our minds. We are here by reason of the failures in care of those patients. However, what went wrong at the hospital has already been fully examined and the terms of reference to this inquiry specifically require us to ensure we do not duplicate the work of the first.

We are aware that some contributors of evidence to this inquiry would wish us to examine the issues of how many unnecessary deaths can be attributed to poor or negligent standards of care at the trust. However, such an inquiry would be outside the terms of reference, would itself be very lengthy and would have the effect of diminishing the purpose and effect of this inquiry. We do not, for one moment, ignore the terrible fact that poor care at this hospital led to early and unnecessary deaths. The prime purpose of this inquiry is to do all that we can to prevent that happening again.

The terms of reference specifically require we conduct the inquiry in a manner which minimises interference with the Mid Staffordshire NHS Foundation Trust's work in improving its service to patients. It is important to bear in mind that this inquiry deals



with events at a hospital which is not very far from here, a few miles up the road, and which continues to treat patients. There are hard working, conscientious and competent staff there now, who will not be assisted in their duties of caring for the sick and frail by this inquiry indulging in further extensive criticism of what has happened there previously. We will not shirk from identifying where problems persist, but we must bear in mind that both staff and patient moral is an important factor in ensuring good quality care and treatment and recovery to health, and we have no wish whatever to damage the morale of the hard working nurses and doctors who are striving hard to make things better.

I am going to turn now to the history of the NHS. Before launching ourselves into an examination of the background to the problems at Mid Staffordshire NHS Foundation Trust and why they were not spotted sooner, it is worthwhile spending a little time on the creation of the NHS, its structure through various changes and initiatives, and the effect of the changes wrought by various governments. We all have our own idea as lay people of what the NHS is, but rather like the elephant, actually describing it is harder.

At the inception of the NHS, in 1948, a wholly nationalised system of healthcare funding was created.



Comprehensive care was to be provided free of charge for all on the basis of need funded from taxation.

Secondary care in the NHS was to be provided by a national network of NHS-owned hospitals and community services such as district nursing. Public health services and the ambulance services were also to be publicly provided initially by local authorities, until the 1974 reorganisation, when they were run directly by the NHS itself. However, primary care, i.e. general medical, dental and ophthalmic services and pharmaceutical services were to be provided by independent practitioners acting as independent contractors to the NHS.

The NHS in its initial form planned services that it provided itself, in particular in hospitals and through a national contract, and local committees procured services from independent providers, which were largely cottage industries run by self-employed clinicians who became, particularly in the case of GPs, closely bound in with the NHS.

Before 1980, the only example of a regulator of the NHS was the Health Advisory Service, the HAS, set up in 1969 at the insistence of then Secretary of State for Health, Richard Crossman. The HAS reported directly to the Ministry of Health and its primary role was to



advise and support the health services by spreading good practice and promoting improvement.

While health policy for several decades after 1948 can be characterised as fairly modest adjustments to the original design of the NHS, the need to restrict public expenditure growth from the mid-1970s, led to an increasing focus on how to make the NHS more efficient. Eventually this resulted in the most significant cultural shift since the inception of the NHS with the introduction of the internal market, outlined in the 1989 White Paper Working for Patients and passed into law as the NHS and Community Care Act of 1990.

The then government stated that the reforms would increase the responsiveness of the service to the consumer, foster innovation and challenge the monopolistic influence of hospitals. Proposals were made to make hospitals compete for resources in an internal market and to make doctors more accountable and involve them more effectively in management, and these changes were implemented in 1991. That has been referred to in the past as the purchaser/provider split.

The 1991 market reforms were based on the purchaser/provider split and it was thought that whereas in the past providers, usually hospital doctors, had largely determined what services would be provided now

commissioning bodies would act on behalf of patients to purchase the services which were really needed. Purchasers, health authorities and some family doctors were given budgets to buy healthcare from providers, acute hospitals, community health services, organisations providing care for people with mental health problems.

To become a provider in the internal market health organisations became NHS trusts, separate organisations with their own management. This occurred in stages rather like the foundation trust inception at the present time.

The role of purchasers came to be defined as commissioning. This term has had numerous definitions over the past two decades and continues to be contested, but it is intended to indicate that being a purchaser is, or should be, about much more than simply contracting with and paying providers for supplying healthcare services. The Department of Health in November 2009 described to the Parliamentary Health Select Committee its understanding of the roles of the health service commissioner in the following term:

"To be the advocate for patients and communities -- securing a range of appropriate high quality healthcare services for people in need.



"To be the custodians of taxpayers' money -- this brings a requirement to secure best value in the use of resources."

The department added:

"Commissioners increasingly need to be advocates for health and well-being, encouraging and enabling individuals, families and communities to take greater and shared responsibility for staying healthy and managing their health and conditions. This means understanding better the determinants of health, effective engagement and enablement of people and populations and strengthened partnership working to improve health and well-being. As a result, the role of commissioners has grown from a traditional fairly narrow base of needs assessment and contracting. The challenge is to commissioning capability have risen accordingly."

Under the initial model of purchaser/provider split there were two kinds of purchasers: district health authorities, DHAs, and GP fundholders. DHAs had been created in 1982 to run local services, apart from primary care, which meant that they directly managed local acute hospitals.

As an NHS trusts broke free from the district health authority control, DHAs became purchasers of healthcare services from the trusts. In successive waves of



development from 1991 to 1997, many family doctors were given budgets with which to buy healthcare from NHS trusts and also from the private sector in a scheme called GP fundholding. The scheme was voluntary but each year more and more GPs joined, and by 1997 approximately half of GPs had become fundholders. Those who did not have their own budgets had services purchased for them by health authorities that bought in bulk from NHS trusts. Patients of GP fundholders were often able to obtain treatment more quickly than patients of non-fundholders.

During the 1990s some GP fundholder came together in network, multi-funds or fundholding consortia, and this was to enable smaller practices to participate in fundholding schemes and to create organisations which could pool resources and share financial risks. Non-fundholding GPs also started to work together as GP commissioning groups as a means of gaining influence of health authority's purchasing decisions.

In 1994 the government decided to develop a primary care led NHS, which included the addition of total purchasing pilot schemes, which gave volunteer fundholding practices a delegated budget to purchase all of their hospital and community services.

There were thought to be advantages and



disadvantages of fundholdings in the 1990s. There were accusations that the NHS was operating a two tier system, contrary to the founding principles of the NHS of fair and equal access for all to healthcare. Supporters said fundholding saved money, was more efficient and engaged the GPs in the planning and purchasing of healthcare.

In December of 1997, the Labour government set out a ten-year vision for the English NHS with the White Paper The New NHS Modern Dependable.

The purchaser/provider split was retained and overall responsibility for commissioning health services remained with health authorities, but fundholding was abolished, leading to a search for other ways to give primary care power and influence over the use of money in the hospital sector.

From around 1999, 481 primary care groups, PCGs, were established. Membership of them was compulsory for all GPs and primary care professionals, and PCGs effectively took on the purchaser role.

In 2000, the government announced its intention to bring spending in the NHS up to the EU spending average and launched the NHS plan. Its key reforming principles were a patient focused service, offering patient choice and an expanding independent sector, competitive

providers, giving hospitals and GPs incentives to change, including payment by results, money following the patient and the possibility that organisations might fail.

Active purchasers, including PCTs, who were the successor organisations to PCGs and practice-based commissioning and cost-effectiveness and affordability.

Under the NHS plan all PCGs were to become primary care trusts by April 2004. Shifting the Balance of Power, which was published in 2001, brought forward that date to April of 2002. In addition, the 100 health authorities were to be abolished and 28 new strategic health authorities, SHAs, were created, essentially local offices of the Department of Health. SHAs were to develop a strategic framework, agree annual performance agreements and build capacity and support performance improvement. The number of SHAs was reduced from 28 to ten in 2006. By 2002 the 481 primary care groups were reduced to become 303 PCTs.

After the 2002 budget funding increased. Alan Milburn, the then Secretary of State for Health, published Delivering the NHS Plan, which introduced new important ideas: payment by results, PBRs, a change in the pattern of financial flows in the NHS using a tariff system, paying providers for the work they actually did;



foundation trusts, hospitals established as public interest companies outside Whitehall control; patient choice, where patients would be given information on alternative providers, will be able to switch hospitals to have shorter waits; and primary care trusts freed to purchase care from the most appropriate provider, public, private or voluntary.

Since 2003 the primary care trust, PCT, have been the main local public health commissioning organisation in England. Early criticisms included their increasingly management focused or corporate strategy and culture and a falling away of clinical engagement and support. PCT staff had many differing backgrounds and skills. PCTs had to develop new and commercial commissioning skills, as their decisions were open to challenge, particularly when independent contractors tendered.

These criticisms were attempted to be addressed with the introduction in 2005 of practice-based commissioning, which was designed to reignite clinical enthusiasm and involvement by giving GPs a greater role in commissioning.

While GP fundholding had been abolished in 1997, in 2005 the government introduced practice-based commissioning to give GPs a larger role in



commissioning. Unlike with GP fundholding, which gave GPs the money, PBC gives GPs only indicative budgets to commission services on behalf of their patients while the PCT still does the contracting and pays providers.

Moving to 2005, Labour's election manifesto made a commitment to reduce management costs in the NHS by GBP 250 million. Creating a Patient-Led NHS, which was published in March of 2005, promised to move money from management to front line services and reduce the number of SHAs, PCTs and ambulance trusts. Following the 2005 general election, a further wave of organisational change began.

In 2006, there was a reduction in the number of strategic health authorities from 26 to ten. Their new role was to develop plans for improving health services in their local area, performance managing PCTs, improving the quality of these organisations and ensuring that they met national priorities.

It was decided to reduce the number of PCTs from 303 to 152 in May 2006, as the Department of Health realised that there were insufficient skilled personnel for so many PCTs and in order to reduce costs. New chairmen were appointed and the new PCTs were established from 1 October 2006.

PCTs were central to the running of the NHS, but



concern about their weaknesses remained. To bring about improvement, the government introduced its World Class Commissioning initiative in 2007.

In 2008 Lord Darzi's Next Stage Review established as key objectives promoting health and improving the quality of care. The review announced the introduction of CQUIN, continuous quality improvement network, quality accounts and patient reported outcome measures, or PROMs, as ways of being about improvement in quality.

In terms of regulation, in the late 1990s the Hospital Advisory Service was wound up, and in 1999 the Commission for Health Improvement, CHI, or CHI, was established with the remit of a new NHS Inspectorate. The CHI had four main statutory functions: To undertake a four-year rolling programme of clinical governance reviews of NHS organisations; to investigate serious service failures in the NHS when requested to do so; to monitor progress and the implementation of standards set by the National Institute for Clinical Excellence, or NICE; to provide advice and guidance to the NHS on clinical governance. NICE had been set up to provide national guidance and direction on clinical practice and technology assessment, and in essence it still performs that role.

In 2002, just two years after it had been

established, CHI was merged into a new organisation with remit to cover both the work of the CHI and the NHS and the regulation of private healthcare service to be called the Commission of Healthcare Audit and Inspection, or CHAI. This was to become just a year later, the HCC and it came into being following primary legislation in 2003.

In April 2009 the Healthcare Commission was abolished and replaced in terms of its core functions of healthcare regulation by the body that we have now, which is the CQC, the Care Quality Commission.

The history just related may be thought to reveal that a series of changes, initiatives and drives each aimed to ensure that the funding of the NHS is focused upon the needs of the patient and improve the health of the nation have not universally had that effect. Both those who work within the service and external experts all appear to be in agreement on one issue, and that is that constant change, such as has occurred to the NHS, is detrimental to the service and to the regulation of it.

I turn now to previous inquiries and reports into other trusts and doctors. Since 1969 there have been no less than 40 private and public inquiries and investigations into hospitals, trusts and doctors across



the UK. We have as a team reviewed the conclusions of those reports in an effort to ensure that we do not constantly retread old ground. We have drawn particular assistance from the inquiry into the Bristol Royal Infirmary. Many of the inquiries dealt with discrete issues, in relation to specific clinical matters or specific doctors. Others, however, had national significance, with wider implications than the immediate local problems which had given rise to the inquiry or investigation. It is upon those that we will now, briefly, focus.

Looking at the recommendations of each inquiry, some of them certainly appear to be pertinent to the terms of reference of this inquiry, and indeed mirror many of the issues which were raised in your first inquiry. It is worth spending a moment to review the conclusions of some of those reports and to examine the similarity of the complaints.

In making recommendations to the Secretary of State in due course, it may be of importance to be aware of recurring trends of complaints and recommendations as we will see that there have been.

The first is the Epsom and St Helier investigation, which was in 2001, and that was by way of a clinical governance review by the Commission for Health



Improvement into high death rates and the way in which complaints were handled at the Epsom and St Helier NHS Trust. The key area for action and recommendation were as follows:

(1) action was required to ensure a cohesive approach to information use, and the involvement of clinical staff and the public in determining how information is gathered and used to enhance the patient experience.

(2) urgent action was required to implement a trust-wide untoward incident reporting policy and to ensure that clinical incidents report could be made with the relevant forms easily available.

(3) urgent action was required to install compatible IT systems.

(4) action was needed to ensure a strategic approach to involving both patients and the public in setting the quality agenda and ensuring safe and adequate care for patients.

(5) action was required to develop systems to ensure that complaints were dealt with expeditiously and sensitively, and were shared with staff and used to improve clinical standards.

(6) urgent action was required to ensure that clinical risk management policy was implemented and all



staff understood its principles.

(7) urgent action was needed to ensure that staff felt safe to raise concerns, and to ensure that the staff understood and could apply the whistle-blowing policy and harassment at work policy.

(8) action was required to ensure that patients were involved in the clinical audit process.

(9) action was required to ensure that there was a centrally-based approach to implementing evidence-based care.

(10) action was required to implement NICE guidelines and produce plans for implementing those in clinical care.

One can see immediately the similarity of many of the issues which were uncovered back in 2000 with those that were uncovered at the Mid Staffordshire NHS Foundation Trust in your first report.

The inquiry into Mr Rodney Ledward, the specific details of that inquiry were widely reported and are not essential here. However, the independent confidential inquiry into Mr Rodney Ledward, which reported again in 2000 at the South Kent Hospital NHS Trust, made the following recommendations, which again are pertinent to our considerations here.

(1) each Royal college should identify a minimum

list of untoward nonclinical events which should trigger the filing of an incident report form.

(2) any NHS employee should be required to fill in an incident report form if they are aware of an untoward incident.

(3) the clinical risk manager should be proactive in ensuring that the practice of the filling in and filing of untoward incident reports forms is followed by each department.

(4) absence of an untoward incident form in respect of a complaint should immediately be investigated.

(5) each trust should develop a list of untoward, nonclinical events which should trigger a report.

(6) discussions should take place at directorate meetings in relation to all untoward incidents that have been recorded and practice decided upon to implement change.

(7) time for audit should be allowed in each doctor's contract and all doctors, including consultants, must participate in clinical audit.

(8) each trust must have a clinical head of audit.

(9) the Department of Health should consider ways to audit long-term outcomes following inpatient care.

(10) all complaints should be dealt with by a single department within each trust, the manager of which



should be directly answerable to the chief executive and be a member of the clinical governance committee.

(11) patients must be able to raise complaints whilst they are in a hospital and be given a prompt, full and proper response.

(12) the collection of full accurate data is crucial to good quality care.

(13) a confidential hotline should be set up in every trust which can be used to notify concerns about any member of staff to an appropriate person.

It is perhaps obvious that many of these recommendations made in 2000 were still not being acted upon in 2005, and thereafter at the Mid Staffordshire trust. It would be wrong to assume that the Mid Staffordshire trust was alone in this failing.

The Bristol Royal Infirmary inquiry report in 2001 was an independent investigation into the care of children receiving complex cardiac surgery at the Bristol Royal Infirmary. The inquiry made recommendations in relation to securing high quality care across the NHS. Again, it is surprising perhaps that many of the themes bear a remarkable resemblance to those raised in your first report.

The findings in relation to failings at Bristol could be summarised in this way:



(1) there was no agreed means of assessing quality of care.

(2) there were no standards for evaluation of performance.

(3) there was confusion as to who was responsible for monitoring care.

(4) there were concerns raised at the hospital but not taken seriously by staff.

(5) there was a lack of openness at the trust.

(6) there was a lack of candour towards patients.

(7) there was no traditional culture that the trust board should be involved.

(8) there was no external system for monitoring the quality of care. The supra regional services advisory group thought the Royal colleges were doing it and vice versa.

(9) the Department of Health national database, the hospital episodes statistic database was not recognised as a valuable tool for analysing performance.

(10) there was no mechanism of surveillance to ensure that patterns of poor performance were recognised and addressed.

(11) clinical negligence litigation may act as a barrier to openness. That is a specific issue upon which we will be inviting comment from experts in this



hearing.

The recommendations that were made, which may be thought to be particularly pertinent to this inquiry, were as follows:

(1) that doctors, nurses and managers must work together as healthcare professionals with comparable terms of employment and clear lines of accountability. That was attempted to be brought in by the Code of Conduct for NHS Managers in 2002.

(2) there must be agreed and published standards of clinical care for healthcare professionals to follow so that patients and public know what to expect. There should be a single coherent and coordinated standard, now the work of NICE, National Service Frameworks, NPSA Never Events guidelines in 2008 and the NHS constitution are in place.

(3) hospitals which do not meet set standards should not be able to operate within the NHS.

(4) there must be effective systems to monitor standards of clinical performance. Well, now, again there are the national clinical assessment service, part of NPSA, Monitor and now the CQC, and the use of Dr Foster data.

(5) the system of inspections of trusts and PCTs should be replaced in with a system of validation and

revalidation under the auspices of a single body. Well, now, of course, we have the CQC and Monitor for foundation trusts.

(6) clinical audit should be compulsory for all healthcare professionals and should be at the core of a system of local monitoring and performance. Now one of the core standards of the CQC healthcare check but still not mandatory is a requirement for a clinical negligence scheme for trusts.

(7) a single system of data collection should be adopted from which information about both clinical and administrative performance can be derived. There is now the annual healthcare check and the NHS league tables.

(8) the hospital episode database should be supported as a major national resource, which can be used reliably. This was hoped to be actioned by the setting up of the NHS Information Centre in 2005.

(9) quality of healthcare would be enhanced by greater respect and honesty between healthcare professionals and patients. The CQC Registration Regulations have a duty to report incidents, but in fact there's no statutory duty to inform patients. Similarly, GMC Good Practice Guidelines require honesty between healthcare professionals and a duty to confess immediately when something has gone wrong to the



patient.

There should be a clear, one-stop shop in every trust for addressing concerns of patients about the care provided and the conduct of healthcare professionals; the Commission for Patient and Public Involvement in Health created in 2006 but abolished in 2008, and Patient and Public Information Forums, created in 2006 and then PALS, and Links from 2007.

(11) trust boards must be able to lead healthcare at the local level.

(12) there should be an independent and overarching body. The Council for Quality of Healthcare to coordinate the activity of NICE and the Commission for Health Improvement which should report To the Department of Health and to Parliament.

(13) there should be an overarching mechanism to coordinate the regulatory bodies, such as the GMC and the NMC, the Council for the Regulation of Healthcare Professionals and, of course, the creation of the Council for Healthcare Professionals and then the Council for Healthcare Regulatory Excellence had been brought into effect.

(14) a culture of safety requires the creation of an open, free and nonpunitive environment, in which healthcare professionals can feel safe to report adverse



events and near misses. Confidential reporting should be provided for and a failure to report should attract disciplinary action. Again, there's the work of the NPSA and CQC regulations making it a requirement to report adverse events.

The National Patient Safety Agency should bring together interested parties to tackle persistent causes of unsafe practices. There is now the National Clinical Assessment Authority within the NPSA.

The NPSA should be responsible for publishing regular reports on patterns of sentinel events and remedial action, the NPSA, of course, publishes safety alerts.

(17) NICE should set standards of clinical care and draw on the expertise on the Royal colleges. It does, but we query the extent to which it draws on the experience of the Royal colleges and we will hearing from the Royal colleges about that.

(18) data must be collected as the by-product of clinical care and there should be a single, unified accessible system for reporting and analysing sentinel events, which should be managed by the patient safety agency.

(19) Staff should have immunity from disciplinary action by an employer or regulator if they report an



event within 48 hours. Well, already in existence in fact was the Public Interest Disclosure Act 1998, which was supposed to protect whistle-blowers, but again during the course of this inquiry we will have to see how effective that is.

(20) failing to report such an event should be a disciplinary offence.

(21) the public voice should be embedded into all organisations concerned with quality of performance rather than be represented on the outside, and the widest public voice should be encouraged. We will be hearing about patient and public information forums, PALS, Links and also, of course, the oversight and scrutiny committees.

(22) there should be an NHS appointments commission responsible for the appointment of nonexecutive directors of NHS trusts, health authorities and PCTs. This was acted upon by way of the setting up of the Appointments Commission, which is about to be abolished.

(23) nonexecutive directors should be provided with training and support to ensure that they play an effective role.

And this comment in the Bristol inquiry was also made of general application to our work here, and it is a comment upon public inquiries:

"A public inquiry [they said] should seek to restore public confidence by carrying out a full, fair and fearless investigation into the relevant events. Second, a public inquiry should identify the lessons to be learned. A public inquiry should attempt to promote understanding of what went on and what led to certain events. The public inquiry should offer a form of public catharsis and not be adversarial in nature. The approach should be inquisitorial and non-adversarial."

Those comments we have taken firmly on board.

In relation to the Bristol report, there were fundamental and structural changes made within the NHS, which were broadly in line with many of the recommendations, central to which was the setting up of the Commission for Health Improvement and the various patient forums in their various forms. Those additions to the spectrum changed the landscape of regulation, and we must bear in mind that many of those organisations were relatively new at the time of the events at Stafford which we are now considering.

Can I turn to Lord Darzi of Denham High Quality Care For All report of 2008. In 2008 an important review was published with input from clinical leads from ten strategic health authorities, which in fact included Professor Cooke from the West Midlands, Professor



Lakhani and Dr McLean from the East Midlands. There were also contributions from some 2,000 other clinicians and other health professionals.

Again, without going into great detail, we think it would be helpful to provide a summary of the conclusions and recommendations of that report such as are pertinent to this inquiry.

The report recognised that despite good intentions there were significant variations in the quality of care provided across the NHS. While the NHS needs to be flexible to respond to the needs of local communities, people needed to be confident that standards were high across the board. This meant tackling the variations and giving the patients greater information and choice.

The comments and recommendations included: patients repeatedly expressed the view that they wanted greater control and influence over their healthcare.

The new NHS constitution was to include the right to choose both treatments and providers and to have access to information on quality so that patients could make informed choices.

The service should continuously seek improvements in safety and reductions in healthcare associated infections.

NICE should be expanded to set and approve more



independent quality standards, and the new National Quality Board would offer transparent advice to ministers.

Information about the quality of care will be systematically measured and published, and that information should include patients' views on the success of their treatment and the quality of their experience.

There should be clear measures of safety and clinical outcomes.

All registered healthcare providers working for the NHS will be required to publish what were called quality accounts, just as they publish financial accounts.

Funding for hospitals that treat NHS patients should reflect the quality of care that patients receive.

Drawing on the experience of healthcare in the United States, the NPSA should work with stakeholders, draw up a list of never events and payment should be withheld should they occur.

PCTs should challenge providers to provide high quality care and there should be a stronger clinical engagement in commissioning.

Each strategic health authority should appoint a medical director to be responsible for overseeing implementation of the local clinical provisions and



providing leadership to all NHS organisations in the area. They will have professional accountability to the Department of Health.

The CQC should have a stronger focus on compliance and more flexible enforcement powers.

It was noted -- and this perhaps is a reflection of a comment that I made earlier -- that there was amongst staff in the NHS an element of change fatigue. Staff were fed up with upheaval when the change was driven top down.

The core of the recommendations, so far as that report is concerned, is the achievement of universal minimum standards strengthened by the setting of independent quality standards by NICE. The extent to which that aspiration has been met, or has at least been tackled by the Department, will have to be considered here.

I am about to turn to the issue of previous inquiries into Mid Staffs NHS Trust and I wonder, given it is 1 o'clock, if that would be a convenient moment.

THE CHAIRMAN: I think that is. We will resume at 2. Thank you very much, Mr Kark.

(1.00 pm)

(The short adjournment)

(2.00 pm)

THE CHAIRMAN: Good afternoon, everybody. Do we have a technical problem? (Pause).

Mr Kark, I think you can start. They have at least one machine working on their desk.

MR KARK: Thank you, sir.

Sir, prior to your first inquiry there had, of course, been a prior series of other investigations and report into what had gone wrong at the trust. Those were taken into account within report 1, and I do not need to go into those in any detail now. Nevertheless, some of the recommendations, which had a wider remit than merely local, may be pertinent to our function here and ought to be recognised as such. Again, the learning from those reports is of some use and should not been thought to have been ignored.

I start with the Commission for Health Improvement.

In 2002, the Commission for Health Improvement, the precursor to the Healthcare Commission, carried out a clinical governance review of the trust. Its report, published in December of that year, advised the key issues to be addressed: resolving problems with a high number of emergency admissions, patients needed to be put into appropriate wards with fewer transfers of patients between wards, the low number of nurses was a cause for concern, the trust needed to improve



provision for the privacy and dignity of its patients, the trust was advised to adopt an open and learning culture.

The report also found that the quality of clinical data was poor. Almost all of these criticisms and recommendations were to find themselves reflected as criticisms in the subsequent report by the HCC seven years later and by the subsequent reports.

In 2004/2005 the trust was awarded one star by the Healthcare Commission in its annual performance star ratings.

In 2005 to 2006, the trust was rated as fair in relation both to quality of services and use of resources.

In 2006/2007 the trust was rated as fair in terms of quality of service, and good in relation to the use of resources.

In that same review, core standards were said to be fully met. The trust was rated as good against existing standards but weak against the new national target score.

When one considers the litany of complaints about the standards of the trust during the period that the HCC was reporting, an examination of the quality of the assessment and how foundation trusts may be better



assessed may be thought to be overdue.

Whether or not there are issues in relation to the performance of the HCC and how it went about performing its function, it did conduct an investigation in relation to the trust, the findings of which are pertinent to the inquiry.

Between April of 2008 and October of 2008 the Healthcare Commission conducted an investigation at the trust, focusing primarily on emergency admissions. Their investigation was triggered in 2007 by high mortality rates for specific conditions at the hospital.

The hospital standardised mortality ratio or HSMR is a comparative measure of an acute trust's overall mortality developed by the Dr Foster Research Unit. It focuses on a group of diagnoses which account for approximately 80 per cent of all deaths in hospitals in England. The HSMR accounts for the case mix of patients adjusting for a number of factors, including primary diagnosis, age, sex and co-morbidities.

As you, sir, are aware the Department of Health published last week a new method, known as the Summary Hospital-level Mortality Indicator, following a national review, which resulted in fact from your recommendation in report 1.

A value of HSMR of 100 indicates a mortality rate



that is equal to what one would expect given the case mix. A value of higher than 100 indicates a higher than expected mortality rate.

In April of 2007, the Dr Foster's Hospital Guide showed that the trust had a standardised mortality ratio of 127 for 2005 to 2006, and over a three-year period of 2003 to 2006, the HSMR was 125.

The raised mortality rates was a particular concern in relation to emergency admissions. Although the trust responded and laid the blame for the excessive figures at the door of poor coding of clinical data, the HCC was ultimately unpersuaded and the investigation proceeded. It is disturbing, of course, that more effort appears to have been spent by the trust defending its position than seeking to identify and remedy the underlying problems.

The nature of the HCC investigation included 300 interviews and a review of over 30 patient case notes. The results of their investigation are set out in their report, which unfortunately took a considerable time to publish. Eventually they published their report on 18 March 2009.

As a matter of record, Monitor had awarded the trust foundation trust status as recently as February 2008. The lack of communication between those two organisations will have to be the subject of some

analysis in this inquiry.

In any event, the conclusions of the HCC investigation were damning. They found that there were deficiencies at virtually every stage of the pathway of emergency care. The numerous deficient features which they found could, in their view, have contributed to poor outcomes for patients. They found that serious problems of care, which required consideration and resolution, were rarely being considered by the trust board, which seemed to be ignorant of the issues. They, the board, appeared to be insulated from the realities within the hospital and the culture did not encourage open reporting.

Those findings are mirrored by other reports elsewhere, and by the findings of your first inquiry, and where relevant I have dealt with them in this opening under the various areas of care and management upon which they touched.

Although we must be careful not to retread the same ground in this inquiry, the issue of the failure by the trust board will be of importance to an understanding of how boards should be structured and operated to ensure that such failures do not recur either at Stafford or elsewhere within the NHS.

A further issue highlighted by the HCC report was



the way in which the trust went about making savings in the year 2006/2007 of some GBP 10 million. The reorganisation of the wards and the loss of staff following little consultation was badly managed and damaged care of patients.

The issue of the relationship between those who managed the budget and the clinical staff responsible for ensuring that appropriate level of care in the face of staff cuts will be one for this inquiry to consider.

One of the most damning comments in the HCC report was this. It was clear from the minute of the trust board that it became focused on promoting itself as an organisation with considerable attention given to marketing and public relations. It lost sight of its responsibilities to deliver acceptable standards of care to all patients admitted to its facilities. It failed to pay sufficient regard to clinical leadership and to the experience and sensibilities of the families. Its strategic focus was on financial and business matters, at a time when the quality of care of its patients admitted as emergencies was well below acceptable standards.

Three further reports followed that of the HCC. The Alberti report, the Colin-Thome report and the National Quality Board report. I will deal with each in turn as



briefly as I properly can.

We are fortunate enough to be able to call Professor Alberti and to use the findings and conclusions of his report as indeed was the first inquiry. Professor Alberti published his report on 29 April 2009, some 19 months ago. It is sufficient for me to summarise his key findings.

His terms of reference were to carry out a review of emergency admission and treatment at the Mid Staffordshire NHS Foundation Trust, to review the trust progress since the HCC's report in March and link closely with Dr David Colin-Thome who was reporting on practice by the PCT and SHA and lessons to be learnt by commissioners.

In Professor Alberti's view, there were improvements at the trust in terms of the number of A and E consultants and the quality of care provided in A and E. There were now three acute physicians who had greatly improved the timeliness of care of medical emergencies. There were still issues in relation to the flow of patients through the hospital, too few surgeons working in each surgical speciality, equipment deficiencies identified by the HCC were still apparent, there were still too few qualified nurses, patients and the public were not included sufficiently in discussion and



decision-making, and the PCT needed to ensure that the quality and safety indicators were built into all commissioning and performance management arrangements. The trust needed a coherent five-year plan to identify where it fitted into the overall health economy and be clear about what it can do well and safely and what should be handed on to others.

A recommendation that the PCT needed to ensure that quality and safety indicators were built into all commissioning and performance management arrangements is of particular significance to the terms of reference of this inquiry. Whether the system is about to change as a result of the coalition government's White Paper, there is likely always to be a system of commissioning health services. Certainly, there is no sign of any government inclination to return to the system pre-1991.

Professor Alberti's recommendations were no doubt a reflection of his disappointment that in his meetings with the PCT their focus appeared to be more on patient throughput and business than patient care. Accordingly, one issue that this inquiry must examine is how the commissioning system could be better structured so that quality and safety indicators are a necessary part of setting budgets and awarding contracts. As Professor Alberti put it, all organisations involved,

the trust, the PCT, the strategic health authority, Monitor and the Healthcare Commission must learn from the previous problems that have beset Stafford, particularly regarding prompt diagnosis and solutions to problems that emerge.

It will be of interest to this inquiry to discover to what extent that sensible and worthy aspiration has been converted into reality.

Dr David Colin-Thome also published his report on 29 April 2009. His report sought to look beyond the hospital and to make recommendations directed towards other relevant organisations that also act to safeguard the quality of care of patients. His terms of reference from the Secretary of State for Health were to review the circumstances surrounding Mid Staffordshire NHS Foundation Trust prior to the Healthcare Commission's investigation, to learn lessons about how the primary care trust and strategic health authority within the commissioning, performance and management system that they operate failed to expose what was happening at the hospital.

It focused on the period between the HCC report, between 2002 and 2007. As Dr Colin-Thome put it:

"A key lesson is that all organisations (including the PCT and SHA) should be focused on prioritising high



quality patient care as judged buy outcomes, and whilst process targets are very helpful on the journey, they must not become a distraction from the bigger picture."

Again, he identified, as had the HCC report, that striving for FT status meant an over-allowance on process measures and targets at the expense of focusing on quality of service of patients.

He was critical in his report of both the PCT and the SHA for failing to seek out information and data from the trust. They were unaware, for example, that the reporting of patient complaints to the hospital trust board had been suspended for three years between 2003 and 2006.

The key criticisms and recommendations were as follows:

(1) a closed culture within the trust and a lack of willingness to share data outside the trust.

(2) the reconfigurations of those organisations led to failures to act on poor quality, but he did think that the reconfiguration of the PCTs and the SHAs had been effective in pooling expertise and strengthening the management of the health system.

(3) foundation trusts must still be answerable to their PCTs as commissioners, performance managers of the service and guardians of high quality care.



(4) lack of patient involvement engagement was a key to why the hospital continued to provide poor care for such a long period of time.

(5) accountable and clinical leadership was lacking at all levels and could have been more effective at the PCT and SHA.

(6) he was concerned that in his view the public and patient involvement forum had been largely uncritical of the hospital and was, therefore, ineffective.

(7) more use should be made of GPs, the eyes and ears of their communities.

(8) there was a lack of clarity about the roles of the PCT and SHA and what the accountability of each was.

(9) there was over-reliance by the PCT and the SHA on Monitor and the Healthcare Commission, and there was an assumption that regulation of quality would be fulfilled by those organisations.

(10) the Department of Health should describe the roles of the PCT, the SHA and the regulators and explain how they are different and how they interrelate.

Those questions posed by Dr Colin-Thome are at the heart of the issues with which this inquiry has to grapple.

I am going to turn then to the government response to those reports.



On 30 April 2009 in a written Ministerial statement the government issued its response to the Alberti and Colin-Thome reports, and the government accepted the recommendations made and indicated their proposed response.

The key elements of that response were as follows:

(1) the government declared that it accepted all of the recommendations in the two reports and would work to implement them in full.

(2) Monitor, it declared, would oversee the implementation by the foundation trust of the recommendations made by Dr Colin-Thome and by Professor Alberti as well as the recommendations made by the HCC.

(3) the response identified the significant changes adopted by the trust in response to the criticisms. The CQC, Monitor and the PCT were to take stock of the trust in three months -- that would make it late July/early August -- and the CQC would undertake a follow-up investigation in six months, October.

(5) Monitor would continue to hold the trust to accountable for its progress based on the CQC's assessment.

(6) NHS organisations would be required henceforth to publish a new annual statement of involvement to

demonstrate how they are implementing the legal duty to involve patients and the public, which would include a statement from the relevant local organisation such as LINk and the local oversight and scrutiny committee.

(7) the complaints system was to be reformed and strengthened. Hospitals were, as it was put, to do better at resolving complaints at a local level, and a Parliamentary and Health Service Ombudsman was established as the ultimate arbiter on patient complaints.

(8) hospitals were to be required to publish annually how many complaints they received and how they were resolved.

(9) the government said that it would convene a summit on best practice in delivering A and E standard with patient representatives. NICE, CQC, the College of Emergency Medicine, and other Royal colleges and other key stakeholders.

(10) working tandem with CQC and Monitor the government intended to tighten up the quality of aspirants for foundation trust status and give the CQC a greater role in agreeing that there are no significant concerns about the level of quality that trusts are delivering before they can be authorised as foundation trusts.



(11) HSMRs were to be published on the NHS Choices website.

(12) all NHS acute providers would be required to publish what would be called quality accounts and the government intended to impose a legal requirement for commissioners to validate those accounts prior to publication. This was said to "ensure commissioners have a central role in overseeing and improving the quality of care provided to their patients."

(13) finally, the new National Quality Board was to look at the issues of how to ensure that early signs that something is going wrong in the NHS are picked up immediately, that the right organisations are alerted, that action is taken quickly. The NQB were to review key issues relating to alignment and co-ordination at a system level and were to report by the end of 2009.

(14) Sir David Nicholson, the NHS chief executive, was to write to all NHS organisations to bring the reports to their attention and Monitor was to do the same in relation to foundation trusts.

(15) however, the failures discovered at Stafford were described as a "local failure", and it was stressed that the HCC had no similar concerns about any other NHS organisations. As an aside, one might comment that this was the same HCC which was only alerted to the problems



at the trust by Dr Foster's mortality figures.

On 21 July 2009 the Secretary of State, Andy Burnham, issued a further Ministerial statement announcing a further independent inquiry under the chairmanship of you, sir.

Before turning to the first report, we need to deal briefly with a further limited investigation of events at the hospital, which took place before your inquiry, and that was the independent case notes review performed by Dr Laker. Unfortunately, his review is not regarded by some to be independent, but nevertheless, his report threw up relevant issues for this inquiry.

In April of 2009 Dr Laker was approached to undertake the role of lead clinician in an independent case notes review that the trust was offering to patients and their families who had concerns regarding the care that they had received. Dr Laker agreed to undertake the review on the basis that he would commit to three days per week, and estimated that the task would take some six months to complete. His tasks included meeting with patients and families, providing guidance to assessors on the review process, editing final reports and participating in feedback meetings with relatives. But within a few weeks of starting the review, a number of problems emerged:



(1) the trust believed that the written reports of the families would be the end of the process and did not think that there was a need for face-to-face feedback, and Dr Laker disagreed. The trust then altered their position and wanted Dr Laker to conduct the feedback sessions. Dr Laker considered that this was a role which was beyond his clinical competence and that someone with a genuine governance background would be better suited to the task. That issue was never resolved.

(2) Dr Laker had to intervene to prevent the head of governance at the trust from seeing the case review reports before they were sent to the families.

(3) the trust allocated, says Dr Laker, inadequate resources to the review.

(4) within a few weeks it was readily apparent that the task was beyond the capacity of a single lead clinician. The trust agreed but took no action to resolve the issue.

(5) the notes of meetings with families contained action points for the trust. These were not acted upon.

(6) some of the families questioned Dr Laker's independence because he was appointed and paid by the trust and this could have been avoided had the Strategic Health Authority or PCT commissioned the review.

In order to progress to be made with the reviews, the management of the ICNRs was passed to South Staffs PCT and Dr Laker considers that the PCT managed the process in a highly professional manner, and that from that point on the process was adequately resourced.

Most of the issues identified in the HCC and your report were apparent from the ICNR process. Dr Laker's view of the lessons to be learned is informed by his knowledge of the principles of clinical governance and clinical leadership and he believes that these are key to the prevention of future occurrences.

In Dr Laker's view, lower priority is given to safety and quality due to the immediacy of financial pressures and this is especially so when services have been reorganised. Dr Laker believes that clinical governance should be apparent throughout all levels of an organisation. It was not effective at Stafford, and the issue that arises in terms of prevention of a recurrence is how NHS organisations are accountable for the quality of their services.

Dr Laker has concerns that the development of the current assurance mechanism through the CQC is unlikely to address fully the concern regarding the safety and quality of services. In his view, assuring safe and high quality care requires the involvement of the local



health economy in addition to a national system.

Dr Laker has two major concerns about the recent White Paper and the developments intended to prevent a future major failure in healthcare provision. The first is the danger that explicit standards of care will continue to drive the target culture that the current reforms are trying to get away from, and the second is that service-based standards are unlikely to explore standards in all areas of clinical governance.

With regard to clinical leadership, Dr Laker considers that it is the responsibility of the medical director and director of nursing to champion the clinical quality agenda at board level. He does not believe that this happened at Stafford and considers that problems are likely to occur in other organisations if clinical leadership is poor.

Dr Laker considers that the roles of the SHA and PCT should be investigated, because the problems at Stafford were long-standing and, in his opinion, the local health economy should have been aware of them. Dr Laker is also keen that the role of the Royal colleges and deaneries should be investigated.

Dr Laker rejects the suggestion that the ICNR process is capable of identifying the excess deaths believed to have occurred at Stafford.



Dr Laker is keen that the difficulties with interpreting hospital standardised mortality rates are recognised and addressed.

In his written statement to the House, accepting the conclusion of the two rapid reviews by Professor Sir George Alberti and Dr David Colin-Thome, the minister, Andy Burnham, said this:

"It is clear from listening to those affected that rebuilding local confidence and restoring trust will take time. The full impact of what happened at Mid Staffordshire is revealed through personal stories of those affected and it is clear to me that these experiences need to be properly aired if the local NHS is to learn and in time move on. I have therefore decided, following detailed discussion between my department and the new management of the trust, that it would be appropriate to set up a further independent inquiry. I do not believe it is necessary for this to be a full public inquiry, given the thoroughness of the reports already produced by the HCC, Professor Sir George Alberti and David Colin-Thome as well as the availability of an independent clinical review to those who have concerns about the care they or a loved one received at the hospital.

"This inquiry's focus will be on ensuring that



patients or their families have an opportunity to raise their concerns. It is important, given the events of the past, for those who depend upon the care provided by the trust to be confident that they have been listened to and that any further lessons not already identified by the thorough inquiries that have already occurred be learned."

The brief terms of reference to that inquiry were:

(1) to investigate any additional case relating to the care provided by the trust between 2005 and 2008 that in its opinion causes concern and to the extent that it considers appropriate.

(2) in the light of such investigation, to consider whether any additional lessons are to be learned beyond those identified by the inquiries conducted by the HCC, Professor Alberti and Dr Colin-Thome; and if so

(3) to consider what additional action is necessary for the new hospital management to ensure the trust is delivering a sustainably good service to its local population.

The minister continued:

"The Mid Staffordshire case has also illustrated that the current regulatory framework for the foundation trusts needs updating. The FT model is a key plank of reform in the NHS successfully rewarding high

performance with greater freedom and autonomy. The policy is based on the premise that the FT status is a privilege to be earned and valued. An incentive to drive up quality, innovation, productivity and local accountability. However, it is clear that in some exceptional circumstances where an FT has failed to live up to this standard and public confidence has been damaged, it may be right for the privileges of the FT status to be withdrawn. That is why I intend to consult on legislative proposals to enable Monitor to de-authorise a foundation trust, subject to agreement by the Secretary of State, where it is clear an organisation has forfeited its right to the freedom and flexibilities afforded by FT status."

Well, we note that to date, although the powers of de-authorisation have been enacted under section 15 of the Health Act 2009 by way of an amendment to the NHS Act 2006, by inserting section 52B of the Act, the legislation is not yet in force. No trust has been de-authorised. Monitor does not yet have the power to do so, although a consultation document was published in March of this year.

Nevertheless, thus was your first inquiry brought into life.

Prior to your inquiry commencing, yet a further



report was commissioned, this time from the National Quality Board, to review specifically the systems and processes in place in the NHS for safeguarding quality and preventing serious failures.

The National Quality Board began operating in 2008, with a specific remit in relation to health to:

"... align the system around quality, advise on priorities for quality improvement and overseeing the development of tools and system levers to support front line NHS in bringing continuous quality improvement."

The report was presented in early 2010 by Sir David Nicholson, NHS chief executive and chair of the National Quality Board, Dame Jo Williams, acting chair CQC and member of NQB, and Christopher Mellor, who is acting chair of Monitor and member of the NQB, and written so as to describe how the system should work in the future to prevent and where necessary respond to serious failures in quality.

They comment that there were to be changes by April 2010 to improve regulation by providing the CQC with new powers of enforcement and a new system of registration for providers of healthcare, a new performance framework within the NHS supporting swift detection of underperformance in the NHS and professional standards and obligations to be



strengthened by a new revalidation system for doctors.

The writers opine:

"To create a self-improving and responsibility NHS, we need to aim for a culture of open and honest co-operation. This means individuals and organisations being open and honest about the quality of care being provided to patients and the whole system working collaboratively to address concerns and raise standards. This means staff having confidence to raise concerns about before performance and unacceptable levels of care, rather than waiting for patients or their families to notice the fault lines."

A summary of their findings:

(1) the systems of monitoring and performance managing the quality of care of patients is almost entirely dependent upon the values and behaviour of the staff working in the system. Strong leadership is needed at every level.

(2) the NHS needs to embrace a culture of open and honest cooperation, particularly where there are shortfalls in quality.

(3) an open and honest culture requires a two-way dialogue between patients and the public and the NHS. We need to shift the culture of the system from one of reluctance and blame, where failings automatically



result in a race to point a finger to one of openness, learning and continuous improvement.

(4) listening to patient experiences and concerns is a key part of the early warning system, but relying on patients alone is insufficient, so there must be a robust performance and regulatory framework in place to safeguard quality.

(5) NHS staff and clinical teams are the first line of defence in preventing serious failure in the NHS. It is their duty and responsibility to speak up when they have a concern as well as striving to deliver continuous improvements.

(6) the ultimate responsibility for safeguarding the quality of care provided to patients rests with the provider organisations through its board.

(7) PCTs and SHAs and the Department of Health are responsible for securing provision of high quality care at local, regional and national levels.

(8) the regulators must ensure that providers are adhering to their statutory obligations.

(9) in the event of failure, a single organisation needs to take responsibility for ensuring that the management and regulatory responses remain aligned and coordinated at all times. The report recommended that the SHA take on that role.

Particular importance was placed upon the role of PCTs in managing contracts and ensuring robustest contract monitoring was in place, and this should include clear performance measures.

Similarly of Strategic Health Authorities. It was said that they hold the PCTs to account by ensuring that they are effectively managing the contract with the PCT and they have a role in driving up the capability of PCTs through the World Class Commissioning assurance process.

Well, we will need to explore whether that aspiration or any resemblance to reality in Stafford and what World Class Commissioning is meant to mean.

It is important to bear in mind that under the White Paper setting out the coalition government plans for the restructuring of the NHS, both the PCTs and SHAs as organisations will be abolished.

The role played by the public is set out and comments that PCT should take account of concerns raised about providers, and goes on to deal with the role that Links play in this scenario. The inquiry will we anticipate hear that Links in Staffordshire was a particularly ineffective organisation to bring concerns of the public to the notice of the trust concerned.



Similar importance is placed upon health oversight and scrutiny committees, which the writers believe bring democratic accountability to healthcare decision and make the NHS more publicly accountable and responsive to local communities. The effectiveness of the local oversight scrutiny committee will be examined with care in due course. On one view of the evidence, which we expect the inquiry will hear, they singularly failed either to oversee or scrutinise the trust in question in any effective way at all.

The National Quality Board report also delved into the newly developed system within the CQC to assess quality and risk known as the quality and risk profile system. This is intended to provide a more up-to-date system for collating information on risks to quality of care presented by providers. The sources of information listed are wide and varied, and QRPS is intended to enable the CQC to share information on provider risks across the NHS system, to help risks and failures to be rapidly identified.

One of the causes of continuing failure at the hospital examined in inquiry 1 was whether there was a failure by the Healthcare Commission to share the information in relation to the trust with Monitor. It will be of importance to this inquiry to establish



whether the new system would work better than the old, which appears to have led to such a fundamental failure of communication between one body so concerned about the hospital that it decided to investigate serious failings there, and the other granting it foundation trust status in the same period.

A diagram is produced in the report demonstrating how the NHS early warning system is intended to work.

As is clearly accepted within the NQB report, there are critical factors which will decide the effectiveness of the early part of the warning system:

(1) it depends on a culture of open and honest cooperation being in place within the provider organisation.

(2) healthcare professionals need to be confident that if they raise concerns, they will be listened to and not punished.

(3) clinical teams should be measuring and benchmarking quality of services and being open and honest about where improvement is needed.

(4) the board should be scrutinising quality and fostering an open and learning culture throughout the organisation.

(5) the organisation as a whole should be listening to and acting upon feedback and complaints from patients



and public.

The first inquiry established failures of each of those five criteria in the hospital, but the real issue is: how can that sort of failure be avoided in the future? Part of the answer to which may come from asking and answering the question: how does one establish and nourish an open, honest, self-reflective culture throughout each hospital?

The diagram demonstrates that unless such a culture is established at the levels of providers A, then there will be a lack of information flowing from A to B. What is needed then is a strong and robust regulatory power to ensure compliance with national standards. This is a critical area for this inquiry to examine and report upon.

Turning now to your first inquiry, sir. There was, as you know, some criticism of the fact that the first inquiry was a private one and that evidence was heard in private. Although the criticism is understandable in personal terms, so too was the decision to hold that inquiry in private session. There was much greater cooperation than there might otherwise have been from individuals who, as a consequence of being able to do so privately, were able to speak their minds and find their voice. We have the benefit of that body of evidence

from the first inquiry in the form of the conclusions produced in the report. Because of that it is not necessary now to revisit issues on that level.

There is by contrast no reason for this inquiry not to receive the vast majority of this evidence in public. There are still some patient relatives who would wish to remain anonymous, and there may be whistle-blowers giving evidence to whom the same considerations would apply. It is important that everything is done to ensure that the inquiry receives the material it needs and if that requires anonymity orders, then we will apply to you, sir, for that to be granted.

There were, as we have seen, prior to your first inquiry into Mid Staffordshire NHS Foundation Trust a number of other investigations and consequent reports but it was the first inquiry, your inquiry, which examined the trust overall and heard the detail of the patient stories. Your first inquiry made a series of 18 recommendations, and we intend to examine the extent to which those recommendations have been taken up and complied with.

Some of the recommendations were for the internal use of the trust, but other recommendations had a wider audience, and it is those which we find particularly pertinent to the role of this public inquiry. It is



worth, therefore, briefly examining some of the recommendations made.

Your third recommendation, the trust together with the PCT should promote the development of Links with other NHS trusts and foundation trusts to enhance its ability to deliver up-to-date and high class standards of service provision and professional leadership.

First, we will want to examine the ways in which the trust has sought to meet that recommendation and, secondly, we want to look at the issue of whether communication and constructive links between hospital trusts are a way to ensure an increase of standards across a particular area and a method by which the shortcomings of one hospital might be identified by comparison with another apparently more successful hospital.

Recommendation 4 suggests that the trust, in conjunction with the Royal colleges, the Deanery, and the Nursing School of Staffordshire University should review its training programmes for all staff to ensure that high quality professional training and development is provided the at all levels at that a high quality service is recognised and valued.

We in this inquiry will be examining the role played by the Royal colleges to see if their wisdom and



experiences as a body could be put to better use in both identifying failings and in providing guidance and training in areas where failings are identified.

Recommendation 5 referred to the use of audit in all clinical departments and making participation in audit a requirement for all relevant staff. The board should review audit processes and outcomes on a regular basis.

The underuse of accurate audit seems to have been one of the failings at the hospital and this inquiry will need to examine the use of audit across the NHS. How is the relative value of audit from one hospital assessed as compared to another?

How can audits be homogenised and standardised within various specialities?

Whether there is value in doing so?

Who should undertake such a task if is valuable?

And, how can the results of audit be better used?

Recommendation 6 referred to the handling of complaints and among other suggestions recommended that full information is given to the board, the governors and the public of complaints made and the action taken to resolve deficiencies.

Recommendation 7 and 8 refer to policies in relation to complaints, oversight and discipline of staff and the treatment of whistle-blowers, what steps can be taken to



ensure that staff are not frightened for themselves or others of reporting untoward incidents, and how is the standard set and homogenised in terms of the threshold for reporting an event as untoward incident. How can staff who do complain be best protected, if protection is needed?

Recommendation 9 was that the Secretary of State and Monitor should review the arrangements for the training, appointment, support and accountability of executive and nonexecutive directors of NHS trusts and foundation trusts, with a view to creating and enforcing uniform professional standards for such costs by means of standards formulated and overseen by an independent body given powers of disciplinary sanction.

This inquiry will want to know: what action has been taken to follow this recommendation? What action has been taken to increase the relevant skills and standards of appointed executives so that they have a real role to play and are willing to use the powers that they have independently?

Recommendation 15 related to the use of comparative mortality statistics and recommended that an independent working group be set up by the Department of Health to examine and report upon the methodologies used. The group should make recommendations as to how such

statistics should be collected, analysed and published both to promote public confidence and understanding of the process, and to assist hospitals to use such statistics as a prompt to examine particular area of care.

Well, as already mentioned, the Department of Health has responded to that recommendation and they published last week a new method known, as I've said, as Summary Hospital-level Mortality Indicators. This inquiry has received submissions from the Department of Health and we will be calling witnesses from that department to provide us with information as to how these statistics are now being used and how it is proposed that they could be better used under the new system.

Let me turn, perhaps before we break, to the general issues of relevance to this inquiry.

It is important that we bear in mind that part of the terms of reference include these words:

"To examine why problems at the trust were not identify sooner and appropriate action taken."

That necessarily entails some examination of what the problems were, but we must be astute to avoid retreading old ground. Again, we take the issues identified in report 1 and the conclusions flowing there from as our starting point.



In order to examine the regulation of the hospital, and why things were allowed to get into the state which they did, we may have to examine a number of different clinical specialities and areas in particular to discover what has changed since your first report, and what systems have been put in place to ensure the recurrence of those events does not take place. These will include those areas which were specifically highlighted by the first report A and E, the emergency assessment unit, and wards 6, 7, 8, 10, 11 and 12.

On these wards there appears to have become established a particularly poor standard of care, of basic nursing skills and on occasion plain human compassion. There were references to witnesses of a bullying attitude.

In this inquiry, as I've said repeatedly, we do not intend to retread the established ground, but the question we have to try to answer is: what can be done to prevent such a culture establishing itself?

What can the hospital management do to ensure that nurses are trained to recognise this type of culture?

What can the nurses' regulators do to spot problem wards in hospitals?

Patient safety.

The first report deals extensively with the issue of



patient safety and the numerous clear examples of a lack of care leading to the conclusion in certain areas that the trust was not a safe place for patients to be.

Some of the issues referred to in the first report were falls leading on occasion to serious injury, a lack of cleaning in the wards, lack of good hygiene practices among the staff themselves, hospital-acquired infections, lack of control over confused and sometimes aggressive patients, lack of attendance to patient's personal and oral hygiene, a failure to address the needs of patients in relation to nutrition and hydration, a failure to keep proper records of fluid balance and nutritional intake, poor keeping of notes generally, a lack of care in relation to the avoidance and treatment of pressure source, a failure to respect patient's privacy and dignity, misdiagnosis by medical staff and unacceptable delays in diagnosis, lack of follow-up.

As was said in the first report, what has been shown is more than can be explained by the personal failings of a few members of staff, so it is not our intention to single out for blame individuals. The problem seems to have been a systemic one of culture across a number of specialities.

The first inquiry identified a number of themes



which I have termed "themes of failure". Each one is an example where a different approach may have led to a different outcome.

We will have to examine some of those failures, not to identify what they were -- as a result of the work done by inquiry 1, we know what they were -- but to identify why these failures were allowed to continue and who should have identified them sooner and changed things.

What role did the commissioners of the service have in contributing to these issues?

And what part could others outside the trust have better played to prevent the failures persisting?

The themes were identified in paragraph 80 of your report, and those themes which it has seemed appropriate for us to investigate are:

A corporate focus on process at the expense of outcomes.

A failure to listen to those who have received poor care through proper consideration of their complaints.

Staff disengagement from the process of management.

Insufficient attention to the maintenance of professional standards.

A weak professional voice in management decisions.

A lack of external and internal transparency.

False reassurance taken from external assessment.
And disregard of the significance of the mortality statistics.
One issue we will have to examine is the degree to which finance dominated the management thinking. The financial crisis which pertained at the end of 2006/2007 financial year led to the perceived need to find financial cuts of GBP 10 million. Whilst this may have been seen as an internal management issue, if it led to a reduction in the quality of the care provided, which it did, then the question needs to be asked: what could have been done to safeguard the essentials of care in this context and why weren't appropriate measures taken to do so?
The first inquiry report broadly accepted that the pursuit of foundation trust status had in fact been deleterious to patient care. The focus of management appears to have been on the financial criteria which would drive the application through:
Did the organisation responsible for examining and approving that application, Monitor, appreciate what the effect of this application might be?
What was its, Monitor's, role?
Did it in fact contribute to the loss of standards of care at the hospital it was monitoring?



admission of fault be encouraged so that there is a low threshold for reporting untoward incidents and the appropriate action taken by staff and management in response?
What are the factors which militate against a culture of open admission of fault?
Is there in fact a culture of punishment of fault rather than learning from errors which then drives admission and discussion underground?
Do the professional regulators help this process or hinder it?
What is the role of litigation in this process?
Is the fear of litigation beneficial by improving standards, or does it lead to a denial of responsibility, such that lessons are never learned?
Warning signs. Another area we will examine is what were the warning signs which were not picked up, or if not noticed not reacted to in an appropriate manner.
The hospital mortality statistics for the hospital were significantly above the national average. Although it was this figures that attracted the attention of the HCC and caused it to launch an investigation, the reaction of the management of the hospital was to claim that these were caused by so-called coding issues.
In your first report it was accepted that there is



This issue is crucial and the lessons learned must be acted upon, given that it is the present government's intention to give every NHS trust foundation trust status.
The same factors which appear to have driven standards down rather than up must be identified and prevented from having the same effect in the future, and we will be hearing expert evidence to assist the inquiry panel to make recommendations.
We turn to the heading of complaints and whistle-blowing.
The culture of the hospital does not appear to have encouraged the reporting of untoward incidents and the inquiry found that a number of deaths had not been reported in the appropriate way. The investigation of complaints resulted in reports which lacked credibility and remedial action was not carried out when it should have been. Complaints did not find their way to the board, and if the chief executive knew about them, he does not appear to have responded appropriately to them. Whistle-blowing was not encouraged and whistle-blowers do not appear to have received the support which their actions deserved.
One of the issues this inquiry will be invited to examine is, how can a culture of openness and frank



strong evidence to suggest that these figures mandated a serious investigation of the standards of care being delivered, rather than reliance on the contention that they had been caused by coding, and recommendation 15 of your rep was that an independent working group be set up to examine the methodologies used.
But as part of this inquiry we will also look at other warning signs which might have been picked up and alerted management to difficulties which could have been created. We have accepted as part of the foundation for this inquiry the findings of your first report in relation to the specific areas of care where significant failings were found. Now we need to examine what signals there were that were missed both internally and by those looking at the trust from without.
One central issue for this inquiry is why so many regulatory bodies failed to spot what was going on and act upon it sooner. Once the HCC report was published, the trust was swamped with interested parties peering at the hospital and examining the data, but where, we need to ask, were all of these organisations through 2005, 2006, 2007 and 2008?
One question that requires an answer is whether there were simply too many bodies, none of which were focusing on the right things. In terms of organisations

which either had a role in commissioning, regulation, advice-giving or training there was at the time the HCC, Monitor, the PCT, the SHA, the various patient support bodies, both the charitable and governmental AvMA, PALS, PPIF, LINk, POhWER, the oversight and scrutiny committees, the NHSLA, the GMC, the NMC, the HSE, National Confidential Inquiry into Patient Outcome and Death, National Patient Safety Agency, Patients Association, the deaneries responsible for training graduate doctors, the PMETB, the universities responsible for training nurses, the relevant you unions, the Royal colleges, the coroner, the Parliamentary Ombudsman. There were, of course, others.

Is there a strong argument for rationalising these bodies and providing them with a better focus and specific role so that everyone knows whose job it is to inspect and assess hospitals?

Is there are a simple answer to the question: who do I call when I want to call the regulator of my local hospital? The diagram that is now showing on the screen may demonstrate there is no simple answer to that question.

Would that be an appropriate moment to take a short break?

THE CHAIRMAN: If I look at that diagram for too long,



I will need more than a cup of tea. But we will have a break for 15 minutes. Thank you.

(3.01 pm)

(A short break)

(3.15 pm)

THE CHAIRMAN: Yes, Mr Kark.

MR KARK: Sir, the terms of reference required this inquiry, among other things, to examine the operation of the commissioning supervisory and regulatory organisations and other agencies, including the culture and systems of those organisations in relation to the monitoring role at Mid Staffordshire NHS Foundation Trust between January of 2005 and March of 2009, and to examine why problems at the trust were not identified sooner and appropriate action taken. This includes, but is not limited to, examining the actions of the Department of Health, the local Strategic Health Authority, the local primary care trust, the independent regulator of NHS foundation trust, Monitor, the CQC, the Health and Safety Executive, local scrutiny and public engagement bodies and the local coroner.

In order to meet the terms of reference, the inquiry intends to meet a step-wise approach and to build a foundation of evidence early on, which will inform the debate early on in the proceedings.



In phase 1 we will hear first from a series of experts who will set out the structure of the NHS and the regulation of it and also to speak about concepts of safety and good clinical care and how those issues can best be approached.

We will then begin to hear evidence from patients' relatives and patient groups to examine specifically how their complaints were dealt with or more frequently not dealt with.

We will gradually shift the focus of the evidence outwards from patients to hear from local and national patient groups, whether government funded or charitable, the PPIF, LINks, PALS, POhWER, AvMA, and the Patient Association and like groups, and those who are charged with role in protecting patient interests.

We then have a period for the doctors outside the trust, the local consortia, and those who may in the future be charged with commissioning services. We will examine their communication with the trust and how it worked or failed to work and why. How do they perceive their role in the future?

Then in phase 2 we will move on to hear from those who might or should have had specific information flowing from the trust, the local area medical committee, the Royal College of Nursing and the unions.



Why was there silence from them, or were the doctors and nurses whom they were representing silent?

We will move on to examine the working of the local authority oversight and scrutiny committees, which came in for considerable criticism from patient groups. How was the system intended to work, and why did it not, how could things be better arranged?

Again under the coalition government plans, local councils appear to have an even greater role than previously. How will this work in reality? Will it work? And what is needed to make it work?

We then move on to the role of the coroner. Could the information which the coroner received have been better used? What is the system for alerting a wider audience if there is recognised to be an outlier number or pattern of fatalities at a particular hospital.

A number of patients complained to their Members of Parliament with very varying degrees of success. What was the reality from the MP's standpoint? Were those who did complain able to make their voices heard by the hospital, the Department of Health or by the government?

We will then move into phase 3 of the inquiry when we will hear from some of those with responsibility now for looking after the patients at the hospital, from the clinical lead in emergency medicine and some of the

consultants who work with him, how have things changed, if they have, and what are the systems that work better and still do not work?

We will then hear from the management of the hospital, both old and new. We will resist any temptation or pressure to call witnesses simply to vilify. That is not the point of this public inquiry. However, it is important to hear from people who made mistakes to try to find out why those mistakes were made. We hope to find some introspection and reflexion.

We will then hear from the commissioners of the service, the PCT and the SHA.

How were their roles defined for them and how did they carry them out?

In amongst peering at the finances, were they keeping a weather eye on the quality of service?

Was that part of their role and did they see it as such?

Is there a buffer or a divide between the commissioning of the contract for service in the financial sense and the provision of the terms of the contract in terms of the quality of care meted out to patients?

Should the commissioners of the future be better equipped to assess the quality of the care which it is



their responsibility to commission?

Then we move to phase 4A to look at the various regulators who had responsibility for preventing the failures at this hospital. We will be hearing from representatives of the Healthcare Commission, as it was, the Care Quality Commission and Monitor.

Was there sufficient communication between those bodies?

How did it come about that Monitor was granting to a hospital the accolade of foundation trust status just at the time when the HCC was so seriously concerned that they were starting a formal investigation into the same hospital, which was a year later, to produce such a damning report?

In phase 4B we will hear from all of the relevant regulators, both of the system, the professionals within it and those responsible for training, the Health Protection Agency, the Health and Safety Executive, the Postgraduate Medical Education Training Board, the GMC, the General Medical Council, the Health Professions Council, the National Institute for Clinical Excellence, or NICE. And finally in that section we'll hear from the Royal colleges, the Nursing and Midwifery Council and the British Medical Association.

In phase 5 we turn to the national advisory bodies



and those responsible or with the capability of data collection. The National Health Service Litigation Authority, the National Patient Safety Agency, the National Clinical Assessment Service, the Audit Commission, the National Audit Office, and we hope to be hearing from Professor Jarman at the Dr Foster Unit at Imperial College.

We will examine the issue of data collection. What data is collected from primary and secondary care trusts? How is it collected? Who looks at it? Who is meant to react to it?

In phase 6 we hope to hear from regulators in other fields of life. The Civil Aviation Authority sometimes held out as a beacon of good regulation, how do they try to instil a culture of open admission of fault, introspection and correction?

We hope to hear a perspective from the Prison Inspectorate. How do they ensure that their inspection work properly and are effective in spotting signs of weaknesses or failure where the prisoners' lives or well-being or the safety of the wider public may be at stake. Those organisations are in the process of being contacted.

Phase 7 is the final phase of the formal evidence-gathering process and in that phase we will be



hearing from the representatives of the organs of the state, the Department of Health itself, the chief medical officer, the chief nurse and those in government responsible in the past and present for designing the system of healthcare and regulation in the UK.

We expect that after phase 7 there will need to be a short period of introspection for ourselves, a consideration of which witnesses might need to be recalled during phase 8, in the light of all of the evidence given and to think about what we might have covered but have not. If witnesses are to be criticised, there may then be an opportunity for a small number of witnesses to return and clarify their evidence if that is deemed appropriate by you, sir.

That is the intended structure of the inquiry. Some witnesses will not be able to give evidence when we would like them to, no doubt, and we will be as flexible as we properly can to accommodate them. We understand that many of our witnesses are busy and have high-powered and important jobs but they will all no doubt recognise the importance of the business of this inquiry and the importance of helping you meet your terms of reference.

We will all recognise as well the importance of concluding the inquiry in as efficient a timeframe as

possible, with a particular view to contributing the lessons to be learned from Mid Staffordshire to the current process of healthcare reform proposed by the government.

I am going to turn to deal in a little more detail, therefore, with the phases of the inquiry and the witnesses who will be actually giving evidence.

Phase 1A is headed "Overview of the service expert evidence". To set the foundation stone of this inquiry, we will, first of all, hear from Professor Christopher Newdick. Professor Newdick is a barrister and the professor of health law at Reading University. His special interests concerns the right sand duties arising within the National Health Service.

Dr Judith Smith has co-written a report with Professor Newdick. She is head of policy at the Nuffield Trust and is an experienced health services researcher, who has studied healthcare organisation and management in the UK and internationally. Before joining the Nuffield Trust in 2009, she was based at the Health Services Management Centre in Birmingham for 14 years where she both carried out research and taught on health commissioning and purchasing, as well as the organisation of primary care and health management.

Professor Newdick and Dr Smith have assisted the



inquiry by providing a report which deals with the structure of the NHS, how it has transformed into the organisation that it is today and how the commissioning supervision and regulation of health services within the NHS is intended to work.

In addition to Professor Newdick and Dr Judith Smith, we will call at the beginning of the inquiry Professor Charles Vincent. We have been very fortunate in securing the assistance of Professor Vincent, who is one of the world's leading experts on patient safety and author of a book by that title. His evidence, which is to be called early in the proceedings, will help to set the foundation stone from which we can properly examine and test the evidence of those who are called later in the proceedings. He will set out where the difference lies between safety and good care and the different ways that there are in approaching these fundamental issues.

A further expert we propose to call in the inquiry is Dr Kieran Walshe. His expertise is medical regulation and he will assist us both as to how the system of medical regulation is meant to work and compare it with how it works in reality and practice.

Let me turn to phase 1B and what I have headed as "Patient relative evidence".



Following the evidence intended to give us a solid grounding in the foundation of the NHS structure and its regulation, we will then begin to hear the lay evidence, the patient evidence. We will begin the task of hearing evidence about people's experience within the trust.

During the course of this part of the opening, you will see some photographs appear on the screens. These are all photographs of patients who died at Mid Staffordshire NHS Trust and other relatives and witnesses from whom we obtained statements. We wanted to show some of the photographs of patients to bring a strong sense of reality and purpose to this inquiry.

I am very conscious that there are many patient relatives watching these proceedings. Some may have given statements and others will not have done. Everyone will appreciate that we cannot show the photographs of all who died at the hospital, and many witnesses have not wanted their relative's photograph displayed.

By not making reference to all of the patient evidence or by not displaying a photograph, no one should think that their role in this inquiry is diminished. We are not ignoring the death of any relative or loved one, which inevitably brings with it a huge sense of loss, which is made far worse if there



is a belief that the loss was unnecessary.

The whole focus of this inquiry is ultimately patients. We must, however, avoid this becoming a forum simply to relate the history of ills which befell individual patients. What we need to do is to examine what happened when individuals complain.

How were their complaints dealt with?

Who did they see?

And, where did the blockages occur?

Did they know to whom they could complain or was the system simply too complex?

How fair is the system?

And, how well does it respond to the vulnerabilities of people who have to grapple with it who are themselves either ill or closely related to those who are ill, dying or to those who have died?

If their complaints were taken up, did they see any change of practice?

One of the themes of complaint in inquiry 1 was that there were plenty of action plans, but not a lot of action. We have to find out what could have been done better both to resolve the complaints which will inevitably arise in even the best run healthcare system, but also to ensure that there is a system of feedback and learning from cases where a complaint is found to be

genuine.
We will start by hearing evidence from the witnesses from Cure the NHS, the people who brought the issues at a local hospital to the national debate. A number of patient relatives will wish to give evidence anonymously and you may feel it is important that they are able to give evidence as in comfortable and secure an environment as possible.
I am not going to deal with individual patient relative evidence in any detail, but as the first inquiry found, there are themes which flow from the written material we have received and the complaints covered many areas of the hospital, including the following:
The lack of nurses at night and weekends.
The paucity of numbers of nurses generally.
Poor basic hygiene.
Leaving patients lying in their own urine and faeces.
Lack of staff to assist patients when needed whether to eat, to wash or to go the lavatory. Sometimes the staff were there but seemed not to bother unless requested, and even then to react slowly if at all.
Meals left for patients out of reach or with no communication to the patient that the meal was there.



This often resulted in meals being taken away untouched by the patient.
Confused and agitated patients were allowed to wander the wards, disturbing, threatening and at least on one occasion attacking other patients; nurse assistance when summoned often arrived too late.
Even where patients had had serious accidents such as falling out of bed, it proved difficult to get the attention of the nurses.
Lack of care generally.
A failure to give drugs when required, including pain relief.
Rudeness and bullying towards patients.
A lack of basic equipment such as mattresses, blankets, pillows, hoists. Even once the HCC investigation started the complaints about similar issues continued.
There was a culture of bullying between the senior nurses and the junior nurses.
Patients were transferred or discharged without their relatives being informed.
There were difficulties in communication between doctors and nurses because of foreign accents.
Notes were made but were inaccurate or were not properly filled in or lost.



There was a lack of basic humanity when dealing with bereavement.
What was the reaction to the complaints when they were made? Again, I summarise some of the stories again rather than going into any detail.
Nurses themselves very often ignored the complaint and carried on as before.
The nursing director, Helen Moss, refused to accept that there were problems with the standards of nursing care.
Complainants were fobbed off with action plans which were used as a mere sop to cure the complaint but not the underlying problem.
Action plans were not followed through, and the same complaints arose again and again.
Relatives complain of general confusion about who to complain to, there being so many bodies to which one could complain but none of them being very prominent. One witness described how it was impossible to find anyone who would take ownership of the complaint.
Many patients and relatives simply did not know who they could complain to, and did not know of the existence of many of the organisations which were there to assist.
A perception that following a complaint by



a relative and on being given conducted tours of the hospital to demonstrate that issues had been resolved, the tours were in fact themselves staged.
A lack of openness and accountability at board level.
An inability to communicate effectively with the HCC until all local avenues of complaint had been exhausted.
Over-technicality when dealing with complaint such that the HCC would not deal with secondary complaints unless they had been mentioned in the first complaint.
The local GP consortia seemed to some patients to be too close to the chief executive of the hospital and very supportive despite the serious complaints that there were about the running of the hospital.
Patient relatives found the PPIF were actually hostile and wholly supportive of the hospital.
The chief executive of the PCT did not respond effectively to complaints about the hospital.
When complaints were made to the HCC the process was very drawn out and they appeared themselves to have difficulty getting information from the hospital.
One complaint to the HCC in April of 2007 in relation to a death at Stafford Hospital in December 2006 eventually resulted in the production of an action plan but it related to Cannock Hospital. The

HCC report upholding the complaint did not come out until March of 2008, 11 months after the complaint had been made.

Some letters of complaint written to the hospital simply went unanswered. Other responses which came from the PCT seemed to be in a standard form, which did not address specific issues which was in itself annoying and upsetting.

A number of patients and relatives sought out Cure the NHS and obtained considerable comfort from being part of that group.

It is worth pausing in this somewhat technical narrative to consider for a moment one or two of the actual experiences of patients and their relatives who, first of all, suffered poor care and then suffered again when they tried to make their way through to what to some appeared to be labyrinthine system which more often than not failed to work.

The story of the following patient relatives are typical examples of many that we have read. The witness is June Chell, the patient was Ronald Chell, her husband.

Mr Chell was taken ill on 26 July 2007, having covered a stroke. He was admitted to the hospital via A and E and subsequently moved to the emergency assessment



unit and then to ward 10.

There was a lack of basic equipment on the wards, pillows. Cleaners were attending to patients. Patients were left to wet themselves. Medication was given late. Mrs Chell felt that the nurses resented her being there with her husband. Mr Chell was assaulted by another patient who climb on to his bed and tried to strangle him. The hospital refused to provide any information about the assault, insisting that it made no difference to his death. The family were treated poorly by staff following his death.

Dr Laker's independent case note review into Mr Chell's case subsequently confirmed that the standard of nursing care on ward 10 was unacceptable.

The family wrote to the hospital in September 2007. In response they received a copy of an action plan, signed by a sister. The hospital apologised for the poor standard of nursing care, but Mrs Chell felt that she was being fobbed off and the family received no further communication from the hospital.

About a year later she wrote to the HCC. She did not have a clear understanding of the HCC's role at the time and still does not. She received a letter back from them to say that her letter would be considered as part of their investigation.



Although she now knows that there were a number of patient forums and patient liaison organisations, she did not know nothing about them at the time and saw and heard nothing of their existence. She regards the governors and the trust board as being of equal use of the patient forums:

"They did not seem to want to be bothered or to be part of it. For example, after the action plan was sent to us following our complaint, we never heard anything again. That is why it was so useless. We have no means of knowing if anything was done."

Well, Mrs Chell is a member of Cure. She has attended meetings and protests with them and she believes that the hospital should be closed. She sees the presence of the staff who were working there previously as a barrier to change.

The next witness I am going to refer to as Christine Dalziel. The patient was Thomas Dalziel. Mr Dalziel was diagnosed with bowel cancer in June 2007. He was informed of this in an offhand and distressing manner by a consultant who appeared not to have read the notes prior to the consultation. He was admitted to hospital on 17 July 2007 for an operation on the 18th.

After his operation he complained of pain but Mrs Dalziel was told he could not be in pain because he



was on an epidural. In fact, the epidural was wrongly sited and he was left in considerable pain, despite both he and his wife telling the nurses. He, therefore, did not receive any pain relief for three days post surgery.

He was left for many days wearing the same blood-stained pyjamas from after he had had his operation. He was not washed. He lost a lot of weight. The nurses didn't treat him with compassion. Many did not know how to use the equipment on the ward and basic equipment such as walking frames and pillows were not there. He developed bedsores and his limbs became very swollen. Mrs Dalziel was not informed that in fact the critical care team had to attend to her husband on eight occasions prior to his death.

The hospital attempted to discharge him while he was still faecal vomiting and was incontinent. He pain relief was inadequate. On one occasion Mrs Dalziel found her husband rolling around in pain; he had been waiting for a nurse for some 20 minutes.

After his death on 1 August 2007, the staff did not prepare Mr Dalziel's body before allowing the family to see him. The sight of him was horrific with a tube in his mouth, tape on his throat and his eyes wide open. No one at the hospital was able to tell Mrs Dalziel when her husband had died.

The family wrote to the hospital and it took several months for them to receive a response. They were not satisfied and, therefore, continued to correspond with the hospital.

The family noted that the responses appeared to have been cut and pasted. Mrs Dalziel met with the nurse from the PCT to whom she told her story. The nurse was unable to obtain an answer to all of the questions asked. The family have pursued a successful claim for damages against the hospital.

At the inquest hearing Mr Dalziel's consultant apologised saying there was a culture at the hospital where "no one tells anyone anything".

She says this:

"I appreciate that Martin Yeates is a scapegoat but he is answerable. He cut down the number of nurses in order to get foundation trust status. That is where the danger came in."

She feels let down by other organisations, including the HCC the PCT and Monitor. In her view, PALS appears to keep everything in-house. During her time at the hospital she had not even heard that PALS existed there.

Her comment is:

"If you ask me, PALS should go. They are a waist of time."



Mrs Dalziel is a founder member Cure has attended meetings and protests. She also advocates closing the hospital down and restarting it.

The next witness, wishes to remain anonymous. I am going to refer to her as Mrs A and her husband as patient A.

Mr A was admitted to the hospital on 21 December 2008 by A and E with symptoms, including shortness of breath, a cough and swellings to his legs. He was discharged on 6 February 2009 but died six days later at home on 12 February.

In essence, Mrs A's concerns were about the lack of basic care afforded to her husband, his hygiene needs were not attended to and basic equipment was missing from the wards. She did not raise a complaint formally immediately following her husband's death. She did not believe that it would be straightforward; describes lack of information about how to make a complaint.

Sometime later Mrs A received a letter from Mr David Kidney MP. He sent a letter to all his constituents inviting them to tell him about concerns at the hospital. At this point Mrs A decided to draw attention to her experiences. She wrote to David Kidney enclosing details of her concerns. There was delay in receiving a response, and in the meantime she was



advised to contact PALS. Eventually Mr Kidney contacted the PCT on Mrs A's behalf and requested a case note review. Mrs A did not find PALS to be helpful and felt she was having, as she puts it, to fight the system.

The next witness, Jeffrey Guest, his wife Irene Guest. Mrs Guest suffered from Alzheimer's dementia. She was taken to hospital on 2 January 2008 with suspected urine infection and was suffering with dehydration. The hospital discharged her at 3.30 in the morning -- it was January -- the next morning, wearing only a nightie, and it was only through the assistance of her son, who was a paramedic, that they managed to get her home. When they got her home they found that a cannula had been left in her.

She was readmitted on 7 January 2008, again suffering the effects of dehydration. Following her admission she was moved to ward 7, which is described as being disastrous. She was often left in a urine-soaked bed. Mr Guest was concerned that she was not being fed.

She was transferred from Stafford to Cannock Hospital on 5 February without Mr Guest being informed. When he arrived at Stafford to visit his wife, there was someone else in her bed. By the time he found out where she had gone, he had missed visiting hours at Cannock and was only able to see her very briefly.



Mr Guest says he complained to the staff at Stafford hospital when his wife there on a daily basis, but his complaints were never recorded. He did not know how to make a formal complaint.

Mr Guest wrote three letters to the hospital. The first two received no response. The third was responded to by the PCT, who apologised on behalf of the hospital but it seemed to him that the letter was a standard one. He did not feel it amounted to an apology.

Mr Guest met with Sharon Llewellyn and Liz Onions from the PCT, who explained how things had improved and offered him the opportunity to come and visit. A visit was arranged, which was supposed to be unannounced but upon arrival on the ward Mr Guest was suspicious that it was being staged and he felt deceived.

He also describes himself as a core member of Cure and is very proud of their work. He has participated in a number of protests. He disagrees that Cure's objective is to close the hospital. He describes the LINk as:

"... being hostile to Cure and appeared to want to support the hospital rather than wanting to listen to us or do something about the issues that we had raised", as he puts it.

The next witness, Deborah Hazeldine, whose mother

was Ellen Linstead. Mrs Linstead was admitted to the hospital on 27 July 2006 following a fall at home. She was suffering from bone cancer. She remained there until she died on 13 December 2006. She lost a lot of weight whilst in hospital. The standard of care she received was very poor and she suffered a number of infections, in particular cleanliness was an issue. There was confusion as to whether she had C.difficile when she died. She was therefore buried in a sealed body bag, which caused her family great distress.

Following her death the family complained to the chief executive. At that time Mrs Hazeldine also contacted the HCC but was told she had to go through the hospital complaints process first. The family met with Martin Yeates, Dr Suarez and Sharon Llewellyn on 20 December 2006. The family's impression was that Mr Yeates had not read the notes and knew little about the case. She describes the meeting as being very tense.

Following the meeting, she contacted the HCC again on 28 April 2007 and got their details from the CAB, as it was not clear from the HCC's website what their functions were or how she should go about contacting them. The Healthcare Commission upheld the family's complaint.



The trust sent a letter to the family in May 2007 that purported to enclose a report. The family did not in fact receive the report until it was requested by the HCC.

At the previous inquiry the family were shown a copy of a letter sent to them by the trust, which included a section about how to complain to the HCC but the family had not previously seen that section, which was not included in the copy of the letter that was sent to them. Eventually the trust sent them an action plan. It was for the wrong hospital. It was for Cannock and not for Stafford.

Mrs Hazeldine spoke to the PCT at a meeting in early 2008 but did not get a response from them. She met with Bill Cash MP who took the cause forward for her. She was frustrated at the amount of time this took.

She says this:

"You have to be bloody minded and focused in order to pursue a complaint through the HCC."

She thinks it needs to be easier to complain.

She is a founding member of Cure. She has participated in protests and attended meetings with the group. She is of the view that the HCC investigation lacked teeth. She describes it as being fluffy.

She says in her statement:



"If the hospital had a half decent complaints system, none of this would have happened. That is the one thing I would change and I would do it now but I could not find anyone to take ownership of the complaint. You would think once Monitor or the Strategic Health Authority or the PCT and Westminster are aware of it it would be better but it was not. Who else can you go to?"

The next witness again wishes to remain anonymous. I will refer to her as relative B, and patient B her husband.

Mr B was admitted to the hospital on 4 July 2008 and died the same day. His wife's complaint relates to the callous treatment he received on the day of his death. There were not enough nurses and water was placed out of her husband's reach. His body was simply left as it was after his death, which caused distress to the family. They were treated in an unsympathetic and uncaring manner by staff.

Mrs B received several letters from the trust where he died addressed to her husband. Mrs B did not raise her concerns with the hospital until after the inquest into her husband's death had taken place in February 2009.

The inquest was concerned with whether asbestos had



played a role in his death and Mrs B did not raise her concerns about the standards of care at the hospital. She would have welcomed the opportunity to make a private statement at the inquest but was uncomfortable with the public nature of the proceedings. She contacted David Kidney with her concerns in March of 2009. She met with him in April.

Mr Kidney endeavoured to progress matters with the hospital on her behalf and a meeting was arranged which took place in May of 2009, involving Eric Morton and Helen Moss. Helen Moss expressed sympathy and acknowledged that there were problems. She did not apologise, which is what Mrs B wanted. Mrs B felt that the only way she could get anywhere with the hospital was by enlisting the help of David Kidney MP.

In July 2009 she referred her complaint to the PCT, as she did not feel she was getting anywhere with the trust. Following discussion with the PCT, it was decided that Mrs B would go down the independent case note route before pursuing her complaint with the PCT, as she did not want to do both at the same time.

Following the independent review, she did not pursue her complaint with PCT as matters were superseded by the first inquiry. She was disappointed in the way that the first inquiry was handled and the apparent pressure to

get everything done so quickly. She has found the number of different people and organisations involved in the process of complaining to be confusing and frustrating, and she is in favour of a system of independent monitoring, akin to the system in the Prison Service.

The next witness is Janet Robinson who's son was John Moore-Robinson. John Moore-Robinson was 20 years old when he was taken to A and E at Mid Staffs on 1 April 2006, following an accident on his mountain bike on Cannock Chase. He was an extremely fit young man. The Ambulance Service triaged his case as being potentially life-threatening but moved him across rough terrain on his mountain bike. He was in great pain. He was given morphine by the Ambulance Service.

Once admitted to hospital he was left alone and left untreated for an hour. There was no consultant on duty that Saturday. Mr Moore-Robinson was seen by a one-year qualified junior doctor who ordered an extra of John's chest but failed properly to examine his abdomen. He was told he had bruised ribs and was discharged from the hospital whilst still vomiting and still in great pain. He could not walk. He was given a wheelchair. His friends had to request painkillers for him. His friends drove him home.



Later that evening he called an ambulance himself. He was taken to Leicester Infirmary. He died the following day having suffered a ruptured spleen.

Following the tragic and unnecessary loss of their son, the family were then let down at almost every stage of the process thereafter. The family were unhappy with the way in which the inquest in April of 2007 into John's death was conducted, in particular the decision not to call either the supervising doctor in A and E or the friend who was with John when he died. The trust solicitor is accused of demonstrating a complete lack of respect to the family. They regarded the inquest itself as a sham. When they wrote to the coroner to complain, their correspondence was, they felt, ignored.

At the first inquiry the family discovered a report prepared by an A and E consultant, Mr Phair, which had not previously been made available to them. The report was damning of the treatment provided at the hospital and Mr Phair was asked to alter its conclusion by the trust solicitor. It appears that the report was not sent to the coroner by the trust solicitor. It has been suggested that it was deliberately concealed. A police investigation is, we understand, ongoing.

A second report, written by the same consultant, suggested there was a high probability that the trust



treatment of John had been negligent. Attempts were made by the trust solicitor to have that report amended.

The trust made no contact with the family to offer any explanation of what had gone wrong. The family did not want compensation. They wanted an explanation. They wanted to know why their son had died needlessly.

A firm of solicitors corresponded with the trust on the family's behalf. They were advised by their solicitor that if they wanted to pursue claim for damages against the trust, then they should not utilise the trust's own complaint procedure.

The family accepted an offer of GBP 13,000 in compensation from the trust on the understanding the trust admitted liability for negligence. But it subsequently became clear that the trust was not admitting liability. The family would never have accepted the compensation if they had known that the trust was not admitting liability.

A letter of apology signed by Martin Yeates dated 28 January 2008, nine months after their son had died, was, as they later found out, written by a solicitor acting for the trust.

The Robinson family do not live in the Stafford area and so were unaware of the wider problems at the hospital until the time of the inquest and the



publication of the HCC report. The family have had some contact with Cure and have also enlisted the help of their MP in order to obtain further information about what happened.

The family went through the independent case review process and reported the report in March of 2010.

The family have had no contact from any of the regulatory bodies. From contacting the GMC themselves they have established that the doctors involved are under investigation.

The family are currently pursuing a complaint against the HSE, as they consider their refusal to get involved in the events of Mid Staffordshire was unacceptable. The family felt very let down by the whole process. They regret not having gone public about the case a lot sooner and they say this:

"It is our belief that the bodies responsible for regulating the trust failed in their duty with such tragic consequences for many people and families. Patient safety at the trust was such a low priority. In the period following John's death, none of the following regulatory bodies have contacted us: PALS, Strategic Health Authorities, Patients Association, Health and Safety Executive, GMC or any other body."

The next witness I am going to refer to is

Dr Mark Whitehouse, whose grandmother was Joan Morris. She died at Stafford Hospital and he has since that time qualified as a doctor.

He was completing his training at the time of the first inquiry, and decide not then to become involved but he has now qualified and he says he is conscious of the vulnerability of his position in deciding to speak out. He has been told by colleagues to be careful of what he says. If that is accurate, then it reflects, you may think, appalling badly on the culture within the NHS and it runs directly contrary to the legislation protecting whistle-blowers and contrary to the GMC's own guidance for good medical practice.

THE CHAIRMAN: Can I just interrupt there, Mr Kark, and say this seems to be a convenient point to say that if I get to hear that any attempt is made to deter any witness from coming before this inquiry by threats or implicit threats, then I will ensure that relevant action against them is taken.

MR KARK: I am grateful.

Dr Whitehouse believes that there were not enough staff on the wards at the time his grandmother was at the hospital, either nurses or healthcare assistants.

He says this:

"The current setup at the NHS is like a Swiss cheese



model. There are any number of organisations that are monitoring responsibility. However, there is no clear communication between them. There are too many people monitoring too many aspects."

He also expresses concern about the fact the hospital is usually tipped off about so-called unannounced visits. They are not, he says, a realistic way of assessing the care or culture within a hospital. We will, in due course, hear more about the lack of care in relation to the treatment of his grandmother, Joan, from his mother who is also a witness.

Let me turn to Cure the NHS, who have made a number of useful submissions, in particular through the statements of Mrs Julie Bailey and Mr Ken Lowndes. Julie Bailey will be our first patient relative witness and we will be taking her through a number of documents that she has gleaned over the years of complaint and investigation. It is largely as a result of their insistence that both the first inquiry and this public inquiry is taking place.

In their document entitled "This is our truth, now tell us yours" Cure set out a series of complaints against individuals and organisations who are either represented here as core participants or who will be giving evidence before the inquiry. Again in the



interests of brevity, I will summarise these complaints but many of them are of central importance to this inquiry and will underline much of the questioning of the witnesses to come.

Concerns have been raised as far back as 2001 by a consultant within the trust about junior doctors and nurse numbers. Those concerns were never acted upon and nurse numbers subsequently went down. Even before then, in 1999, the general secretary of the Royal College of Nursing warned the government about cutting nurses staff and to be cautious about diluting the skill mix too much. This was one of the fundamental problems which affected the quality of nursing at Stafford just a few years later.

The complaint system, as it was applied at Stafford, is variously described as manipulation and humiliation, the object being to wear down patient complainants and relatives in the hope they will go away. The complaints process is designed to fob off the complainants with a whole range of meaningless meetings and processes, action plans. The process is extraordinarily lengthy and is designed to obfuscate and protect the NHS, the hospital and its staff rather than genuinely making redress to victims and relatives. It is said to be extremely difficult for patients and relatives to



believe that the Patient Advice and Liaison Service, PALS, based at the hospital are really on their side when they are employed by the hospital. At Stafford Hospital that organisation is said to have been in effective. It is only fair to point out that PALS is now under new management at the hospital and appears to have a far more visible and we believe and hope effective presence, but we will hear evidence from them.

Even an MP, David Kidney, who spent some time working at the hospital is said to have missed the true state of care on some wards.

Another MP Tony Wright who received a number of complaints from constituents and passed them on to the trust was fobbed off with supposedly reassuring action plans.

Peter Carter, the chief executive of the Royal College of Nursing, who sent a day at the hospital wrote a letter in May of 2008 to the local press praising the nursing at the hospital as "of an exceptionally high standard."

The board was wholly in effective, say Cure, and filled with nodding nonexecutive directors who kept changing. Various government ministers have either ignored the complaints about Stafford or tried to assure the public that the failure was purely one of the

management of the hospital and that it was in effect a one-off event confined to Stafford.

Members of Cure entirely reject that as an unrealistic head in the sand approach. They are convinced there are many other trusts in the NHS with similar problems.

The PPIF chairman is accused of colluding with the hospital to suppress the complaints properly raised by members of the forum. The activities of the forum in relation to the hospital are described as being "useless".

The oversight and scrutiny committee of the local council accepted what they were told by the hospital management and failed to make further inquiry.

Cure ask whether the coroner built up any statistical picture of deaths at the hospital and asked "If he didn't, why didn't he?" They criticise the government for making the claim that foundation trust status would increase local accountability, whereas in the Stafford case, they describe such a claim as being totally false.

Contact with the Primary Care Trust produced the response that the complainer should talk to the management of the trust. Cure ask the question: why did the PCT not question the standard of healthcare when



board of Monitor held a board-to-board challenge and raised 46 questions. Cure are critical of the fact that only nine of those questions touched upon clinical matters. Monitor is further criticised for failing to take action as soon as it received the HCC's damning draft report at the end of 2008.

In relation to the patient forums and local oversight and scrutiny committees, Cure take the view that any hope of challenge to what was going on from either the PPIF or the OSC or LINk was misplaced. Cure implicitly and explicitly reject any notion that the failings at Stafford Hospital were attributable simply to the failings of local management.

They do not accept that Stafford was an isolated case. They do not accept any suggestion that similar problems are not happening or are not capable of happening elsewhere in the NHS.

Cure have this to say, and it is a clear and important reminder of the importance of the work of this inquiry:

"Stafford Hospital is probably at the very end of the tail of the poor performers but the big question is: how many more poor performance have been missed? The difficulty and the challenge for the Department of Health and the NHS is that they have no mechanism for



they were concluding their service level agreements with the hospital's management each year?

They ask of the SHA: why when a major deficit at Stafford was found in 2005 was there not some intervention, if only by way of guidance and support? Why, we will ask, did no one seemingly recognise the impact upon service and healthcare that the consequent cuts would inevitably effect? Why was the Royal College of Nursing not more active?

Particular criticism is reserved for Sir David Nicholson in his role of chief executive of Shropshire and Staffordshire NHS SHA, or SASSHA, in 2005 and 2006, when he presided over what Cure describe as "chaos" in the West Midlands as the PCT and SHAs were restructured resulting in those organisations completely, as they put it, "taking their eye off the ball".

In December 2005 the board of SASSHA and the board of the Stafford NHS trust conducted a board-to-board challenge, apparently to help the trust prepare its application for foundation trust status.

David Nicholson wrote a letter to Martin Yeates with a list of points which the hospital needed to address.

In December 2007, just before the trust was granted foundation trust status, the board of the trust and the



finding out; they have not developed and implemented modern safety and quality systems to guarantee high quality care for all, for every minute of every day of every patient's stay; systems designed and implemented by front line hospital carers with the help of patients. We are all patients and potential patients."

Let me turn, please, to the organisations which are there to support patients, both charitable and non-charitable.

Beyond the patients there is, of course, a system intended to assist in their complaints and to provide support or advocacy services to patients and their relatives.

There are a large number of both statutory and non-statutory bodies which exist, any number of which are intended to have a role to play both to protect patients from things going wrong and to provide an advocacy service when they have already done so. They did not prevent what happened at Stafford and there is a complaint that they were either compliant with the trust, complacent, naive or toothless. A brief examination of the recent history of these bodies is worthwhile.

Patient and public involvement is an umbrella term used to describe a wide range of activities and

interactions between the public, patients and the NHS. It has a variety of purposes, including improving the quality of services and securing the accountability for the NHS decision-making. Patient and public involvement are distinct and are achieved in different ways. Current or recent NHS patients are likely to bring different perspectives to bear to those held by the general public. Independent patient and public involvement structures are therefore intended to attend to the differing needs to NHS patients and to the wider public.

Community health councils. The first formal structures to represent the public interest in the NHS were Community Health Councils or CHCs. They were created in 1974 and were in place for almost 30 years before being abolished in 2003. CHCs had a duty to represent the interests of the public, to monitor local health services and to advise and be consulted by local authorities on health-related matters. They also had a duty to handle patient complaints and advocacy issues within the NHS trusts. CHCs had the power to veto proposals involving service redesign, to inspect and monitor services, and to refer matters directly to the Secretary of State. CHCs were criticised for lacking independent and for failing to attract younger members



and people from ethnic minority backgrounds.

In 2001 legislation was passed to abolish them and divide their functions between a number of organisations. In particular section 1 of the Health and Social Care Act 2001 placed a duty on Primary Care Trusts, NHS trusts and Strategic Health Authorities to make arrangements to involve and consult patients and the public.

Patient and public involvement forums were set up in response to the section 11 duty and were intended to replace the representative and inspection elements of CHCs' work. PPIFs came into existence on 1 December 2003. One PPIF was aligned to each NHS trust and PCT in England. PPIFs were made up entirely of unpaid volunteers.

They had a number of statutory powers, including: the right to access some healthcare premises; the right to request written information from trusts and PCTs; the right to refer matters to the local OSC; and typically the work of PPIFs involved patient surveys, service review reports, membership of the PCT and the hospital trust boards and committees, and visiting premises.

The transition from CHCs to PPIFs was not a smooth one, and reportedly result in the loss of expertise and experience. There was a difficulty in recruiting



members, such that forums often consisted of a very small number of people. Following a public consultation entitled a Stronger Local Voice, it was decided that PPIFs would be abolished, less than three years after coming into existence.

The rationale behind the abolition of PPIFs appears to have much in common with the rationale behind the abolition of the CHCs. The performance of PPIFs was considered to be variable and there was a perception that they were not representative of the community, as they had failed to attract young people and ethnic minorities. There was also a concern that PPIFs were overly bureaucratic and failed to provide good value for money. The abolition of PPIFs may also have been driven by a desire to strengthen the role of patient and public involvement in commissioning, in response to the increasing emphasis on primary care within the NHS.

The evidence we have obtained from those who are within the local PPIF tends to support the criticisms. Mr Robin Bastin has provided a statement dealing with his involvement, which began in March 2006. His criticisms of the PPIF structure are relevant to our purpose now, in providing information to avoid the same mistakes that he suggests were made previously. His criticisms were:



(1) the membership of the forum was too small.

(2) meetings were not advertised, so that the public did not appear to know of its existence.

(3) the chairman at the time was overly defensive of the trust, having been successfully treated there.

(4) criticisms of the hospital in meetings were either toned down or quashed.

(5) reports from the trust were not shared openly with members of the forum.

(6) when complaints from patients were passed on to the hospital, such as patients not being helped with their meals, there was no follow-up to see if things had improved.

(7) when Mr Bastin made complaints to the county council Oversight and Scrutiny Committee, he was told these were matters to be dealt with by the PPIF, which did not then deal with them.

(8) the PPIF was reliant upon the information provided to it by the trust, rather than inspecting for themselves or seeking out harder more granular information than they were getting.

PPIFs were replaced by local involvement networks, or LINks, which it was envisaged would give people a stronger voice in how their local health and social care services are planned and delivered and provide

better value for money.

LINks were established under the Local Government and Public Involvement in Health Act 2007. And pursuant to section 221 of that Act, LINks are responsible for: obtaining the views of people about their needs for and their experience of local services; promoting and supporting the involvement of people in the commissioning provision and scrutiny of local care services; enabling people to monitor the standard of provision of local services; consulting people as to whether and how local services could be and ought to be improved; and reviewing the provision of local care services.

Well, LINks are made up of individuals and community groups, such as faith groups and residents associations, said to be working together to improve health and social care services. 152 Local Involvement Networks were set up across England. They were designed to consult people about the local healthcare services, and to give them the opportunity to make suggestions to help to improve services, investigate specific issues of concern, hold services to account, ask for information, carry out spot checks to see if services are working well, make reports and recommendations, and receive a response and refer issues to the local OSC.



The Local Involvement Networks Regulations 2008 describe the duties to service providers to respond to recommendations made by a LINk and the powers of LINk to enter and review premises. The Staffordshire LINk was set up under the auspices of Staffordshire University, which had no previous experience of running such a body.

Linda Seru is the LINk director and sets out the problems which beset its organisation. The Staffordshire LINk was launched in December 2008, although a subgroup had already started work, and they held a meeting with Cure on 21 October 2008, and Cure had raised a number of urgent issues, in particular the care of vulnerable patients of all ages.

In summary, the problems which inhibited effective action by LINk, as Linda Seru sees it, were:

"(1) the HCC investigation was already underway in Staffordshire and the HCC did not feel therefore that LINk could contribute to it.

(2) LINk asked the HCC to make a presentation to them as how patients' views and experiences could be better used to help LINk inform commissioning planning and delivery of services by the PCT. However, the HCC did not feel they could assist with this.

(3) there were problems establishing formal contact with the hospital, and when contact was made the



meetings were held with Helen Moss, the director of nursing. Although good intent to work with LINk to improve patient care was mentioned, there was no evidence of actual activity. It appears that LINk did not or could not identify its specific role within the trust. Once the HCC had been published, the trust was under intense scrutiny from so many other bodies that they could not find time to work with LINk.

(5) there were significant internal problems within the members of LINk and also between LINk and the host Staffordshire University, so much so that in May 2009 the Department of Health had to commission an independent report, which was not published until September 2009, during which four months LINk was in limbo.

In short, it appears that LINk between 2008 and 2009 was a pretty ineffective force, and failed to perform the sort of scrutiny and public representation function that was envisaged for it. Mr Bastin was elected a member of the Stafford district committee of LINk when it got going in September of 2008, having been intended to start operating in April of that year. Again, he is critical of that organisation as being undemocratic and inadequately monitored by the county council. He also speaks of the internecine politics and the difficulties



with the host university.

Let me turn to POhWER and ICAS, the Independent Complaints Advisory Service. The complaints and redress function of the CHCs were divided between the Patient Advice and Liaison Service, PALS, and the Independent Complaints Advisory Service.

Section 12 of the Health and Social Care Act 2001 imposed upon the Secretary of State a duty to arrange for the provision of independent advocacy services to assist individuals in making complaints about NHS services. The funding and management of ICAS services is undertaken by the Department of Health, who have awarded ICAS contracts to several providers, including the Citizens Advice Bureau, the Carers Federation, the South of England Advocacy Project and POhWER, which in fact stands for "People of Hertfordshire Want Equal Rights". Well, POhWER is a register charity, whose aim is to address injustice and social exclusion. It has contracts with more than 20 local authorities to provide ICAS services.

The aim of ICAS is to steer people through the formal NHS complaints procedure. It is not able to deal with other bodies, for example, coroners or the GMC. ICAS is free, confidential and independent of the NHS. In addition to providing advice, ICAS advocates assist

in writing letters, accompanying patients and relatives to meetings, and assist in making decisions about how best to take complaints forward.

In common with PALS, ICAS services have come in for criticism for being provided in an inconsistent way across the country. ICAS does not have any formal links to patient forums, which can mean that valuable information gained through a service is not passed to LINks.

ICAS has also attracted criticism for lacking a public profile and lacking capacity. According to Carol Johnson, the executive director of POhWER, who has provided a statement to the inquiry, between April 2006 and March 2009 102 people contacted POhWER/ICAS with concerns about Mid Staffordshire trust. Of those, 74 received advocacy support. POhWER have sent with their statement a number of case studies that typify the delays and frustrations associated with making complaints to the trust. And POhWER have also submitted with their statement comments from advocates about their experience of complaints handling procedures.

Well, following the publication of the Healthcare Commission report in April 2009, POhWER launched an 0845 telephone number to support people with concerns about their experience of the trust. In November 2009 POhWER



formal manner, while the local formal complaints procedure would be covered by ICAS.

PALS was intended to provide patients with an identifiable person to turn to for advice and information, who would also be able to act as an independent facilitator to handle patient and family concerns, with direct access to the chief executive and the power to negotiate immediate solutions.

According to the Department of Health supporting the implementation of Patient Advice and Liaison Service, a resource pack published in 2002, the core functions of PALS are: to be identifiable and accessible to patients, their carers, friends and families; provide on-the-spot help in every trust with the power to negotiate immediate solutions or speedy resolutions of problems; act as a gateway to appropriate independent advice and advocacy support from local and national sources; provide accurate information to patients, carers and families about the trust's services and about other health-related issues; to act as a catalyst for change and improvement by providing the trust with information and feedback on problems arising and gaps in services; operate within a local network with other PALS in their area and work across organisational boundaries; and support staff at all levels within the trust to develop



delivered a customer care training session entitled "Listening and responding" to 16 members of staff at the trust, and POhWER have provided the inquiry with summaries of the trainers' evaluations of the delegates.

In January of this year POhWER provided the trust with a series of proposals for ideas for helping the trust to improve patient experience. POhWER expressed frustration at the fact that there has been no response to these proposals, and the fact that they have never been approached by either the HCC or the CQC to explore the experiences of their advocates of working with the trust. POhWER's analysis of current complaints handling at the trust is that it still seems unable to respond appropriately when told that things have gone wrong. Clients and advocates continue to be frustrated by defensiveness, miscommunication and delays. POhWER remain concerned that the organisations charged with overseeing the quality of services and compliance with standards failed to seek the views of the clients and organisations that are uniquely placed to offer a view on progress.

Let me turn to the Patient Advice and Liaison Service, PALS. PALS was introduced across England in 2002, and it was established in every NHS trust with the aim of resolving problems reported by patients in an



a responsive culture.

Well, as PALS is part of the trust it cannot be said to be truly independent and PALS perceived lack of independence has been criticised by some. It has been suggested that PALS has become marginalised as a consequence of not being linked into other structures. And further criticisms we will hear include the under-resourcing of PALS services, confusion between PALS and the formal complaint system, and reluctance by PALS staff to provide patients and families with information about independent sources of advice.

Let me turn to non-statutory bodies. AvMA, the Action Against Medical Accidents, is an independent registration charity established in 1982 to promote better patient safety and justice for people affected by medical accidents. They run a helpline and a casework service, an accreditation scheme for clinical negligence solicitors, and working to bring about change to the health and legal system that promote patient safety. AvMA believes itself to be the only organisation offering these services, and that the NHS and the Department of Health has a duty to promote its services.

AvMA was not aware of the issues at the trust until the publication of the HCC report in March 2009. Although AvMA did receive contact directly from patients

relatives affected by the trust and 45 were subsequently supported by AvMA caseworkers. There are, according to AvMA, lessons to be learned. With that sentiment we can no doubt all agree.

They set out their perspective on lessons to be learned as follows:

There needs to be greater awareness of the services AvMA can provide, since it is the only independent charity offering such support. Other bodies failed to advise patients' families about AvMA until very late in the day. The Department of Health and the NHS need to engage with AvMA.

Regulation of trusts. They say there must be joined-up thinking in who should monitor and regulate NHS trusts. This is a need to define clearly the roles of regulatory and commissioning bodies. The White Paper "Librating the NHS" proposes that Monitor concentrates on financial matters and the CQC is sole national regulator dealing with quality and safety, with an NHS commissioning board replacing PCTs, SHAs and National Patient Safety Agency.

This poses both opportunities and threats. NPSA issues vital patient safety alerts, but currently lacks teeth and cannot do anything to monitor or regulate implementation. An NHS commissioning board may have



more teeth, but will lack the pure focus on patient safety.

Data. There must be a consistent approach to dealing with data that comes to the attention of regulators and commissioners, such as high mortality rates. The Department of Health has set up a working party, as we know.

Regulation. There is a reluctance within the NHS, AvMA say, to interfere with the trust until the problems were so severe that there was no option but to do so. There were opportunities for the Strategic Health Authority and the Healthcare Commission to intervene much earlier. The reluctance to intervene persists in respect of the CQC, SHAs, PCTs and Department of Health, shown by their continued failure to intervene over the non-implementation of patient safety alerts.

AvMA research shows large numbers of outstanding patient safety alerts, despite the Department of Health writing to all trusts saying they must complete the required actions in the alerts by the given deadline. AvMA has made enquiries with the CQC and found it has taken no action at all in relation to the non-compliance with patient safety alerts.

The CQC is developing a system for quality and risk profiles for each trust, combining a whole range of



indicators. This tool, say AvMA, may be too blunt. They need to be more proactive. If a trust is out of line on a single indicator, it should prompt questions and closer scrutiny.

Fragmentation of family/patient support and advice. Community Health Councils were abolished by the government, as we know, controversially, they say. They had been a one-stop shop for advising about patient rights within the NHS, providing help in making complaints within the NHS, raising issues of concern for CHCs to follow-up within their monitoring role as a national body. From 2004, say AvMA, they replaced with a confused and fragmented range of bodies, PALS, ICAS and LINks.

AvMA say of PALS that because it is part of the trust it not seen as truly independent. It is sometimes poorly resourced and there is confusion between PALS and the complaints system. Often PALS fails to advise patients' families of independent sources of advice. ICAS, in AvMA's view, the contractual relationship between the Department of Health hinders independence. ICAS aims to steer people through the normal complaints procedure, but it is not sufficiently specialist or able to deal with other bodies, such as the GMC and the coroners.



The White Paper: Trust, Assurance and Safety 2007 recommended a specialist independent service to advise and support people who may wish to report concerns about health professionals, but that was not taken forward.

LINks, say AvMA, failed to have a sufficiently strong patient voice in the trust. They are separate from the complaints function, lack their own paid staff and have no national association, all weakening their ability to act effectively. AvMA supports the proposal for HealthWatch to replace LINks, as proposed in the Librating the NHS White Paper, but is concerned that housing it within the CQC will weaken its independence and force.

There must be a culture, say AvMA, of openness and transparency: (1) to enable staff to report problems without fear of reprisal; and (2) to ensure that NHS bodies are open in dealing with complaints. AvMA suspects that a critical report was suppressed by staff at the trust in one case that AvMA is supporting, where the report only came to light as a result of the first Mid Staffs inquiry. I suspect we know which that is. We will wait to hear from AvMA.

The Department of Health recognises, they say, that there is a culture of denial within the NHS. Librating the NHS says the government will require hospitals to be

open and honest with patients when things go wrong. AvMA proposes a statutory duty of candour. They propose that foundation trust boards should not be able to sit in Private. It is essential to promote accountability and transparency, and they also propose that there should be clear guidance on when a public inquiry should be held.

AvMA was disappointed by the lack of involvement it was allowed in planning the independent case notes review by Dr Laker, despite its offers of help to the Department of Health.

Use of information from clinical negligence claims should be used to inform work on patient safety and regulation. The NHS Litigation Authority, NHSLA, should play a major role in this through its clinical negligence scheme for trusts. The recent development of sending anonymised risk assessments to NHS trusts to inform their risk management processes is welcomed.

Clinical and non-clinical staff should be accountable without there being a blame culture. Within the trust between April 2005 and August 2009, only two doctors had been referred to the GMC and one nurse to the NMC. No accurate records were held by the trust for these figures. Other trusts also do not hold accurate records. Trusts must be more aware and involved in such



referrals and to be aware of problems arising. The fact that non-clinical staff with senior management roles in trusts are not bound by a professional code or a regulatory body is, they say, a flaw in the system.

Well, AvMA have therefore posed a number of questions for the inquiry and made some helpful suggestions which frequently find support elsewhere. What, perhaps, those at AvMA need to address themselves is the issue of why there was a lack of public awareness about their activities and the help that they could offer, and whether there was more that they could have done and could do to increase that awareness.

Let me turn to the Patients Association. The Patients Association is an independent charity that highlights the concerns and needs of patients. It works with the government and a broad range of individuals and organisations with a view to developing better and more responsive health services. It aims to reduce health inequalities by helping patients to be better informed and by campaigning for patients to have the right to be involved in decision-making.

The Patients Association produces a range of guides and advice booklets, and provides a helpline to support patients with any challenges of any kind they experience in health or social care. Now, we are still waiting to



see a preliminary statement from the Patients Association. But, sir, I have been told today that that is in the making, as it were. We should have that this week and we will be grateful for it.

We hope to hear from the director of the Patients Association, Katherine Murphy. The Patients Association has been involved recently in a number of national initiatives, directed towards ensuring increased and more effective patient involvement, including the institution of patient ambassadors, designed to be their eyes and ears across the UK, but of whom there are currently only 20, and the formation of local patient focus groups. We look forward to receiving the submissions of the Patients Association.

The functions previously undertaken by CHCs were divided into three distinct areas of responsibility: representation and inspection; scrutiny; and complaints and redress. The representation and inspection functions were initially undertaken by PPIFs, which were then replaced by LINks. The scrutiny function passed to the Oversight and Scrutiny Committees, whilst the complaints and redress function was divided between PALS and ICAS.

At present, patient and public involvement in the NHS is the shared responsibility of LINks, the OSCs,



PALS and ICAS. Foundation trusts also have a duty to engage with their local community and encourage local people to become members of the organisation. Foundation trusts, therefore, also form part of the public and patient involvement landscape. The extent, however, that the organisations listed above were effective in the roles they were intended to play is for us to examine.

Sir, I am about to turn on to local professionals and quasi-regulatory evidence. I am your hands whether you want me to continue at this stage or break now. I have asked, just so that you know, for a short meeting with the core participants when we rise, but if you would like me to --

THE CHAIRMAN: Having the advantage of your (a) speaking note, which you have more or less been loyally following, I can see you are nearly halfway through what you have to say.

MR KARK: Everybody in the room will be relieved, I expect, of that. Not quite halfway, but nearly halfway.

THE CHAIRMAN: Not quite halfway. But on the other hand we do possibly have a little more time tomorrow if we start on time than we have had today.

MR KARK: Yes.

THE CHAIRMAN: It is a long day and it must feel even longer

for you, being the only person to have said anything so far. So I think it would be a convenient moment for us to stop and we will resume again at 10 o'clock tomorrow.
MR KARK: I am grateful.
THE CHAIRMAN: Thank you very much.
(4.38 pm)
(The inquiry adjourned until 10.00 am
on Tuesday, 9 November 2010)



INDEX

PAGE