Wednesday, 19th December 2012 the issue to do with Forfar & Arneil. That's (9.30 am) 2 238-003-001 and you have already given evidence in 3 (Delay in proceedings) relation to that the last time you were here. 4 (9.52 am) Another one, that's responses to comments THE CHAIRMAN: Ms Danes? Professor Young has made. The reference to that is MS ANYADIKE-DANES: Good morning. Could I call, please, 238-004-001 and you have given evidence about that as well Dr MacFaul? DR RODERICK MACEAUL (called) 8 A. Yes. Questions from MS ANYADIKE-DANES Q. During the last occasion, you gave quite extensive 10 THE CHAIRMAN: Have a seat please, doctor. Thank you for 1.0 evidence on your experience and expertise both as 11 coming back. 11 a clinician and hospital management and governance and 12 MS ANYADIKE-DANES: Good morning, Dr MacFaul. 12 just generally as an expert. You have given that 13 Just to clarify matters in terms of reports, you 13 evidence and I don't propose to ask you anything further have prepared a full governance report for the inquiry; about that, but I just confirm that in relation to the 14 14 full governance report that you are adopting that report isn't that right? 15 15 16 A. Yes. 16 as your evidence, subject to anything that you deal with 17 Q. Just to make sure there's no confusion over the 17 here in your oral evidence. references, the reference for that is G238-002-001, and 18 18 you prepared a version which was an extract from that 19 Q. Thank you. We have, in part and with the benefit of 19 20 report of those parts that really dealt with the 20 your full report, explored with the governance witnesses clinical matters. 21 a number of issues and I don't propose to go through all 21 22 A. Yes. of that with you now. I understand that you've read 23 O. The reference for that is 238-002-001. That was dated 23 quite a number of the transcripts; is that correct? 24 July 2012. You also prepared some shorter responses for 24 A. Yes. ves. us. One, dated 3 September 2012, which was dealing with Q. What I would ask you, before we go into the issues that 25 I do particularly want to address with you, is there was before, that you have some input and relationship with some discussion, certainly yesterday, on the continuing the BNF -significance of some of the issues that this inquiry is 3 A. Yes.

dealing with. I wonder if you have had an opportunity to see the e-bulletin from the BNF, the British National Formulary, which is issued only in December 2012. For reference that is -- we can pull it up -- 311-048-001. If we go to the second page of it, 002, so this was issued this month, and one can see under that update 10 "Risk of fatal hyponatraemia with hypotonic 11 12 intravenous infusions." 13 What they are trying clinicians' attention to is: "The use of hypotonic intravenous infusion fluids in 14 15 children has been associated with fatal hyponatraemia 16 and the quidance of the British National Formulary section 9.2.2.1 has been updated to reflect recent recommendations in relation to the sodium chloride 0.1818 19 per cent and glucose 4% in intravenous infusion 20 throughout [which we have referred to throughout as 21 Solution No. 18] and is now contra-indicated in children 22 16 years or less, except when initiated and maintained under expert medical supervision in paediatric 23

4 $\,$ Q. Particularly in relation to the paediatric BNF, if I can 6 A. Yes. O. So does this still remain a live issue, how these fluids are use in children's cases? A. Yes, it does. I think there have been a number of 10 publications in the late 2000s -- around 2007, 2008 -where hospitals dealing with paediatric patients have 11 12 reported how they have implemented the recommendations 13 or the concerns, let's say, that have been expressed about Solution No. 18 and -- but it is an incremental 14 15 change. It has not -- there hasn't been a step change 16 and I think those papers reflect several things. One is in respect of the BNF -- this is 2012 -- the 17 18 NPSA alert came out in 2007. 19 O. Yes. 20 A. So we have a five-year interval, and the Northern 21 Ireland guidance came out in 2002. So there was 22 an interval of five years between the Chief Medical Officer's report from here, then another five years 23 before the NPSA issues an alert, and then another five 24 25 years before the BNF, which has just come out. What

I recognise from your CV, when you were discussing $\label{eq:cv} \mathbf{3}$

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specialist settings."

I think this illustrates is that, within the healthcare system, governance at the highest level -- that is the Department of Health and so on -- it does take time. The intervals are very similar in how science gets into textbooks and then an interval after textbooks gets into guidelines and these cycles take several years each time. So whether it's possible to speed up this process is an issue. It should be nowadays, but it is a matter for remark how the intervals are present and relevant 10 perhaps to this inquiry. 11 O. Thank you. Thank you very much. Just on that guestion 12 of what's topical still, there was -- I think it was 13 Professor Lucas who was talking about death certification. 14 15 A. Yes. 16 Q. We can pull this up also, 311-045-001, which is the most recent report from the Office of National Statistics. 18 This is a new issue that they have reported on; it is not one of their series of statistical data and you can 19 20 see it is: 21 "Death certification reform: a case study on the potential impact on mortality statistics." 23 If one just looks at the key findings there,

although they accentuate the positive that the case

study on medical examiner scrutiny of death certificates

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certificate a 1:5 to a 1:4 chance of it being potentially inaccurate. This report was based on a study, I think -- if one looks at the document -about half a dozen regions that they -- yes, here we are: Brighton, Mid Essex, Gloucestershire, Powys and Sheffield. So that's five regions that they were 10 looking at. 11 If one goes over the page to page 2, one sees 12 certainly in England how they are going to seek to address that by appointing a local medical examiner and all deaths that are not reported to the coroner are going to be scrutinised by that person and that system 16 is going to come into force apparently in 2014. Can you help us with what's underlying this concern and how it relates certainly to the cases that we have where we had death certificates changed? 20 A. Yes. I think it's a very positive step that this is 21 happening, in my view, but just to provide some background, at the moment, as far as I understand it -well, not at the moment, and I will explain it -- but in 23 2.4 1996 and in 2005, once a death certificate has been completed, the only quality check in that process seems

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found that in 78 per cent of cases the underlying cause

of death remained unchanged, which means on 22 per cent

it was changed, which gives you on any given death

to be when it is registered at the registry office. That's as far as I understand it. There have been concerns expressed over a number of years about the quality of death certification, for example, in the report which was under the aegis of the chief medical officers of Northern Ireland and England of sudden death in epilepsy, which I referred to in my report to do with the appropriateness of the conclusion that Claire had died from status epilepticus because that study showed that something like -- well, it was a high figure -a significant proportion of death certification was regarded as unsatisfactory. The deaths from epilepsy in children were found to be very few -- I think there were 80 in the country at that time -- and this was a study including adults. The conclusion was when the death certificates were

reviewed, a significant proportion of them were poorly completed, and in my own collaboration with Professor Goldacre at Oxford looking at deaths in children -- I had a particular interest in deaths from infection because I had come to the conclusion that the commonest cause of death in children, after the newborn period, after age 1, was infection, and yet the ONS, Office of National Statistics, reports did not indicate, because they said congenital malformation was the

nonest cause of death, but actually infection in children with congenital malformation leads to death. And if you die from cancer, infection is often the So professor Goldacre, in Oxford, had done some record linkaging and managed to look at categories 1, 2 and 3 on the death certificates and found that, ves. infection was important, but they would put cancer first or something like that. So it was obscured by the 10 quality of the death certificates and much of the data 11 in the categories was incomplete. 12 So there was a concern then about death 13 certificates. So to find some process of quality control is good and it is welcome and it happened after 14 15 Shipman, but Shipman was in 2003, and it is going to 16 still be 2014 before it is widely adopted that there's 17 a quality control. So again we have these periods, if you like, between 19 a recommendation or a concern being raised and then some

20 form of implementation. 21 Q. But if I ask you how that might perhaps relate to this 22 inquiry: so if the department, for example, or for that matter the Trust, wanted to look at the incidence of 23 24 deaths by examining the death certificates where 25 hyponatraemia was involved, they are dependent upon how

accurately, either as a primary cause or any of those 2 secondary options that -- quite often it is the junior doctors, it seems to be, who are completing those certificates, how accurate they are in ascribing any of those to hyponatraemia. Is what you are saying that if they don't ascribe it even as a contributing factor to hyponatraemia, you might miss the incidence of hyponatraemia, if that's your source of data? If the -- yes. Death certificates, of course, are not 10 usually reviewed in a hospital setting. The cause of 11 death is, but not the death certification. The Office 12 of National Statistics is entirely dependent on what is 13 recorded. So when they produce data and statistics, 14 they've only got what has been registered and unless they cross-check it with the hospital system, such as 15 16 the Patient Administration System. I think in paediatric practice where deaths fortunately are few -in most general paediatrics they are few. They are 18 higher, of course, tragically in paediatric intensive 19 20 care and in cancer treatment, but many paediatricians --I have spoken to several of them over the years -- would 21 choose to fill in their own death certificates rather than leave it to a junior -- in general paediatrics 23 24 rather than speciality paediatrics -- because of this concern and medical students still are not particularly

well trained -- nor are junior doctors -- in how to fill in death certificates.

3 Q. Thank you. Thank you very much. What I propose to do to get your best assistance is, in the course of both the clinicians and those who had, if I can put it that way, governance roles -- and sometimes that means one and the same person -- in the course of evidence that we've heard over that's weeks, a number of concessions have been made about a range of matters or acceptances 10 that things perhaps could have been done slightly 11 better. And if I go through them by way of category, we 12 have the transcript references for all of these. 13

I am not going to burden or take up time giving all those, but if I give the broad categories of things, if anybody feels that I have misrepresented them, then I am happy to hear them.

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One category is the issue of document recording and documenting. That seems to be an area where a number of the clinicians have conceded that things could have been done better. I am talking about 1996 standards. They would range from Dr Steen to Dr Webb, Mr Walby, a number of them who have given evidence and have recognised that.

Then there is the issue of communications, and that's quite a broad field, and people have recognised

that whether we are talking about those recognising who was the consultant who was actually primarily responsible or whether one is talking about the communication between clinicians, senior and junior, or communication between the clinicians and nurses, or indeed the communication with the parents, that a number again of those who have given evidence have recognised that there were deficiencies there, most certainly in relation to the communication with the parents.

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If one moves on to the clinical issues, whether one talks about the failure to do a blood test earlier than appears to have happened on the Tuesday, or the drug administration and the failure to pick up errors in the dosage and so on, down to the failure perhaps to appreciate or communicate quite how seriously ill Claire was over the Tuesday and perhaps also leading into the failure to discuss Claire with the PICU personnel, irrespective of whether she might have actually been transferred, or at least initiate that discussion, and again a number of clinicians have accepted in those areas that there were -- things could have been done

Then there is an issue of resources, and that is --I suppose it spans from whether the CT scan was easily accessible in that hospital. One had to take the child

in an ambulance across the site. There was an EEG service, but that was not an emergency one and there was only one technician at the relevant time. A number of clinicians have commented on that. Whether that actually influenced the decisions they make, but certainly it was something they were aware of, if I can put it that way.

Then, of course, there seems to have been quite a big area about staffing levels, cover and workload and so on.

Then finally, another large area where there have been concessions or acceptances about things that could have been done better is the area of investigation from the referral of Claire's death to the coroner, which a number of them felt might have happened -- should have happened -- to what sort of post-mortem examination was arried out, through to the clinicopathological correlation, the discussion between clinicians and pathologists, through having grand rounds and paediatric mortality meetings.

21 There has been a debate about whether they happened, 22 but certainly there seems to have been an acceptance 23 that if they did happen, then there doesn't seem to have been an identifiable outcome from them. 24

Finally, if one looks at 2004 to 2006, the whole

issue of whether there was a proper complaints process about the concerns Claire's parents were mentioning, whether there might have been an earlier SAI or discussions with the coroner and PSNI to enable that to happen, whether there could or should have been a root cause analysis and whether, in general terms, there should have been some review of Claire's case in some way from a multidisciplinary point of view.

Those seem to have been the broad headings under

which the clinicians and those who are charged with governance have accepted that things perhaps fell short.

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What I wanted to ask you about is: if one looks at that, and it seems quite a catalogue if one does, but if one looks at that, how and by whom should those matters have been identified apart from in the way that they were ultimately -- some of them were identified in the inquest and yet more have been identified in the process of this inquiry.

Leaving that aside and looking at that time from the hospital, from the Trust's point of view, how should those matters have come to light in your view?

A. Well, there are two main phases that you referred to.

One was in the immediate aftermath of Claire's death in

1996 and then there was the situation in 2004. Perhaps

structured way of doing it. They wished to be able to

if I deal with the two separately.

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say they were doing it -- and they were -- and there was good enthusiasm for doing audit, but the actual way they did it was not all that understood. From my own experience, although the quidance which came out from the Department of Health and so on was quite strong about collating an audit report at the end of the year. reporting your audit into the medical director and the chief executive of the trusts, in my experience that hasn't been done very often. It certainly wasn't done in the late 1990s, although the guidance was there. Rather as we were discussing earlier, there is a lag, an interval, before something is put in place and then it is adopted and this was the same with these reports. So that's why I feel we have to look at 1996 through a different prism or viewpoint. I was not able when I was looking through the reports of clinical incidents for example, in the Royal Hospital Group, to identify any pattern of analysis of the clinical incidents, at least up to about 2000. There was a detailed analysis of falls and tripping or things happening to patients that shouldn't have done and excessive radiation given perhaps by mistake, but the clinical incidents, I didn't see any collation. It may be that document exists and if so, it would be helpful.

Because clinical governance, as it came to be 2 embedded further, was still -- apart from audit -relatively rudimentary in the late 1990s even, because the involvement of clinicians as clinical leads or clinical directors was in place, and we know it was in place at the Children's Hospital, but the process by which it was conducted and the responsibilities understood by clinical leads and clinical directors was very wide and often was not fully understood. There was 10 little guidance on what they should be doing other than 11 common sense. They were part of a system which was well 12 embedded, which was general management, and how 13 a clinical lead or clinical director could influence 14 what went on was, to an extent, dominated by saving money in the end. So if you identified shortages of 15 16 medical staffing and you could have done -- and I believe Dr Hicks did -- you are then having to create 18 a case against other cases to very often restrain -- to protect yourself from budgetary restraint rather than 19 20 develop. So it was all a little bit still in evolution. There was much more control of consultants' work 21 patterns from the early 1990s, and much more embedded 23 and taken up was audit, clinical audit, but even there 24 the practice of clinical audit by clinicians was done sometimes without due acknowledgment of the more

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So that's the 1990s. The 1990s was an evolutionary
    phase and a considerable lack of awareness perhaps.
    Nevertheless. I would have expected a clinical director
    or clinical lead at that time to be assured that audit
    was in place and to request or make sure somebody
    aggregated every year what was the general trend.
O. If I can just pause you there at that stage: when you
    say you would have expected that to happen, given the
     sorts of things that you ever read about in terms of
    what people have conceded or accepted was deficient in
    Claire's treatment and care during her admission and the
    sort of categories of things that I just read out to you
    then, summarised to you there, is what you are saying
    that the clinical lead should have been able, after
    Claire's death, to have in some way or other identified
    those failings?
    Well, I think it was -- and I have referred to it in my
    report -- the extent to which the clinicians recognised
    that this was an unexplained and unexpected death. This
    is where -- if it was unexplained, then clearly there
    would have been an incident raised. The profile of the
    event would have been higher and it would have been
    investigated, but it seems to me that the clinicians had
    come to the conclusion that this was a natural death.
    The certification was flawed because it seemed to me
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that with Dr Steen sending a letter to the parents in November giving a leaflet about meningitis, that she had in her own mind come to the conclusion that this was a death from encephalitis; in other words, an infection. Q. Then if she forms that view, Dr MacFaul, are you saying because she is -- both she and Dr Webb, who are senior consultants dealing with Claire, if I can put it that way, if they form that view, does that stifle any overall review of Claire's case to enable the clinical 10 lead to identify these sorts of deficiencies or 11 failings? 12 A. Well, I think it does. I think that there's clearly --13 because it's a regional training hospital and it's dealing with complex cases, there are, as we have seen, 14 something like two deaths a month, 24, whatever it is, 15 16 a year. And amongst those, from the data that was submitted by the Royal, I was able to try to try -- and it is very subjective -- to identify these that would be 18 unexpected and unexplained, looking at the diagnostic 19 20 coding that was given, and I have submitted a note to 21 you about that. There were six of those in the year. It seems to me that six is not a large number of unexplained or unexpected, but the problem is whether 23 24 that was seen by the clinicians and I don't think they saw this as unexplained. I think Claire's death, in

their minds, had been explained, and so it wouldn't be raised. On the other hand, the only way you can assemble a picture of the deaths would be to look at the causes,

and it would be reasonable for a clinical director to not only make sure there were mortality meetings in place, but to say what the purpose of them was. One of the purposes is to aggregate the causes of death and the reason for that is to identify any unusual patterns. 1.0

O. Yes. I am going to ask you to develop that, because 11 otherwise you're left with the situation where, if the 12 consultants don't regard the death as anything other 13 than by natural causes, and therefore -- so, for 14 example, it doesn't go to the coroner, who would conduct its own investigation. Then if all this investigation 15 16 in relation to the circumstances of what happened is dependent upon the recognition by those consultants as to the classification of the death, if you like, then 18 19 that might mean that you never get past first base, if 20 I can put it that way, in terms of analysing what 21 actually happened, even though some of the others who did have something to do with Claire's death in this 23 case did feel that there were concerns. 24 If one takes Dr Bartholome, for example, she was of

the view that Claire's death should have been reported

to the coroner. She is the last most senior person who

dealt with Claire. She is at registrar level. What I am trying to get from you is. leaving aside the consultants recognising it and then reporting it to the clinical lead because they have recognised something went awry, is there any kind of routine way, in your view, in 1996, where the circumstances of any death of a child are looked at so that there is someone more than just the consultant or other clinicians directly involved who are actually looking at the circumstances of what happened, because we know that the clinical 12 lead, Dr Hicks, was of the view that if she knew what she knows now, that's the kind of case she would have expected to have been referred to her? 15 A. Well, the route would have been through -- in 1996, the route should have been through the mortality meetings. because audit was well embedded, and that would have been the route, providing that there was documentation of what was discussed and that there was an aggregation 20 of what was discussed and perhaps reported now and again, but, for example, a death from status epilepticus is not all that common, and when it occurs -- and that was one of the things on the certificate -- it is 24 an unusual event of its own, but when it does occur, it is usually from major tonic-clonic status, not from

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So had a audit meeting been held, not just with the clinicians who signed Claire off, but other consultants would say, "That's a bit odd", and, "Should we look at that?". So in that sense, yes, I do think that the clinical directors' process and the meetings should have identified it, and we know that in the late 1990s there was sufficient concern about sudden, unexpected death in epilepsy to generate a national study, the SUDEP trial, which I referred to earlier, where there was an investigation of every death from epilepsy in the whole of the United Kingdom and it reported only 80 So it was an unusual event in and of its own, but I would have expected the forum, where, if you like, there's a cross-check quality control of the clinicians' conclusion to have been through the audit meetings at that time if they hadn't seen it as a major adverse event. Q. So what then, in your view, is the purpose of the mortality meeting? 22 A. It is a form of the -- it is within the framework of audit and if you are wanting to -- I mean, to take

a little time, audit is done in structure, process and

outcome and the structure is what facilities you have:

do you have enough staffing, do you have enough access to investigation? The process is: was a particular condition managed against the standards for the management of that condition? If there are standards and good guidance on how you manage condition A, did we manage it according to that? So that's the process.

Outcome is death or outcome is loss of a limb or something. What I know about the problems in paediatric medicine, as opposed to surgery -- where in surgery you have deaths or you have post-operative infections, so you can count it -- is that in paediatrics it is not easy to identify sufficient outcomes to make it useful.

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In the BPA, British Paediatric Association, in the 1990s, we set up a working party because of that concern and were not able to come up with anything particularly helpful.

It is for that reason what is done is to come back to the middle, process: we believe we can improve outcome if we manage a child according to good guidance. You are using the process there to be a proxy for good outcome. Therefore, that's how audit is done. You record what you've done, because the purpose of audit is then to do what's called a cycle. You identify what you've done, find out whether you're meeting a standard, and you won't 100 per cent. Nobody does. So you find

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3 A. Yes.

recorded. The linkage with the index patient, in this case Claire, was by the guidance of the audit working party of the Royal College of Physicians, on which I sat as the paediatrician from the early 1990s, was that there should be anonymisation and that any records which could be linked to that patient should not -- and any discussion in relation to the patient should not be recorded and that -- but the issues that arose should be, and just to follow that on, the Patient Administration System would have recorded the cause of death, so that was linkable, but at that time we were told to tear up any notes that we had made and not store them, and certainly not put them anywhere near the case records, so that if there was a litigation later, those could not be insisted -- they couldn't be released to a litigation process, but that was as audit was developing, and the advice we had from that was, a very high level, endorsed by the Chief Medical Officer. So that's how audit got in, and in 1996, that's 20 possibly how it was understood, and I would agree that the linkage with the patient should have been anonymised, but the issues which arose should not MS ANYADIKE-DANES: Just to be clear: the advice you said 23 from a very high level, the Chief Medical Officer, that 24 advice wasn't that you shouldn't record the issues, just

then you either change your guidelines or teach people in them and you then do another audit later, and the only way you can do audit properly is to record what happened at point one in time and then leave an interval, revisit it, and see if you've improved. So the failure of recording in an audit meeting means that it's rather a futile process. THE CHAIRMAN: But I was given to understand, doctor, that 1.0 failure to record was standard and the argument was that 11 this allowed open debate, sometimes critical debate, 12 though not necessarily so, about whether things been 13 done which should been done better, and it avoids -- the fact that it is unrecorded allows that debate, but also means that any recorded discussion is not available 15 16 for -- by way of discovery in any medical negligence 17 18 Whether it is right or wrong, is that approach one with which you would have been familiar in the 19 20 mid-1990s? 21 A. I think it's -- yes. The problem is that you do want to encourage open debate and argument and you do want to 23 encourage people to admit perhaps error or failure to 2.4 meet a guideline. The importance, though, is the

a percentage where you haven't. You record that and

linkage with the individual case. The issues should be

that you shouldn't record them in such a way that they

could be linked back to the particular patient?

 ${\tt 4}\,{\tt Q}\,.\,$ Thank you. From what you were saying, you need to record the issues so you can complete your cycle of audit. A. Yes. There is another way that a clinical director can obtain the information. I have to say that many people do not have confidence in the hospital coding system for 10 good reasons, but it seems that many consultants are not 11 aware of what the hospital coding system can deliver to 12 them. The coding systems are used by the hospital 13 management system to count the numbers of patients, 14 their date of birth, age and so on, but also to put 15 their discharge diagnosis or the cause of death, and 16 that data, the coding clerks -- you have heard from the 17 Royal about this -- they are quite skilled, and they are trained in what to do and they don't just take it from 19 the discharge letter if one is produced. Then take it 20 from going through the records. That is a source of 21 information which is available. Many consultants say 22 they didn't know and, of course, that distresses me, because I published in the Archives about how you could 23 24 use medical information systems, but the fact is that

I don't think many people have used it to the full

- extent that they could in audit process.
- 2 It is possible, for example, for a clinical director
- at the end of a year to say, "Let's look at all our
- admissions. What were the diagnoses? What were the
- diagnostic profiles and how many died?"
- Q. And to look at patterns you mean?
- A. Yes.
- THE CHAIRMAN: Was that happening in the mid-1990s in your
- 10 A. In some hospitals, yes. The surgeons didn't use it
- 11 much, because they were completely disparaging of the
- 12 coding system for good reason. I mean, some hospitals
- 13 only had coding for about 80 per cent, 70 per cent, and
- other hospitals were not coding accurately. We know 14
- that, and the surgeons didn't have confidence in it. As 15
- 16 a consequence of that, many surgical departments would
- have their own audit IT and so did the PIC unit, as we
- have learned s0 they could feel more confident of what 18
- 19 had been put in it.
- 20 MS ANYADIKE-DANES: Is that is that not a governance issue
- 21 in itself, that you have a coding system that clinicians
- or directors who would otherwise like to use it for the
- 23 purposes you have described don't feel confident they
- 24 can?
- A. It is current now. Still continues.

- proactively saying to their clinical departments, "Where
- is your annual audit report?" I know that that happened
- in the 1990s and it must have been only a minority where
- that was being done.
- THE CHAIRMAN: Does this explain, doctor, why, when the
- inquiry looked through the records of meetings of the
 - board of the Royal Group of Hospitals Trust, it found
- only three instances over a number of years at which
- deaths of patients had been discussed? Overwhelmingly,
- 10 the board discussion was about important issues about
- 11 staffing and new the children's hospital, new buildings
- 12 going up, and so on, but there was almost nothing to do
- 13 with deaths of patients.
- A. That's true, and I think the other way through that, 14
- 15 sir, would be through the clinical incident reporting 16 system, and I haven't been able to see any analysis of
- 17 the clinical incident reporting system other than the
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- 19 THE CHAIRMAN: So when that -- if that was happening in the
- 20 Royal, as it was happening in the Royal, the Royal was
- 21 in keeping with other hospitals and trusts that you are
- 22 aware of throughout the UK?
- A. Yes. 23
- 24 THE CHAIRMAN: Right. Thank you.
- MS ANYADIKE-DANES: To what extent at that time was that

- THE CHAIRMAN: The problem still continues?
- 2 A. It does indeed.
- 3 MS ANYADIKE-DANES: So then I think you would say this is
- how the clinical director or the medical director could
- have learned of these things presumably through it going
- to the clinical lead.
- 7 A. Yes.
- O. In this case it would have been the paediatric clinical
- lead and then up to -- do you say that some of thes
- 1.0 issues should have found their way to the medical
- 11 director?
- 12 A Well --
- 13 Q. If you do say that, then how do they get from the
- clinical lead to the medical director in your 14
- experience? 15
- 16 A. Well, my experience is it didn't happen very much. The
- 17 point about -- if there was an issue, if you had
- 18 an abnormal pattern or there were some concerns, you
- would obviously take it up with the medical director and 19
- 20 the Trust management, but the process of annual
- reporting, which had been identified as part of audit 21
- and had been recommended by the Department of Health
- 23 from the early 1990s, was not done, and furthermore it
- 24 wasn't sought by general management. In other words.
- the chief execs and medical directors were not 25

- recognised as a problem and a deficiency, even though
- not just the Royal but others were also failing in the
- way that you have just described?

- 4 A. Well, in my experience, management systems in hospitals
- are overwhelmed with other things. They are all signed
- up to and all would acknowledge that quality is of high
- importance, but delivering high quality care is
- competing with the other pressures that are present in
- trusts and management and they are largely financial, I
- 10 have to say, and so there is a tendency for the focus to
- 11 be on those and not on being able to improve quality or
- to focus on it. Certainly that was the case in the late 13 1990s, but as matters have moved on, of course, there
- 14 has been increasing concern and, for example, now
- 15 Dr Foster can produce or is trying to produce clinical
- 16 outcomes by surgical consultants, for instance, rather
- 17 than just a unit. It's been a matter of some of
- that surgeons were worried that on the websites will
- 19 appear their individual mortality rates. They are
- 20 worried because it can look bad if you are choosing
- 21 a case mix of people with serious illnesses selectively
- 22 rather than less serious illnesses to operate on. They
- were concerned that it would identify somebody who was 23 perhaps what you might have called a brave or courageous 24
- 25 surgeon in the past and he would have bad results. The

reason surgeons have been concerned about it is because of the coding system and the systems are not sufficiently sophisticated to identify the severity of the patient's problem. They just record the surgery. That was also one of the concerns that came up in the Bristol inquiry, generally.

When I worked in the -- just after I retired in the National IT Process, I appreciated that there had been quite a lot of work done by the surgeons and the Royal College of Surgeons to improve surgical outcome by creating databases separate from the NHS database. One of the problems that the IT system faced was how do you adopt and bring in these what are called -- what they called legacy data collection systems, because there were processes in hand by the National IT Programme even in the early 1990s to improve data acquisition.

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One of the best ways is for the consultants themselves to write down the diagnostics that they have done and for that to be put into the system, but that doesn't happen. So what they would do is create their own databases and some of those were funded by the Department of Health. For example, in Wales they had a clinical workstation project which was run. They had a pilot site in Aberdeen and they had a pilot site in Pinderfields. The pilot site in Pinderfields was the

wireless-enabled ward in the country because there was concern that the wireless would interfere with our monitoring systems, but we were able to get a process where we acquired data and we coded it ourselves and it was coded automatically by the secretaries. That was in place from 993 onwards until I retired, and it meant that we were able to get much more accurate coding of our discharges, and also we were the only paediatric 10 department in the country to code every outpatient with 11 a diagnostic code because the money had been put in. 12 Was that accepted by the hospital trust? No. 13 Pinderfields wouldn't continue it. They wouldn't adopt it. They chose to go along with their own coding 14 system. That's where conflict comes. I mean, the 15 16 reason that it stopped after I left was I was clinical director until I left and I insisted that it was kept 18 going, but once that leverage had gone, they said, "Good, he's gone. We will go back to the conventional 19 20 system". So this is -- this is the kind of pressure that clinicians have in trying to influence what happens 21 in quality in hospitals. 23 THE CHAIRMAN: Doctor, can we look at Claire's case from 2.4 a slightly different perspective? Let's suppose what

Burns unit and my own ward. We were the first

process, but it should be more developed and perhaps a bit more sophisticated than it actually is, but even by the standards of the time, is there not a terrible lack of curiosity among the doctors about why Claire

A. Yes. I mean, I think one would have to say that what is

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outstanding there is, in Claire's case, a lack of reflection upon -- for example, the death certificate showed "status epilepticus" and then they had later the information from the pathologist that it was meningoencephalitis, but I would have --13 THE CHAIRMAN: You don't need any developed or sophisticated

governance structures to think -- surely that must have 14 15 made people pause and think and really reconsider what went wrong in Claire's case.

16 I would have to go back over the transcript. I am not sure Dr Webb knew what the death certificate had 18

19 written, but I don't know about that; I just raise it as

20 a question. But I don't know how he formulated her 21 death. I think that he had come to the conclusion that

it was cerebral oedema, because obviously that had been present, but he didn't seem to reflect on how that had 23

been caused, because if it was status epilepticus, then it would be unusual for non-convulsive status to do

that. We know he didn't expect her to die. If it was

encephalitis that had been put down and was their higher

you are talking about in the mid-1990s there is an audit

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consideration, then I can understand that they may not

have reflected too much on the management, because

encephalitis has a high mortality, and acyclovir, which was the drug that was chosen, only works on herpes

simplex encephalitis, which is only a subset of the other viral causes

So to have a girl die from encephalitis and from 10 cerebral -- encephalitis can cause cerebral oedema on

11 its own -- would perhaps make them not too concerned

12 about what had happened, but in the immediate aftermath

13 I don't know to what extent Dr Webb had signed up to 14 status epilepticus, but clearly from the fact that

15 Dr Steen later sent the parents a leaflet on meningitis.

16 that's an infection of the brain. That meant she was

17 still thinking that that was encephalitis. So neither

of the clinicians appear to have reflected that it was

19 something in the management that might have led or 20 contributed to the cerebral oedema.

21 THE CHAIRMAN: But would encephalitis not be a very rare

22 cause of death?

A. Well, encephalitis is not very common, but it is 23 a recognised illness of severity and it does have a high 24 25 mortality -- I think something like 30 per cent.

MS ANYADIKE-DANES: Dr MacFaul, you are now answering the chairman from the point of view of leaving aside all the systems there might be for audit, almost on a case-by-case basis, and that if there are things that seem unusual or rare for some reason, then one looks at them just to see that you're absolutely sure what happened, then the process might lead to further investigation, but if one starts -- what you have identified is the possibility that the two consultants 10 involved in Claire's care had slightly different -- not 11 slightly -- totally different views as to what had 12 caused that cerebral oedema, if I understand you. 13 If we go with your concern that Dr Steen was thinking very much more of the encephalitis side of 14 it --15 16 A. Yes. 17 -- if that's the case, and sticking with the chairman's view about reflection, when she gets the post-mortem 18 report that tells her, "Well, we did find some evidence 19 20 of it, but it is very low grade, it is sub-acute", and 21 that, as we understand it now, means not really the sort of thing that is triggering or leading to death. So

cerebral oedema, they actually haven't found that. Does that then not spark another discussion? Either way it gets you into some sort of examination of actually why Claire had died. 5 A. Well, I think the opportunity to do that was in the --

was in the mortality meeting and in what we have learned was the clinicopathological conferences, the neurosciences grand round.

In their own mortality meetings, I think the Royal 10 or the Children's Hospital, by their own standards, 11 would have expected the clinicians to be present and that would have been Dr Webb and Dr Steen, ideally, and 12 13 ideally -- and indeed by a proper standard -- the junior doctors because one of the purposes of audit is to improve education and to improve practice. 15 16

So a properly constituted mortality meeting should have been set up on Claire and in that meeting should have been Dr Steen, Dr Webb and Dr Sands and Dr Bartholome and, if they were available, the SHOs together with the pathologist. And it is in that debate that that issue about whether this mortality was consistent with the severity of the histology.

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Without that debate, a clinician, knowing that a child has died from a brain illness, who gets a pathology report which gives them a natural cause,

they wouldn't necessarily understand the fact that the

when she gets that, do you not have a moment's pause and

reflection there? Well, what I thought I would find.

given what my view was as to what had led to the

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pathologist didn't grade it as sufficiently bad unless there had been an active debate. Therefore, the omission of the properly constituted mortality meeting is a major flaw and a major shortcoming. O. So am I understanding you to say that, leaving aside what the formal structures were for audit and so forth. there was nonetheless enough in 1996 to have generated some proper discussion of Claire's death, the reasons 10 for it, what role her treatment might have played in it and some of these other ancillary matters that people 11 12 have conceded were also perhaps failures or 13 deficiencies? There was enough there to generate that kind of debate. 14 15 A. I believe so, ves. 16 O. And that kind of debate, in your experience, is the 17 outcome of that, admittedly anonymised -- but does the 18 outcome of that feed its way up to the medical director, 19 so the medical director appreciates something -- I think 20 some have referred to it as untoward -- has occurred? 21 A. Whether it would reach a hurdle high enough to 22 constitute a serious untoward or serious adverse event is another issue. On the other hand, if there had been 23 a clear debate which said that, "We really -- one of the 24

of encephalitis appropriate to the time? We have had quite a long discussion about that in these hearings, but it wasn't appropriate to the time, and if they had -- in terms of the fluid management. If they had had an opportunity reflect, "Okay. Well, Claire has died from encephalitis, what other factors might have been present?", then, "Was she managed for encephalitis according to the guidance at the time?". I have noted in the transcripts that Dr Webb has 10 stated that cerebral oedema and hyponatraemia is not particularly common in encephalitis. That doesn't stand 11 12 up to the literature where it is reported as being 13 present in between 10 and 20, 30 per cent, nor, for 14 example, in the textbook current at the time, 1994, an 15 American, Swaiman, on the two major textbooks of 16 paediatric neurology. There was Menke and Swaiman. 17 Swaiman states that cerebral oedema is usual. He states that electrolyte management is of great importance and 19 fluid restriction should be imposed on first 20 consideration of diagnosis. 21 By those standards, if they were managing 22 encephalitis, they would have reflected or could have reflected that the management of the identified 23 24 condition was not up to the standard. Q. Yes. I mean, might they also -- if you are having the

things in an audit meeting is to sav: was the management

kind of lively debate that has been expressed to us that
certainly happened in the grand rounds, if they are
having that kind of debate and certainly the one you say
should have been encouraged in the mortality meetings, $% \left(1\right) =\left(1\right) \left(1\right$
might have not even have been some sort of maybe
challenge is too strong a word testing of the cause
of death itself and perhaps even as to the decision not
to refer to the coroner?

If I just give you one example so that we see -perhaps see what I am talking about, this is the
evidence of Dr Bartholome of 18 October. If we go to
that at page 94. I think it starts at line 19. Yes.
This is -- the chairman is asking her here as to -Dr Bartholome as you know is the registrar over the
evening of the 22nd and into the early morning of 23rd:
"Would you have expected Claire's death to be
reported to the coroner?"

She says:

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"I personally would have expected that because, as I state in my statement here, but also in my CT request, we did not know why she did what she did. We had possible differential diagnoses, but none of them had been proven at that stage. The only thing that was proven, in inverted commas, was the fact that she had cerebral oedema. Seizures were not proven."

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as sufficient to say, "We must do something now", like

2		report it to the clinical director or medical director
3		as a serious adverse event which was justifiable
4		I mean that's an argument or to the coroner, then
5		there is a minimum one. This is the purpose of audit:
6		we must try to improve in the future, how can we do that
7		to avoid it happening again? That's the minimum. None
8		of those things seem to have happened.
9	Q.	Then if you move on to the next time phase you have
10		mentioned, which is 2004, what were the opportunities
11		then? The case comes back through no action of the
12		Trust or the hospital, but because Mr and Mrs Roberts or
13		Mr Roberts contacts the hospital, but irrespective, they
14		get out Claire's medical notes and records and, as you
15		know, Professor Young is appointed to look at them from
16		the perspective of the potential role of hyponatraemia,
17		but that period is a period is another period of
18		reflection. Can you help us with what could or should
19		have been done to advance matters in terms of
20		a consideration of Claire's case then?
21	A.	Well, I believe that after Professor Young had read the
22		notes and he had read quite properly the question that
23		hyponatraemia was a significant factor, I believe the
24		next steps that followed from that could have been done
25		better would be the minimum statement, because, firstly,

1 Perhaps if you go on to the next page: 2 "We do not have an EEG result. Infection was not 3 proven, because we do not have any CSF fluid. CSF fluid And then she explains what that is: "The viral cultures and the bacterial cultures from that fluid would take at least 48 hours to come back. but Claire had only been with us for a little bit more than 24 hours. Basically we had possibilities, but 10 nothing was definite." 11 That was the view of the registrar, who was the most 12 senior doctor who was treating Claire over the evening 13 and early hours. If you had had that robust exchange, which she could have actually tested, on what bases did 14 you have -- if she was brave enough to express it in 15 16 that way -- did she have the confidence to form that

17 view? That might have led to some examination like you are talking about. 18 A. There could have been two outcomes from that. One would 19 20 have been; we have seriously mismanaged that child and 21 we have must report this upwards. The other would be to say: we have not managed here properly, let's do a guideline. You know, there are various outcomes, but 23 2.4 it should then have appeared in the aggregated -- at the 25 end of a period of time, if, in fact, it wasn't regarded

a referral to the coroner should have taken place, and
that's what they did, but I think that there should have
been a formal review from an independent paediatric
neurologist or a paediatrician with a knowledge of
management of acute encephalopathy, because it would
only be through there that you could truly tease out the
issues which were relevant to the hospital and relevant
to the management of further cases that may come in.
Set aside the coroner's inquest, there was evidence here
of well, I am not sure it was fully grasped from what
I have seen of what was given in the written
communications which were done by Dr Rooney on behalf of
the Trust. It is not her responsibility. She was
conveying, she was a conduit. But from what was in that
correspondence, it wasn't absolutely clear to me that
they had fully understood that Claire had not been
managed properly. So that was the wrong conclusion, at
least as it was written to the parents initially, but
then conceded a bit more after the second set of
questions was placed by Mr Roberts.
If they had done as I have suggested, get
an external expert, then I think a number of things
would have come out from that: one, the midazolam dose;

two, the fluid mismanagement by the standards of 1996

and 2004, which didn't differ. They could have done $$40$\,$

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a root cause analysis, but a root cause analysis -- and 2 this is my personal view -- is basically structured common sense. That's all it is. Structured common sense would have come up with what had happened, how it happened, and why. That's the structure of root cause analvsis. In Claire, why? Well, was there a failure of knowledge? The answer is yes. It had come out that the clinicians, neither Dr Steen nor Dr Webb, seemed to appreciate how to manage encephalopathy with fluid and electrolyte management. Was there a care delivery problem? That's the second category. The answer was yes, because the fluid wasn't managed properly. The blood testing wasn't done appropriately and there is an overlap between these categories and she didn't have an EEG done. Then the last category of: was there a service delivery problem? Well, there was a service delivery problem. There was a CT scanner less accessible than it should have been. There wasn't 20 an emergency EEG service and there weren't enough doctors on at night to give Claire the attention that she needed, and there wasn't a consultant involved. So the structured common sense -- the so-called root would have not just a consultant paediatric neurologist,

but a nurse who would look at the records, a pharmacist

who would have identified that dosage immediately, and

that needed to be done, in my view, by the Trust,

irrespective of a referral to the coroner.

Q. Dr MacFaul, what Mr McBride, who was the medical

would say, "Yes, we could have done that, but what, in

director in 2004, when the case came back to the Trust,

fact, we had done was we had referred that to the

1.0 coroner and the coroner was going to conduct

11 an investigation and appoint his own experts. And, not

12 only that, if it hadn't already happened, there was

13 a very great possibility that the PSNI would have been

involved and if we had started doing that sort of thing 14

and carrying out that kind of internal investigation,

16 then there was a risk that we might compromise those

17 investigations. So since they are already looking at

it, we thought it better [that's one way of 18

19 encapsulating what he was saying] to await the outcome

20 of those investigations". Now what --

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21 THE CHAIRMAN: There is one other element, which is Mr and

22 Mrs Roberts asked -- had strongly indicated they would

23 want this inquiry to take over and to investigate

2.4 Claire's case. So Dr McBride was saying: look, this was

an unusual scenario he had never faced before where he

understood there was definitely going to be referral to

cause analysis -- needn't have been done in that

formula, but the advantage of such a thing would be you

the coroner, possibly a PSNI investigation, and

possibly -- or probably -- Claire's case being absorbed

into the inquiry. For that reason, I think he says that

in those circumstances at that time he took the view

that the Trust should leave those other routes to be

followed.

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Я A. Yes. I hadn't factored that in, of course, because of

the backdrop here. I was thinking of it as a hospital

10 manager.

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11 THE CHAIRMAN: Let me say what my instinct is at the moment

on that. I understand that Dr McBride could well have

13 thought that between the coroner, the police and this

14 inquiry these issues would be explored and that might

be -- that's a different scenario that the normal one, 15 16

and to be fair to him, he couldn't have apprehended for a moment that this inquiry would still be sitting in

18 2012. He probably thought it would be long, long

finished by now so that lessons would be learned. So to

20 what extent would you be against that developed

21 scenario? To what extent would you be critical of the

Royal for not doing the root cause analysis between 2004

and 2006? 23

24 A. I think that I had not factored that particular

dimension into what I have just been saving, but I think 25

there was -- it is not clearly evident to me from

reading the correspondence between Dr Rooney and the

parents that Professor Young had fully grasped the lack

of -- let's put it this way -- the gap between what

should have been done in the management of an acute encephalopathy in a child specifically and what was

done. I took the view that it would have -- that gap

would have become more clear if they had got

a paediatric neurologist to do what Professor Young had

10 been asked to do.

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11 MS ANYADIKE-DANES: Well, in fairness, Professor Young, as

12 I understand his evidence, and for that matter the

Trust's, he was actually brought in to examine the case

14 notes and to see the extent to which there was any

15 evidence that the hyponatraemia had played a role in her

16 death. That as I understand it is actually what he

n brought in to look at, and he did that and he

formed the view that it had and he reported that and the

19 result of that was that the case was referred to the

20 coroner, but when you talk about that gap -- and all of

21 the other things surrounding the issues that I first was

22 putting to you early this morning -- I suppose what I am

23 trying to ask you is, when one takes on board what the 24 coroner is going to do at the inquest, the issue that

the PSNI, if they become involved, are likely to look at

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in their investigation, and the terms of reference of this inquiry and what it was set out to do, is it -- is there still anything there, if I can put it that way, that the Trust or the hospital needs to know about that may not be being investigated from that particular perspective in those three forms of investigation? A. Well, I think I do fully understand Professor Young's position. He had been -- at least I think I do now in what has been said. He was confining himself to the 10 electrolyte concern, but I'm not sure that the overall 11 picture, therefore, was evident either to him or to the 12 Trust from that involvement that there was this gap 13 between what should have been done and what was done Therefore there was an issue about what happened in 14 2005, say, to a child in January or February coming in 15 16 with acute encephalopathy. What would happen to such a child? There was no written guidance in the medical guidelines in use in the Children's Hospital at the time 18 to steer the juniors. Therefore there was 19 20 a responsibility of the Trust to be able to continue to provide or improve its care of children with that 21 condition, and that was quite a priority. 23 O. You mean not to postpone their lessons learned --2.4 A. Yes.

-- until after the conclusion of those other

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A. Yes. So that pathway was there, but the opportunity was lost, in my view, for the Trust to have learned an important clinical management lesson, which could have then reflected into practice quite quickly. MS ANYADIKE-DANES: Thank you. THE CHAIRMAN: I had asked you what you think of Dr McBride's position, given the unusual combination of potential investigations which were pending. Do I understand you to be answering that in terms by saying 10 that that was a very unusual position he was in with 11 these, not so much from the coroner's perspective, but 12 perhaps most significantly from the perspective of the 13 inquiry, but that it would still have been better if 14 Dr McBride had arranged for something equivalent to 15 a root cause analysis to be conducted or for some type 16 of investigation, whatever it was called, so that in the meantime, if a girl arrived in a condition like Claire's, or another child arrived with encephalitis or 18 19 some form of encephalopathy, there would have been 20 a clear picture or procedure for treating that child? 21 A. Yes. I think that the position that Professor Young was put in was probably a difficult one for him when seeing the parents. I think the step I am trying to elucidate 23 24 is that Dr McBride having got the information from Professor Young, "Yes, there is a problem in management 25

investigations? 2 A. Well, in an ideal world, yes. I think the point that I am trying to make is: had a paediatric neurologist been asked to do what -- Professor Young had given his opinion already to Dr McBride. He had said, "There is a problem with hyponatraemia in Claire. That does deserve evaluation". Well, Dr McBride could have then said: okay, well, what was the diagnosis made or what was the problem being managed? The problem that was 10 being managed was cerebral oedema and a neurological 11 problem. It was either encephalitis or epilepsy. Let 12 us not ask Dr Young to meet the parents; let us get in 13 a paediatric neurologist. That wouldn't have stopped 14 Claire's death going to the coroner, but it would at least have provided a broader review of the case 15 16 records. 17 Professor Young has said he was not charged with, 18 nor did he look at the drug usage, for example, and other aspects of management of acute encephalopathy. He 19 20 was focusing himself --21 THE CHAIRMAN: He had a very narrow remit and he fulfilled 22 23 A. Yes.

referred to the coroner.

THE CHAIRMAN: As a result of his advice. Claire's death was

ask Professor Young to meet the parents, to actually just an interval, get a paediatric neurologist from somewhere, get them to go through the note and make a quick report to him. That would not be a full root cause analysis, nor a formal investigation, but it would at least have enriched the information available, even to provide a view to the coroner. THE CHAIRMAN: Okay. I think we're taking a break now --MS ANYADIKE-DANES: Can I ask one final question? In fairness to him, Dr McBride said they were -- he was actually involved in the study to see how, when you had differing statutory investigations going on, how the hospital could nonetheless, without compromising them, conduct investigations to achieve the sort of thing that you are talking about, something to assist in the interim or improve care in the interim, and that ultimately found its way into some sort of memorandum of understanding. I think that is how he described it. My point to you is: do you have experience of, absent some more formalised steps as to how you do this, nonetheless discussion and liaison going on between the hospital and the different statutory agencies to ensure that the

hospital can do what it needs to do in terms of

delivering care without compromising the requirements of

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and the child had a neurological problem", rather than

- those other investigations, in this case the coroner's inquest and the PSNI's investigation?
- 3 A. No, I don't.
- 4 Q. You don't have any experience of that?
- 5 A. No. It's a very complex situation that was being faced.
- I suppose what I am trying to underscore is there was
- 7 also, almost within the clinical governance management
- 8 process, just to try to make sure there was
- 9 a guideline available guickly or something or tease out
- 10 the issues, rather like doing an audit. I mean, you
- 11 wouldn't stop doing a medical audit process because of
- 12 these external things going on. When I say "no" it was
- in respect of her clinical management. Obviously, in
- 14 relation to how you deal with a death where there's been
- an allegation of abuse or neglect, then that's where we
- 16 are quite familiar with those processes, but against
- a backdrop of a public inquiry in the background, no.
- 18 MS ANYADIKE-DANES: Thank you very much indeed.
- 19 MR FORTUNE: Sir, before Dr MacFaul pauses for the
- 20 mid-morning break, can we seek his assistance on two
- 21 matters? It may be I am at fault. We have spent quite
- 22 a lot of time investigating whether or not mortality
- 24 whether it be Adam or indeed Claire, was to take place.

meetings or a discussion after the death of a child,

- did take place, and how it was recorded. We now have

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- 1 I think it was because -- I am recalling the debate --
- there was concern that doctors would not wish to get
- 3 involved in audits. So, if you like, it was a means of
- 4 trying to engage the profession in open views.
- 5 To be clear on the second point, the destruction of
- 6 the discussion and the issues that could be identifiable
- $7\,$ $\,$ was what was being done with a particular patient, but
- 8 there was still a requirement for making a log of the
- 9 issues that arose from the discussion.
- 10 THE CHAIRMAN: Right. So that that would be -- that log of
- 11 issues might say: from now on this is the way in which
- 12 we will treat a child with this condition?
- 13 $\,$ A. Yes, but also this particular child did not have -- you
- 14 might note that the child was not managed according to
- 15 guidelines.
- 16 THE CHAIRMAN: Okay.
- 17 A. As a consequence of this, the child either died or was
- 18 damaged. I mean, these would be the things you would
- 19 expect to be logged and the diagnosis, but not the
- 20 linkage with the patient.
- 21 THE CHAIRMAN: Let me just tease this out finally: if there
- 22 had been such a -- I am not sure the Royal is saying
- 23 that there was, but let's suppose that had been done in
- 24 1996/1997 after Claire died, and let's suppose that the
- 25 Royal then have to go back into this in 2004, after

- heard from Dr MacFaul that any notes made at such
- 2 a meeting, if it took place, were to be firstly not
- 3 linked to the case records and, secondly, to be
- 4 destroyed. Did I understand correctly that the
- 5 destruction of such notes had the stamp of the Chief
 - Medical Officer at the time?
- 7 Secondly, in relation to lessons to be learned from
 - such a discussion, how did those lessons then get to the
- 9 medical director? In what form did they go if there
- 10 were no notes?

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- 11 THE CHAIRMAN: Okav. On the first question.
- 12 A. The first question is a very legal and difficult one
 - and it reflects the issues which were present at the
- 14 time medical audit was being introduced in the early
- 15 1990s in respect of making sure there were no
- 16 discoverable documents. That was clearly something
- 17 which was an awkward arrangement, and I guess that by
- 18 the late 1990s there was probably some change, because
- 19 it was probably -- I think it was from the Royal College
- 20 of Physicians' working party, second report, and
- 21 I provided for the inquiry the appendix about
- 22 confidentiality, which was informed by a professor of
- 23 law I think -- it will be in the papers -- and then
- 24 endorsed by Kenneth Calman as the step, but, of course,
 - that was with the introduction of medical audit, and
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- 1 Mr and Mrs Roberts contact the Trust. Does the removal
- of the linkage mean that the record of the issues cannot
- 3 be identified as relating to Claire?
- 4 A. I think you'd have to ask the Trust's lawyers about
- 5 that, sir. I don't know. I mean, this was one of the
- 6 problems. I don't think -- it was an awkward
- 7 arrangement, and it was something which I don't think
- 8 would have stood for very long.
- 9 THE CHAIRMAN: I fear that -- I mean, all the lawyers and
- doctors here can understand what the issues are, but
- If fear that Mr and Mrs Roberts might think it is not

 really much of an issue. The real issue is how to be
- 12 really much of an issue. The real issue is how to look
- after children and make sure care is better in future.

 14 A. That was why this process was put in, because it was
- 15 felt by introducing what started as medical audit and
- 16 became clinical audit would have to get across some
- 17 hurdles within people's sensitivities about litigation
- 18 THE CHAIRMAN: Okay.
- 19 A. The aim of audit was to improve education and to improve
- 20 outcomes for patients. Undoubtedly, that was the way.
- 21 This was felt to be a step which was important to
- 22 introduce and important to engage across the whole of
- 23 the Health Service, and I think that was a laudable $\mbox{aim},$

and I believe that this initial confidentiality issue

- 25 was just, if you like, a launching arrangement.

THE CHAIRMAN: Okay. 2 MS ANYADIKE-DANES: I take it it no longer exists. A. I don't think it exists at all now because, of course -yes. Things have moved on. THE CHAIRMAN: We will take a break now. We will take a longer than usual break. We will take it for half an how were. Can I say, as we go out from this that today is the last day Ann Kirwan is going to be with the inquiry. 10 Ann on the balcony above you has been the evidence 11 display operator since we started last February. The 12 speed with which documents have been brought up -- and 13 she seems to have been able to anticipate what the next document is going to be -- is something we will 14 miss greatly Ann is leaving us because, foolishly, she 15 16 has decided to become a lawyer. Today is the last day with us, so during the break and later on during the day, I am sure everyone will want to speak to Ann and 18 19 acknowledge her contribution. 20 We will break for 30 minutes. Thank you. 21 (11.12 am) (A short break) 23 (11.42am)

inquest and I have appreciated now the backdrop as to

(Delay in proceedings)

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(12.09 pm)

why Dr McBride wouldn't wish to initiate a full and formal root cause analysis, but I would still feel there was an opportunity then for them to review their audit arrangements, for example, to see whether the audit process -- that is what was done in the meetings, number one -- and how they were documented, number two, and how the documentation was then handled, number three, in terms of producing annual reports. 10 One thing that has occurred to me, though, is that the Royal College visits to determine whether the 11 12 hospital is suitable for training junior doctors would 13 happen on a cycle of every three years, and those visits would have enquired upon what audits were done. By --14 15 so that's a process by which there was an external 16 quality check, and I do not know whether that was handled and how they handled the problems within the 18 Trust, if any were drawn attention to. 19 So that was a process. Maybe there is documentation 20 about that. 21 MS ANYADIKE-DANES: Sorry. I didn't mean to ... A. Just following on, whether the clinical incident reviews, which are documented, were analysed. If they 23 were being analysed, then the lesson they should have 24 25 learned was to review them and to analyse them by

THE CHAIRMAN: Doctor, thank you. 2 MS ANYADIKE-DANES: Good afternoon, Dr MacFaul. Finally, I just would like to ask you: what do you think, with the benefit of having heard the evidence as to what was happening in 1996/1997, and also what happened when the case came back, if I can put it that way, in 2004, what do you think are the lessons that the Trust could have learned and maybe still can learn as 1.0 A. Well, I don't know what processes there are in hand now, 11 so it's difficult for me to comment on what they would 12 do now. In 1996, the problem is that Claire's death was 13 not identified as a major event. So the first step in any investigation, of course, of a major event is to 14 know that it has happened, and whether the Trust has now 15 16 got more robust -- ward pharmacists, for example, is 17 a question which should be addressed. I think they have addressed it from what I have gleaned. 18 19 THE CHAIRMAN: Yes, there are now pharmacists in the 20 Children's Hospital. 21 A. Thank you. So that was one from 1996. Otherwise it is difficult to see, in the system that was there, whether the Trust was in a position --23

well, they could have awaited, as they have done, the

Coming on to 2004, there was an opportunity then --

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1		specialty because I believe it was a Royal
2		Hospital-organised thing rather than just the Children's
3		Hospital, and I believe that it would be helpful to
4		provide more support to the clinical directors in
5		knowing how to fit into the system, and it may well be
6		by that time that clinical leads or clinical directors
7		were given extra training because, by the early 2000s,
8		that would have been available whereas it wasn't easily
9		available in the mid or late 1990s.
10	Q.	Can I ask you in this way? You have said that,
11		periodically, the Royal Colleges do a review and that
12		provides an opportunity to reflect and consider your
13		practices and so forth. At the time of Claire's
14		admission, in fact, almost on the day of it, the Royal
15		were going through a process of trying to gain
16		King's Fund accreditation.
17	A.	Yes.
18	Q.	In fact, one of the queries which we haven't entirely
19		been able to resolve is the extent to which Dr Steen's
20		absence from the ward round that she would otherwise

have conducted was, in part, due to her being involved

in that. We understand from some of the extracts from

of the diaries of the clinicians we have seen that they

the King's Fund team came, they would be able to address

were setting up a series of mock surveys so that when

whatever were the queries and issues that the King's Fund team wished to discuss with them as part of that process of gaining accreditation. So that's what they were engaged it. I am just wondering if that whole process should or could itself -- or could -- have formed an opportunity to reflect on what they did and how they did it. The Children's Hospital was being represented in that as well. As I say, does that not provide an opportunity to consider these sorts of 10 issues? 11 A. Well, I have not been involved in a formal King's Fund 12 audit. I did with, Charles Shaw, contribute to the 13 King's Fund publication which he wrote on medical audit for the King's Fund, but that's early 1990s, but --14 again I'm talking off the top of my head here and it 15 16 does need cross-checking. One of the things that tends to be asked with external visitors is, "Are you doing audit?", "Yes", "How often do you have a meeting, every 18 month?", "Yes". That may tick the boxes without then 19 20 exploring: do you produce an annual report? Sometimes I think -- on one occasion, we had 21 an external review of the system in Pinderfields, and I can't remember who was doing it, but one of the things 23 24 they were asked -- we were asked at the time -- and this appraisals?" Well, the answer no because it wasn't in hand. It wasn't something which we did, whereas by the early 2000s, consultant appraisal, where you have what we call 360-degree appraisal, was well embedded and also it had to be put into the continuing development plan which every consultant at that time had to fill in a form and a folder and submit that to the College to see if you are in good standing, and that would include how many audits you'd done.

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That would also be reported within the clinical
governance system because it was a responsibility for
trust management to ensure that annual appraisals were
in place as part of that process and the documentation
was a structured documentation and sent up into the
system. I don't know whether that applies in Northern
Ireland.

16 17 Well, I think that if they had been asked the issue of 18 whether they conducted consultant appraisals, the answer may well have been "no", because I think that was one of 19 20 the things that Dr McBride actually introduced when he came into his position in 2002, but I think though, you 21 may have seen some of the material in relation to the 23 things that the clinicians thought that they benefited 24 from in terms of the process of applying for King's Fund, and that way, that might give you some

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insight into the sorts of issues that the King's Fund

was looking at. I think it was perhaps Dr Gaston who

is late 1990s -- "Are you subject to consultant

referred to it. I believe, but in any event documentation was one issue and also the communication, oddly enough, with families. A. Yes. O. So if those were the areas in which they thought there was benefit in the process, then that gives some insight into the sorts of issues they were having to consider as 10 part of their application process. If that's the case, 11 and they are dealing with it at the Children's Hospital 12 level, which some of that review would have involved, 13 then it may be that that would have given them an opportunity, in 1996/1997, to consider how they were 14 15 faring, and if Claire's case was current at that time. 16 that may have given some opportunity. THE CHAIRMAN: This all depends, doctor, doesn't it, on the extent to which it is box ticking -- "Do you do audits?" 18 19 "Yes", "How often?", "Yes" -- without necessarily 20 scrutinising or analysing how effective those audits are 21 and what the outcomes of them is. A. Yes. The clinical audit forms which were used in paediatric audit include a section -- you put up a pile 23 of case notes, shuffle them and take a few out. "Was 24 the communication to the parents documented?" was one of 25

those elements. In my own unit -- and I was still doing this process in 2005 and 2006 -- that was very variable. Even when we were trying our best, it was not well documented. So what we did do was put a rubber stamp in the note saying "patient information given" and "leaflet given". To you, that usually means somebody has talked about it with the leaflet. That was a much guicker way of finding out whether what had been said to the parents was documented. So you could analyse "Had parents been involved in information?", "Yes", "What was given?", "A leaflet". Yes. But any more detail was often not completed. It is recommended practice from the GMC and all sorts of bodies that there should be much more written down, but we do know, even from the audit on coma, which was published by the Royal College in 2008. I think, 2009, or even more recently, 2010, that when they looked at children in coma that -- and I produced it in my report -- that the responses to that showed a moderately -- only a moderate proportion of it was well documented. So the standard on that is, "Yes, it should be". People try very hard to keep it up, but it doesn't get high priority in clinical note keeping. MS ANYADIKE-DANES: Can I ask you then another question,

which is, in a way, as we have descended down into the

detail to look at just Claire's case, and when you look

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1	at that from a governance point of view, in a way one
2	could be forgiven for looking at it just in its
3	isolation, but, in fact, it wasn't a case in its
4	isolation, certainly not by the time it came back in
5	2004, but even if we stay with 1996, some of the
6	clinicians who were involved in Adam's case, for
7	example, were also involved in Claire's case to varying
8	degrees. Adam, as you probably know, he died in
9	November 1995. Then, in the summer of 1996, was his
10	inquest, and at that time it was thought that there
11	was $\operatorname{}$ there was some learning about the condition of
12	hyponatraemia and it was believed that that would find \ensuremath{I}
13	its way for broader learning through a seminar and
14	things that might derive from that. That didn't happen
15	for various reasons, but in any event before all that
16	could really happen, and perhaps while the matter was $% \left(1\right) =\left(1\right) \left(1\right)$
17	still relatively fresh in people's minds, just four
18	months later Claire is admitted.

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When Claire died then, and knowing that some of these doctors perhaps had a knowledge of Adam's own death, if you are applying your common sense approach to looking at things and seeing where they went wrong and why, does that not provide a further reason for at least examining whether we sufficiently understand what's happening with children who present in this way?

them signed by a doctor, how many of them have been dated and timed, is the doctor's signature legible, do you know who it was? That sort of thing. Then there are so-called topic audits where you pick out the last ten with meningitis and you get a junior doctor to go through a form and identify the factors. So if you had, for example, the deaths from coma in the last year, then a doctor going through these notes -not necessarily a consultant, usually a trainee, because it is part of their training and it was recommended -would do this topic audit. They would set up a pro forma and they would identify -- and that is how you pick up themes. If that was done, as was advised at the time -- this isn't just off the top of my head; this was advised -then it might well have -- hopefully the Children's Hospital has learned and may well have learned by now to do this in a much more structured way. THE CHAIRMAN: Doctor, can I pick you up on that? From the doctors' perspective one of the issues which is startingly clear is the fact that there were too few doctors and too few nurses. 24 A. Yes.

have had their blood pressure done, how many have had

1 A. Well, I think it is where I come back, perhaps rather 2 obsessionally, to the mortality, because, for example, if you were putting down "child dies with these conditions" and the conditions are identified on the autopsy request form -- so they would have been highlighted in a case note review, for example -- if someone else had been looking at the case notes. whether -- I believe from what I read in the transcripts that the process was for a consultant or somebody to 10 present from the case notes, but the case notes weren't 11 shared. So there wasn't an opportunity to cross-check. 12 whereas one way of doing audit is to get a junior doctor 13 to go through three or four records and then present any themes, but if they had listed the thoughts that had 14 contributed to Claire's death and then somebody, 15 16 a clinical director, might have been aggregating these over a period -- this is hypothetical -- but aggregating them over a period of time, they might have seen 18 hyponatraemia flash up, and that would have been 19 20 an opportunity, and then perhaps: well, why was -- yes, 21 there were opportunities, but that was if the mortality 22 and audit meetings were run in a structured way. 23 I have mentioned mortality, but the audits can do, 24 as I have just described, case note quality. You know, you open a few and see what the records are: how many 25

1		identified that they were short of doctors and nurses in
2		the Children's Hospital.
3	A.	Yes.
4	THE	CHAIRMAN: So while all of what you are saying seems
5		like perfect common sense and it isn't exactly a counsel
6		of perfection, it is not that demanding, but it is
7		identifying what could and should have happened. But
8		when you have a position that people like Dr Bartholome
9		are working for 27 or 30 hours from the Tuesday morning
10		to Wednesday lunchtime or, the night before, Dr O'Hare
11		is working from Monday morning to Tuesday lunchtime, the
12		consultants are potentially overstretched as well.
13		There aren't enough nurses. There are gaps at nurse
14		manager level, so there are people acting up in posts
15		rather than permanently there. I presume that must have
16		a direct impact on the feasibility of all of these audit
17		processes and reviews actually being carried out.
18		Because I assume the doctors and nurses would say,
19		"Well, we are finding it hard enough to cope with the
20		patients we have in front of us at the moment, never
21		mind looking back over what went before".
22	A.	Well, that's one of the reasons why audit has been
23		promoted, not just to improve quality of care, but to
24		improve education, and one of the things that the
25		College visits would do would be to look at the

THE CHAIRMAN: The Royal's internal annual report had

- timetable of registrars and senior house officers to

 determine what protected time within that timetable they

 would have. They would have their on-call commitments,
- which are heavy and busy. Then they would have time
- 5 which is not -- they should have had time which is
- 6 protected time, even in 1996, in order to achieve the
- 7 continued approval of the College for training, and it
- may well that be these approval or College visit reports
- 9 are available, because they were shared with the Trust
- 10 management, and they were shared with the postgraduate
- 11 tutor for the Trust as well as the clinicians. So --
- 12 and clinical directors. So the answer is: there should
- 13 have been time. The workload of the out-of-hours middle
- 14 grade, as you know, is exceptionally heavy, and --
- 15 THE CHAIRMAN: I get the impression it has eased because of
- 16 the working time regulations.
- 17 A. That was a further pressure which came in a bit later
- and that would be one of the things which would be very
- 19 much on their mind. Of course, it costs money to do
- 20 that, which is where you come into this problem. I am
- 21 sure this has been highlighted before, but just in case
- it hasn't been, the registrar was covering, I think, 120
- 23 beds or something like that.
- 24 THE CHAIRMAN: Yes.
- 25 A. Most registrars in district general hospitals like mine

- 1 would only be covering 40, number one. Number two, the
- 2 complexity of the cases would be much less in a district
- 3 general hospital. Number three, I believe that that
- 4 registrar was also covering Accident & Emergency --
- 5 THE CHAIRMAN: Yes, she was.
- 6 A. -- which is an immensely time-drawing activity. That is
- 7 why I raise the point in my report. So that has been
- 8 acknowledged, I think.
- 9 MS ANYADIKE-DANES: Can I ask you this? When you go to
- 10 2004, apart from the fact that the systems for
- 11 conducting audits and reviews and so forth are more
- 12 advanced --
- 13 A. Yes

- 14 Q. -- if I can put it that way, in 2004, but by 2004 they
- 15 have had the UTV programme. So they have had drawn to
- 16 their attention that there were three children, one of
- 17 whom started in the Royal -- which is the first case,
- 18 Adam -- and two others who came there and ultimately
- 19 died with hyponatraemia being implicated in their cause
- 20 of death, and then shortly thereafter, within a day or
- 21 so of that programme, then they had Claire's case.
- 22 At that point, the sort of thematic examination that

you've talked about where you go back and you look and

- 24 see whether this particular condition has arisen
 - 5 previously, would it have been appropriate for the Trust

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- to have conducted some research on its own to see what
 - is the incidence of this, quite apart from the three
- 3 that have been identified to it by virtue of that
- documentary, and the fourth that came from the parents?
- A. I think that is difficult to say, but from the
- 6 information that I have had Adam was a surgical problem,
- a complex problem with his kidneys and so on. So in
- 8 a way, electrolyte disturbance is very problem. Claire
- 9 had an acute encephalopathy, a different condition
 10 altogether, different clinical team. Raychel Ferguson
- 11 was treated in a district general hospital with
- 12 a surgical condition and Lucy in a district general
- 13 hospital with gastroenteritis. So it's difficult to see
 - a pattern there. Obviously with hindsight and with the
- 15 focus on hyponatraemia --

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- 16 Q. Sorry, doctor. That's what I am asking you. Should
- 17 they have been looking to see if there was one? Should
- they have been asking themselves whether they had gained the appropriate amount of lessons learned from each one
- 20 and disseminated that, whether any of this happened
- 21 because, for some reason, the training in relation to
- 22 hyponatraemia was deficient? Should they have been
- looking at it from that perspective?
- 24 $\,$ A. Well, I think what was raised in Raychel Ferguson did
- 25 lead to such a review, and I think it was a pioneering

- 1 event and ahead of the game with the issue of the
- guidance on -- from 2002 in Northern Ireland, and
- 3 I think that is something to be commended.
- 4 Q. Yes. It wasn't so much that I meant. I am talking
- 5 about from the Trust's point of view, the Royal
- 6 Hospitals Trust's point of view: should they have been
- 7 taking that opportunity now that, if you like, matters
- 8 have been crystallised by the UTV documentary? Should
- 9 they have been looking to see about their systems, about 10 lessons learned, maybe identifying for themselves that,
- 10 lessons learned, maybe identifying for themselves th
 11 for some reason, there didn't appear to be much
- dissemination of the issues involved in Adam's case, for
- 13 example? They might have been able to pick that up for
- 14 themselves. So what I am asking is: how feasible was it
- or how appropriate was it that they could have looked
- 16 within themselves to see how they had dealt with those
- 17 cases?
- 18 $\,$ A. Well, that is why I felt that it was appropriate, for
- 19 example, for an internal arrangement. I appreciate the
- 20 backdrop now against the inquiry when Claire's case was
- 21 brought up again by the parents. There was
- 22 an opportunity then. Yes, I think they should have
- 23 reflected: "Are our systems good enough to detect?"
- 24 THE CHAIRMAN: I think, doctor, maybe on a slightly
- 25 different approach to Ms Danes, the time to do that was

- probably in 2001 when Raychel died, wasn't it? 2 A. Yes. 3 THE CHAIRMAN: And that's when the working party was set up which led to the guidelines. THE CHAIRMAN: So if you are going to look back to see about the incidences of hyponatraemia --A. Uh-huh.
- O. -- well, that was certainly an earlier time to do it, in 10 2001, when the working party is going through, and as 11 part of its work, it may be looking at: to what extent 12 is -- we know it was the cause of Raychel's death, but 13 do we have a feel from the regional paediatric centre as to the extent of it has been over recent years? 14 A. Well, I think that it would certainly be an opportunity
- 15 16 to say: Have we got a system which is picking up cases in the Children's Hospital? Is the coding good enough? Does the coding, for example, provide it? Is there 18 a system by which we can pick up similar cases or 19 20 similar problems, not just hyponatraemia, where there's
- 21 a theme? How well supported is critical incident or serious adverse event reporting? Is it being encouraged? Because there is tremendous variation and, 23
- 24 of course, you will have seen from much of the documentation that it wasn't a commonly defined -- what
- (A short break) (12.40 pm) MS ANYADIKE-DANES: I wonder if we could have page 36 of today's [draft] transcript and have lines 6 to 9 highlighted. THE CHAIRMAN: The one person who won't have it is Dr MacFaul. Page 36, lines? MS ANYADIKE-DANES: 6 to 9. If you don't have it there Dr MacFaul, I can read out to you what it was, because 10 this is your comment: "Now by those standards --11 12 THE CHAIRMAN: Can you steer the microphone? MS ANYADIKE-DANES: I am so sorry. Too much technology. 13 14 Right: 15 "Now by those standards, if they were managing 16 encephalitis, they would have reflected or could have 17 reflected that the management of the identified condition was not up to the standard." 18 19
- That was your comment. 20 A. Yes. 21 Q. The issue is this: do you get that from your assessment or reading of the medical notes and records? A. Yes, because it was to do with the fluid management and 23 electrolyte management in acute encephalitis. 24 25 Q. And if they were reviewing matters in the way that you

is a serious adverse event was not actually specified. 2 So that's going to lead to variation. Then, there is the reluctance or willingness of systems to report. Nurses are much better at that time with their booklets that they fill in and, although the majority who are filling in are filled in by nurses, it was certainly our experience with critical incidents that we would say, "Well, we think that should be a critical incident", and the nurses would fill it in. 10 So it wasn't always to the credit of the nurses. Sometimes the doctors identified them. So there was 11 12 a system in place, and I think they had such a -- well, 13 maybe somebody should ask what the system was with the booklet to be filled in. So there are various opportunities, but the first point is: can you identify 15 16 the problem and have you got a good enough system to 17 acquire the data? THE CHAIRMAN: Thank you. 18 MS ANYADIKE-DANES: Mr Chairman, I think there might be just 19 20 one or two issues. If we could have just a few minutes? Subject to that, I have no further questions. 21 22 THE CHAIRMAN: Okay. We will wait for one or two minutes. Thank you, doctor. 23 24 A. Thank you very much indeed.

(12.35 pm)

2	A.	Yes.
3	Q.	If the first pass is to raise a query over whether the $% \left(1\right) =\left(1\right) \left(1\right) $
4		fluid management was adequate $$ and by the first pass
5		I mean just from looking at the medical notes and
6		records
7	A.	Yes.

were saying they could and should have done?

8 O. Is then the thing to do to enquire or investigate further with the clinicians involved to see exactly what 10 had happened and what their thinking was to ascertain whether the treatment really doesn't accord with the 11 12 standards and why it does and whether, to use the 13 expression that you have been using to the chairman before, that was a lack of knowledge, a lack of care, 14 15 what exactly was happening in relation to the 16 encephalitis

17 A. Well, it appeared to be a lack of awareness, it seemed to me, about the need to, if you -- we have been over 19 this before and the fact there was a high likelihood of 20 development of syndrome of inappropriate ADH secretion 21 and the guidance for the day in 1996, once you had had 22 an encephalitis, you should seek that condition, and when you seek it by blood tests, you manage it by fluid 23 restriction and by increasing the blood sodium if the 24 25 level is low

- 1 O. No, I understand that, Dr MacFaul. I think the issue is
- more to do it in this way: if you are looking at that
- time from a governance point of view and the first
- consideration of medical notes and records leads you to
- form the view that that is what has happened --
- A. Yes.
- O. -- when you then to go -- because that would be
- a serious thing --
- 10 Q. -- if you were to form the view, just on the medical
- 11 notes and records, that we have a child here who
- 12 ultimately died. We believed the condition of
- 13 encephalitis was involved and somehow the treatment for
- the fluid management of that child was inadequate, that 14
- would be a serious view to form on the notes. So if you 15
- 16 are conducting some review in relation to that, do you
- then investigate further with the clinicians who were
- involved to try and understand how it was they treated 18
- the child in the way that they appear to have done from 19
- 20 the notes because at that would disclose the extent to
- which you really were dealing with a lack of knowledge? A. Yes. Also the dose of midazolam should have been
- 23 identified because, to everybody looking at it, it was
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Q. So you would be wanting to address the responsible

- prescribed and administered it in that way to see
- exactly whether you were dealing with a deficiency in

clinicians directly to understand why it was they

- knowledge or there was some other issue. It could be
- a recording problem: they did exactly the right thing,
- it is just poorly recorded.
- 7 A. Yes, but I think it would be a guestion of whether the
- issues that arose at the audit meeting were shared with
- the clinical director and, if they weren't, then
- 1.0 clinical director or the system at large wouldn't have
- 11 the opportunity.
- 12 O. Yes.
- 13 A. If it had been part of the debate in an audit, then that
- should have been logged. The patient's name and details
- 15 shouldn't have been logged --
- 16 O. Yes.
- 17 -- but the issues should have been.
- 18 Q. That issue would have come and that is an issue
- therefore that the director could take up and deal with? 19
- 20 A. And the other issue would be the death certification to
- say, "Well, how did non-convulsive status lead to 21
- cerebral oedema?" That would be a perfectly reasonable
- 23 thing to discuss.
- 2.4 I forgot to mention earlier this morning about the
- cross-check on death certification, because I don't know 25

- whether it happens in Northern Ireland, but in 2008 the
 - Children Act in England was changed so that every child
- who died has a copy of the death certificate sent to the
- local Children's Safeguarding Board, and that was following a change in the law in 2008, and the local
- Children's Safequarding Board would then be another way
- of aggregating deaths to look at any abnormal or odd
- patterns, but I don't know whether that applies in
- 10 MS ANYADIKE-DANES: Thank you. Thank you very much indeed.
- I have no further questions. 11
- 12 THE CHAIRMAN: Okay. Nothing further for Dr MacFaul?
- 13 Mr Lavery? No.
- 14 Thank you very much again, doctor.
- 15 (The witness withdraw)
- 16 THE CHAIRMAN: Ladies and gentlemen, that brings an end to
- today's hearing, unless there are other issues to be
- raised. Are there? I see Mr Green rising. 18
- 19 DISCUSSION
- 20 MR GREEN: Yes. I will be short. Given the careful and
- 21 measured way in which you have properly dealt with the
- new allegation, as we have put it, against Dr Sands yesterday, those who instruct me have considered very 23
- carefully whether to continue to seek a ruling on the 24
- point from you. Sir, the product of that consideration 25

- is that a ruling is still sought from you, sir. For the
- reasons set out in my written submissions, which I don't
- propose to rehearse out loud and for two additional
- reasons.

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- The first of my two additional points is what
- I might describe as a public interest point, and I start
- by asking rhetorically: what is the parent of a child in
- Belfast with a poorly heart who watched the BBC news
- last Thursday evening and whose son or daughter is to be 10 seen between Christmas and the New Year by Dr Sands
- about that prospect, having heard the allegation that 11
- 12 was made? In particular what is that parent to think
- 13 when they start to give the child's history and Dr Sands
- gets his notebook out. Frankly the thought might at 14
- 15 least cross their mind, "Is this man a forger who will 16
- be prepared, if something goes wrong with my child's 17 care, after the event, to alter notes?"
- I start with that rhetorical question cum example,
- 19 because, in my submission, one of the principal
- 20 functions of a public inquiry is to allay public
- 21 concern. That function may, I suggest, be prejudiced if
- 22 a witness is treated unfairly. I recognise that

on or give witnesses an easy ride.

- 23 fairness does not require the inquiry to put kid gloves
- 25 Legitimate criticism and, indeed, excoriating and

sometimes criminal allegations can and should be properly made where there is an evidential foundation for them and it's within the scope of the inquiry. The witness at the butt end of them cannot complain of unfairness just because it is very uncomfortable or, in other words, if a witness is caught out in a lie by you, sir, just because they are going to be publicly exposed and humiliated when you make them trip over their own falsehood doesn't mean there is any unfairness to them, but the allocation against Dr Sands, in my submission, is unfair, and it is not supported by a shred of evidence, and if it is not, in my submission, tackled head on soon, it could quite unjustifiably heighten rather than reduce unjustifiable public concern. So that's the first point.

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The second point is a shorter one, and I preface it by saying that I recognise that this inquiry, as is the stakeholders, if you will pardon that awful modern management expression, but when I said yesterday that Dr Sands is finding this process trying, I chose my words very carefully. Suffice it to say I simply make the general observation that where a person faces

properly, Mr Chairman, but sometimes this has had -- and

often the case where people face criticism or probing in a public forum, has the potential for negative impact on a serious but unfounded allegation of this nature and

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continues to have -- a devastating effect on their personal lives. As I say, it was palpable the effect this has had on Dr Sands and the way it was reported in For the reasons that Mr Green has set out, Mr Chairman, we also support his application on the basis that public confidence in the ability of the clinicians and staff, particularly in the Royal 10 Children's Hospital, to carry out their duties in 11 a professional and efficient manner, the public have to 12 be given some assurance in respect of that. 13 THE CHAIRMAN: Mr Lavery, where does that take me to? For 14 instance, in September, we recalled some witnesses and 15 called others for the first time on the Brangam Bagnall 16 consultation note, and the suggestion which was implicit in that note, if not explicit, that there had been 18 a cover-up of what happened during Adam's kidney 19 transplant. It might not have been as explicit 20 an attack as the one that Mr Roberts has found himself 21 driven to after sitting here for a number of weeks of hearing the evidence, but the issue was pretty clearly a question of how -- how it could that be the evidence 23 24 that had been given during May and June despite what's in the Brangam Bagnall consultation note. So how do 25

on their physical and mental health is self-evident, and because it is self-evident, I needn't labour it further. So for all those reasons, I invite a ruling on the point that has been raised more fully in the skeleton argument. Those are my submissions. THE CHAIRMAN: Thank you. Mr Quinn, do you have any anything to say. Sorry, Mr fortune. 10 MR FORTUNE: Sir, it would follow that I too should and do 11 support the submission, because, of course, the 12 allegation is one of conspiracy: that Dr Stands conspired with Dr Steen or the other way round. So, for the reasons outlined by my learned friend both in his written submissions and now orally, we support the 16 submission. 17 MR LAVERY: Could I also say, Mr Chairman, on behalf of the 18 Belfast Trust that we also support Mr Green's application for a preliminary ruling on this point? 19 20 I think it was palpable in the chamber vesterday the distress and grief and upset that this has caused to 21 Dr Sands. I can't speak directly, of course, to 23 Dr Sands, but I can tell you, Mr Chairman, that a lot of 24 the Trust witnesses who have given evidence, much -serious questions have been asked of them quite

has it hanging over them for weeks or months, the

potential for a serious and sometimes devastating impact

Dr Sands and Dr Steen from that earlier case? Or does this not end up as me giving rolling rulings as the inquiry continues along? 5 MR LAVERY: I accept, Mr Chairman, that there is a danger that each and every time a similar allegation such as this is made, you would be called upon to deal with it by way of a preliminary ruling. THE CHAIRMAN: If I give a ruling now, does that mean, when we sit again in January, somebody is going to come in on behalf of Mr Keane or whoever else and say, "Look, since you have given Dr Sands and others a ruling, I want a ruling in my case going back to 1995 or going back to the evidence earlier in 2012?" MR LAVERY: I can see it from your point of view, Mr Chairman, there is a danger that might happen and one an't anticipate that at this stage. This is a different case in my respect. This is an allegation that came out of the blue. It had not been raised before. It had not been raised during any of the police investigations and, although Mr Quinn says that some concerns were raised about the note, it seems to really have come from Mr Roberts as he was giving his evidence. Dr Sands has been given an opportunity to address that, I accept that, but the point that Mr Green

I distinguish what is represented today on behalf of

1	makes which we support, Mr Chairman is that this
2	does and will have an effect on public confidence.
3	THE CHAIRMAN: Okay. Thank you.
4	MR GREEN: Sir, I didn't adequately address the point that
5	you very properly raised with Mr Lavery, and which you
6	raised yesterday and I should have pre-empted in my
7	submission. So I apologise, but may I try and provide
8	a clear answer to it?
9	First of all, one distinction is that, no doubt for
10	good reason, because there's more evidential foundation
11	for the less serious allegations that have been
12	previously made, no-one to my knowledge and I have
13	checked this with Mr Uberoi and I'll submit to your
14	better knowledge of this has sought a ruling of this
15	sort yet.
16	The second distinction is this allegation is
17	particularly serious and particularly baseless. Drawing
18	those two points together, I submit that a fair but
19	bright and clear line can be drawn between outstanding
20	allegations of greater or lesser merit that are hanging
21	over others and this particular allegation.
22	THE CHAIRMAN: Okay.
23	MR FORTUNE: Sir, we wish to address the issue of the
24	consultation note. There is, in relation to the
25	consultation note, considerably more evidence. There is

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1	MR FORTUNE: I am making it clearly as counsel for Dr Steen,
2	but I have to say, in all honestly, I am drawing on my
3	recollection of the evidence when representing
4	Professor Savage.
5	THE CHAIRMAN: I understand. I understand why you are
6	drawing on recollection, but when you are saying on
7	behalf of Dr Steen there's a clear difference between
8	this allegation against Dr Steen and Dr Sands on the one
9	hand and the earlier enquiry about the Brangam Bagnall
10	consultation note and Professor Savage's presence at the
11	meeting, you are drawing that distinction as counsel for
12	Dr Steen only, not as counsel for Dr Steen and
13	Professor Savage.
14	MR FORTUNE: No, I am certainly not making a submission on
15	behalf of Professor Savage at this time.
16	THE CHAIRMAN: That's the point: because you are not making
17	a concession on behalf of Professor Savage, I should go
18	ahead and make a finding in relation to Dr Steen and
19	Dr Sands and not make a finding about the Brangam
20	Bagnall consultation note?
21	MR FORTUNE: Let me go back one step, sir. Had you not
22	raised the consultation note, our submissions would have
23	stood as they were made. Having introduced the
24	consultation note point, we need to address it, speaking
25	for myself as counsel for Dr Steen

obviously a dispute as to when in that meeting those there at the beginning were joined by Professor Savage. It comes some 15 minutes or so after the start of the meeting, but is not totally clear exactly at what point in the discussion -- because if you remember, sir, the evidence is one of themes. It is not a word-for-word or a shorthand minute of the note. There is also considerable agreement amongst the clinicians who attended as to what was said in much of that meeting. There is one paragraph about which we spent a great deal of time debating how it could have got there. Sir, that is a very different situation to the allegation made for the first time by Mr Roberts last week. It is quite proper to draw a distinction between the situations and, indeed, it is not, we would submit, a good point to say: well, I have not been asked for a ruling on an earlier matter, therefore, why should I now be asked to make a ruling in this situation.? Each part of this case depends on its own facts and. in our submission, the Claire Roberts situation can be distinguished factually. THE CHAIRMAN: When you make this submission, can I take it, 23 Mr Fortune, you are doing it as counsel for Dr Steen and not as counsel for Professor Savage?

no dispute that there was such a meeting. There is

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THE CHAIRMAN: I understand. Mr Quinn?
MR QUINN: May I say, with the greatest of respect to
    Mr Fortune, that my learned friend Mr Fortune highlights
    the difficulty that the chairman would have if you
    followed the submissions that were being made and
    allowed this ruling and had a ruling on this point
    because we would have numerous interventions coming up
    in the next two cases about doctors similarly slighted
    by allegations that are made in the witness box by
    parents.
        Secondly, we understand how this matter will be
    hanging over Dr Sands over Christmas, but I must say
    that Claire's death has been hanging over the Roberts
    family for 16 years and for someone to come along now
    and say they want some relief from their mental turmoil
     after what the Roberts have gone through I think is
     beyond belief because their allegations are not baseless
    and I don't want to go into all of the points I have
    already made in writing and that have been submitted by
    way of argument, but I feel what I should do is sum up
     what you said yourself, Mr Chairman, at page 125 of the
     18 December transcript, when you said:
         "I am not critical of the fact that the issue was
    not raised in September/October. During that period..."
         Again on page 125, you expressed how the Roberts
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1	must reel frustration, cynicism and even anger and you
2	went on to say at page 127, where I agreed with you,
3	asked for my agreement, when you went on to sum up:
4	"Would it be fair to say that it was a result of th
5	exasperation and disbelief that the Roberts now have in
6	relation to the evidence that they have heard?"
7	What we say and these are submissions that I make
8	on behalf of the Roberts are that this sets a very
9	dangerous precedent. The Roberts may come along and
10	say, "I would like a ruling before Christmas to ease my
11	mind". Mr and Mrs Roberts may want a ruling on whether
12	or not Dr Sands really did convey to them whether or no
13	their child was the sickest child in the ward. They
14	might want that ruling, because that would ease the
15	turmoil you can see in their mind, because they went
16	home at 9 o'clock the night before Claire died. Now
17	that's a turmoil for parents to suffer.
18	So we don't need to go over Dr Stewart's evidence
19	again it is outlined on page 15 of the argument
20	but if one looks at the following references, that's
21	witness statement 141/1, page 9 we don't need this
22	brought up where he gives where Dr Stewart thi
23	is a working diagnosis.
24	THE CHAIRMAN: Dr Sands.

MR QUINN: Dr Stewart. This is page 15 of my learned

now have Professor Kirkham and Professor Rating

together. So we are not going to have what was looking like a very unhappy arrangement where Professor Rating would come in first and be succeeded later in the week. So I think -- we will confirm this as soon as possible after Christmas. For now, I think you should take it that on Monday and Tuesday -- the 14th and 15 January -we will be taking the evidence of Professor Kirkham and Professor Rating. We might even have an international 10 multilingual witness box for that with a translator. Then during the rest of that week we will do Dr Carson, 11 12 Mr McKee and Professor Mullan. Okay. 13 MR FORTUNE: Can I ask you whether you are going to have the 14 two professors in the witness box at the same time? 15 THE CHAIRMAN: We are thinking about that was we have not 16 decided vet. We now know they are both available on the Monday. Professor Kirkham I think is only available on the Monday. I think Professor Rating is available on 18 19 Monday and Tuesday. We had Haynes and Rigg together, 20 but that was because they were sort of dual authors of their report and it didn't make sense to take them separately. We'll consider what the advantage would be 23 of -- sorry, Forsythe and Rigg, not Haynes and Rigg. 24 We will consider over the break what the advantages 25

and disadvantages of professors Kirkham and Rating

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friend's written argument, the skeleton. He has brought up various issues that Dr Stewart has said in support of the diagnosis of encephalitis. I would simply say there are other references in his witness statement where he doesn't mention encephalitis. Those references are: WS141/1, page 9; WS141/1, page 14; WS141/2, page 5. He makes no mention of encephalitis. One can pick through all of the transcripts, all of the witness statements and all of the evidence in this case and find similar arguments on both sides. I am not doubting that my learned friend Mr. Green, has found a reference to where Dr Stewart corroborates the mention of encephalitis, but I have found three references where he doesn't mention it and I have also found an entry on the transcript -- which is the transcript 6 November 2012, page 15, lines 1 to 9 -where he says he remembers hearing non-fitting status epilepticus mentioned. One could go on like this all day. My submission is it is dangerous to set a precedent and it should not be set. 21 THE CHAIRMAN: I am not going to give a ruling today. I will have to consider this over the break and I will come back to it on 14 January. MR GREEN: Thank you very much. 2.4 THE CHAIRMAN: Okay. On 14 January, I am pleased to say we

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together. At least they are going to be in the chamber at the same time, which is considerably better than before. Anything further? MR LAVERY: Do I accept that Mr McKee and Mr Carson would be giving evidence on Tuesday and Wednesday? THE CHAIRMAN: I would like -- the truth is, Mr Lavery, I don't know how long -- with Professor Kirkham and Professor Rating, we are certainly not going to go back through the endless Newcastle meetings and endless 10 reports. The issue between them now is quite a specific one. I am not clear how long we will take to go through 11 12 that evidence. I think we will provisionally have one of them lined up -- whether it is Dr Carson or 13 Mr McKee -- on Tuesday, but we are not -- Tuesday into 14 15 Wednesday and perhaps try to deal with them. We might 16 get it down from a five-day week, which I had feared, 17 into a four-day week. That will depend on how long Professors Kirkham and Rating take. 19 MR LAVERY: I am grateful for that indication. 20 THE CHAIRMAN: Anything else? Enjoy the break, ladies and 21 gentlemen. 14 January. 22 23 (The hearing adjourned until 14th January 2013)

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