THE INQUIRY INTO HYPONATREMIA-RELATED DEATHS

DEPARTMENT'S OPENING

(30 October 2013)

[Appearances]

1. The Chairman has kindly allowed me to make this opening on behalf of the Department. The purpose of this opening is threefold:

   a. to explain the Department's role in this Inquiry

   b. to say a little about the historical context of the events that give rise to this Inquiry and,

   c. to touch on some of the issues that will arise in this segment of the Inquiry's hearings.

The Department's Role in this Inquiry

2. This Inquiry was set up by the then Minister, Angela Smith, announced on 1 November 2004 that she had asked the Chairman to set up this Inquiry. The terms of reference were announced on 18 November 2004. On that latter date she said:

> *"The death of any child is tragic and it is essential that the investigation into these deaths is independent, comprehensive and rigorous. The Terms of Reference I have set for the Inquiry and the powers available to it are wide-ranging and should ensure that the Inquiry deals with all the issues of concern."*

3. The powers of the Inquiry include the Power to require witnesses to attend to give evidence on oath and the power to require the production of documents. These powers are available in relation to the Department itself. Indeed the Inquiry has exercised those powers extensively in requiring the production of a vast amount of Documents held by the Department and that witnesses, who are past or present officers of the Department, attend to give evidence.

4. That the Inquiry is comprehensive in its scope can be in no doubt. Even the briefest of perusals of the Inquiry's website reveals the breath of the examination conducted. Dozens of witnesses both as to fact and as

expert matters have been called to give evidence. Thousands of documents have been examined and scores of statements and further statements called for.

5. That it has been rigorous again can be in not doubt. It is a tribute to the Inquiry's legal team that no issue has gone untested. Every witness who has either given a statement or given oral evidence has been pressed on every point. No one has been allowed to get away with a general statement or to gloss over any event. No doubt some have found the giving of evidence a far from pleasant experience. That is a small price to pay to find out the truth.

6. Equally this Inquiry is robustly independent. While the Minister set up the Inquiry and it is to the Minister that the Inquiry will ultimately report, the Department is open to the same searching scrutiny as every other participant. Minister Smith has been succeeded, most notably, by the Ministers of the devolved Executive. Each Minister has upheld the independence of this Inquiry which is as it should be. Indeed, those Ministers are directly accountable to the Assembly and thus to the people of Northern Ireland. While it would be wrong to take anything away from Minister Smith in setting up this Inquiry, the intoduction of democratic accountability brings an extra element that double locks the integrity of this Inquiry.

This Segment of the Inquiry

7. The Terms of Reference relate to the investigation of the roles of the various statutory bodies including the Department. The Chairman has put flesh on those bones with his remarks on 2 July 2013. In that you spoke of the dominant culture of keeping quiet about mistakes and the changes that have occurred in the period since 2000 in particular. Hopefully you will hear evidence that will lead you to the conclusion that change has occurred in at least two domains.

8. First is the clinical domain. We are all aware of the old culture of "*the doctor knows best*" and no one was going to second-guess him or her never mind criticise the care provided. No doubt those of us of a certain vintage will have their own experiences. We were also brought up on a diet where this culture was immortalised in books, on TV and in the cinema. But the days of the tyrannical consultant have gone. This has been a result of particular drivers. Society at large is arguably less stratified and certainly less deferential to traditional authority figures. Such changes are not the part of the direct subject matter of this Inquiry but form an important part of the historical context.

9. The second domain where change has occurred is the extent to which the Health Service has developed through the concept of Clinical Governance. A lot has been said about that ever-evolving concept. I will touch on this issue later in this submission.

The Department's Role in the Health Service

10. Those without a detailed understanding of the arrangements for the provision of health-care could be excused for believing that it is the Department that provides health services via doctors in Northern Ireland. In fact this has never been the case. When the Health Service was originally set up health services were provided by Regional Health Boards. These Boards ran hospitals and employed doctors, nurses and other healthcare staff.

11. The position changed in Northern Ireland in the middle of the 1990's. There was a division between the commissioners of health services (Boards and GP Fundholders) and the providers of the same. The providers were newly constituted Trusts included hospitals.

12. The arrangements for the clinical governance of those at the sharp end of health-care provision has developed over that time In considering the evidence that has been heard and is to be considered by the Inquiry one cannot but be struck, I would suggest, by the fact that the notion of clinical governance is a relatively recent entry onto the scene. Indeed, some leading UK commentators stated in their 2011 book: *Governing the NHS*:

> *"As this chapter will make clear, one of the most surprising aspects of health-care regulation is how late it was in coming to the NHS. Indeed, until the Commission for Health Improvement (CHI), which was the regulator for trusts, began its work assessing standards and issuing star ratings in 2002, there was no proper system of regulation in the UK for health service … The volatile history of attempts regulations is revealing about the dogged defence of clinical autonomy extending over many years."*[1]

13. Indeed it appears that the publication in the United States of "*To Err is Human*" in 1999 and the Donaldson & Scally paper in the United Kingdom in 1998[2] were seminal events in the appreciation of the need

[1] *Governing the NHS, Issues and Tensions in Health Service Management* (2011): Story, Sullivan & Corbett-Nolan

[2] *Clinical Governance and the drive for quality improvement in the new NHS in England*, G. Scally and L.J. Donaldson, BMJ 1998, 317:61-65

for clinical governance. The former paper, in particular made it clear that the majority of medical errors do not result from individual recklessness or poor performance but more commonly, errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them. It concluded that, mistakes are best prevented by designing a safer health system at all levels, by making it harder for people to do something wrong and easier to do it right. Further, one could not simply leave the matter with the existing orthodoxy that a skilled and well motivated caring profession could be left to analyse adverse events on the basis that they were caused by the defaults of individuals but needed to be considered on a system wide basis.

14. The fact that clinical governance was a late arrival is not suggested as an answer to the issues before this Inquiry. The Department expressly disavows any suggestion that it was not responsible for the safe and effective provision of the health services that the people of Northern Ireland are entitled to expect. Indeed the Department disagrees with any suggestion that any of the bodies under consideration do not have any responsibility in relation to the matters that lie at the heart of the Inquiry's consideration.

15. In particular there have been some differences in the views of witness in evidence[3]. To add to the picture I would refer to a paper written by Ann Lloyd, the Chief Executive of the North Bristol NHS Trust in 2001. In considering the reforms brought in around that time she states[4]:

> *"At the heart of these reforms is the strategy that requires the quality of care delivered to become the driving force for the development of health services. Clinical governance has become the lynch pin for that strategy.*
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> *The responsibility and accountability for the overall quality of clinical care has been placed on the shoulders of the Chief Executive of the employing organisation. This has come as no surprise to the majority of the Chief Executives in the country who always assumed that accountability. Certainly, in their experience of managing complaints and concerns from patients, they have always believed themselves to be held to account by the public for that responsibility … the really tangible change for Chief Executives arising from [The reforms] is that now they have to demonstrate clearly that they have mechanisms in*

[3] see, in particular the evidence of William McKee, transcript day 76, 17 January 2013, page 6, lines 1 – 4.

[4] *Advancing Clinical Governance*, edited Lugon & Secker-Walker (2001), Pages 39 - 40

place through which they can account for this responsibility and take action on the outcome of these processes in the organisation."

16. The much more difficult question is what "*responsibility*" means when applied to the circumstance of any individual or organisation. Clearly the treating clinicians are "*responsible*" in the sense that they make decisions that have consequences. The Trusts are responsible as the employers of those clinicians and as the operators of the various hospitals. The responsibility is real but different from the clinicians. No one expects a Trust manager to stand over a clinician and supervision the treatment provided to a patient. The Trust has a clear responsibility to ensure that patients, at least, are treated in accordance with accepted practice. It also has responsibility when something goes wrong to investigate and take any necessary action.

17. Equally the commissioners of services had and have a clear responsibility for the delivery of quality. Again one does not expect that Board members sit at the desk of Trust managers to ensure that things are done properly. However, certainly when something goes wrong one expects that the Board to be in a position to take any necessary action within the scope of its role and powers.

18. The Department has its own responsibility. At one level it is involved in questions of the proper expenditure of public money and the strategic direction of the Health service in Northern Ireland. It also has responsibility in another sphere. The Minister is accountable to the Assembly and the electorate and must answer for all matters of public concern. It has the power to take action with regard to failings within the Health Service.

19. Underlying the responsibilities of the statutory bodies and their ability to act presumes that they will be provided with the information that they need in a timely fashion. To take the example of the need for Boards and Trusts to report serious adverse incidents to the Department, Professor Scally[5] (in relation to Boards):

> *"It's an issue around seriousness and one can define seriousness in several different ways. It could be seriousness in relation to the reputation of the Health Services or the individual organisations, or indeed it could be seriousness in relation to its effect on the care and treatment of patients. So it would be a judgment call by the senior officers of the board as to when they would inform the Department."*

He went on to make the same point in relation to Trusts[6].

[5] Day 118, page 6
[6] Day 118, page 57

20. As stated above, this system was largely based on the assumption that professional people will act in a manner that you expect and that professional people throughout an organisation will act consistently. If this Inquiry has demonstrated one thing, it is that these assumptions were either unfounded or, at least, they did not operate as an effective governance mechanism. The Inquiry will come to its own view in this regard. One can perhaps offer three interweaving factors that may have been at play:

    a. the traditional notion that clinical matters were for clinicians and should be resolved either by them or by those close to them in professional terms,

    b. the fact that there was a defensive culture in that people are afraid of being blamed which will have a chilling effect on effective reporting and,

    c. the frailties inherent in any system in which is made up of even well meaning person. People, forget things, put things off, are too busy to give something adequate attention or simply make errors of judgment.

21. I do not propose to descend into the detail of the current arrangements in the Health Service. They have been skilfully summarised by my learned friend and are set out with commendable clarity. However it is probably fair to say that the new paradigm of clinical governance recognises that the assumptions made in the past cannot be relied upon. Procedures are now set out for reporting. Protocols have been devised as to when the reporting procedures should be invoked.

22. Where we must, respectfully, part-company with Professor Scally is in relation to his analysis as how Northern Ireland Compared with the position in Great Britain. Whether the mechanisms clinical governance mechanisms in place by 2000, were adequate by the standards of the time is a matter for this Inquiry. What we say is that it would be wrong for the Inquiry to take from the evidence that at 2000 the Department was lagging behind the rest of the United Kingdom. Insofar as the following appears to be a critique of Professor Scally's report the same is not offered in an adversarial manner. The imperative for the Department is to ensure that the Inquiry has all the material information to hand.

23. Professor Scally is correct to suggest that the 2000 paper from Sir Liam Donaldson et al, *An Organisation with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS* marked a change in

the approach to Clinical Governance in Great Britain. This 2000 Report was the first clear acknowledgment in the UK that serious adverse incidents were not simply the product of errors on the part of individuals but a result of a chain of events that the system did not work to prevent[7]. Some steps towards clinical governance were already under way both in Great Britain[8] and in Northern Ireland. The local arrangements were set in train by circular *HSS (MD) 7/00* dated 29th March 2000, where the then CMO in Northern Ireland highlighted developments in the rest of the United Kingdom, the absence of formal mechanisms to establish clinical and social care governance in Northern Ireland, and work that she had commissioned on clinical standards. In the subsequent document, "*Confidence in the Future,*" of October 2000, the CMO in Northern Ireland recommended the introduction of Clinical and Social Care Governance and Appraisal for all doctors in Northern Ireland. This document made fourteen specific recommendations, including that participation in clinical audit and continued professional development be compulsory of all doctors. In particular Recommendation 12 was that "*A framework for Clinical Governance in the HPSS including primary care, be established as a matter of urgency*." Furthermore Recommendation 14 suggested that, "*Methods of Recording Adverse Incidents be put in place in every organisation and a regional register established.*" Subsequently, in Northern Ireland the Department issued a consultative document, *Best Practice Best Care*, April 2001 and also circular HSS (PPM)10/2002, which set out guidelines for the implementation of Clinical and Social Care Governance arrangements. In fact, those guidelines had already been issued to Boards and Trusts via a letter of July 2002.

24. The importance of the 2000 Donaldson report, for the purposes of this Inquiry and the date of the same is that the comparative exercise that Professor Scally was asked to carry out was limited. In fact he was asked:

> "*How did the mean's of the Department's knowledge or lack of knowledge compare with the rest of the UK at the relevant times which are 1995, 1996 and 2000?*"[9]

25. In his report delivered last Thursday, Professor Scally refers to the various mechanisms available in Northern Ireland for the transmission

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[7] para 3.18

[8] *A First Class Service, Quality in the new NHS*, July 1998 and the subsequent circulars HSC 1999 (33) and HSC 1999/065

[9] undated brief to Professor Scally at para 65 (c)

of information to higher levels[10]. He goes on to consider Circular METL 2/93 and suggests that the document "*does not display any interest in patient care issues ...*" What the Professor does not state that at that time the role of the Department was considered to be one of strategic overview which was in accord with Central Government policy. I will return to this below.

26. The Professor identifies various reporting mechanisms that were available in Northern Ireland in the 1990's. An analysis of the 2000 Donaldson report shows that (apart of one mechanism dealt with below) the same reporting mechanisms[11] were in operation in Great Britain at that time. Sir Liam's conclusion on this issue was[12]:

> "*There are no universally accepted criteria for identifying the occurrences or outcomes of health care that should constitute a basis for recording or reporting poor quality. Neither does the NHS have a single comprehensive system of gathering data to enable service failure to be recognised, but information is available from different sources. Some are specifically set up to monitor adverse events, whilst others are designed to gather more general health information.*"

27. The Department would respectfully draw to the Inquiry's attention that the mechanisms identified by the Donaldson Report as being in operation in Great Britain and those indentified by Professor Scally[13] in his latest report are either materially identical or, at least, cover the same ground. If anything the position in Northern Ireland was more favourable in one respect in that there were "*routine meetings between the Department and organisational or professional leaders, such as Directors of Public Health*". What Sir Liam's paper and other papers on this issue, do not display a role for the Department of Health in the collection of information on individual adverse incidents other than to set the framework.

28. The only additional factor in play in Great Britain was the local reporting system set up in 1994[14]. By 2000 that has not provided data that the Donaldson Committee was even able to collect. All it could do is to extrapolate from a few Trusts that did operate such a system and arrive at a figure of 2,500 adverse incidents per annum. When one compares that to the Committee's own study which suggested that 850,000 hospital patients were subject to adverse incidents, one can see

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[10] para 1.
[11] the bullet points at para 4.9
[12] para 4.9
[13] the bullet points at paragraph 1 of his report of 23 October 2013
[14] Letter to NHS Regional Directors from NHS Executive, 10 May 1995

how well even the Trusts, who had some system in place, were operating the system.

29. It is clear, however, that by 2000 some work on Clinical governance was already under way at a local level. This was a work in progress. The Report stated[15]:

> "*NHS organisations are due to produce their first annual clinical governance reports later this years, but as has been explicitly recognised there is considerable variation in states of readiness for the development of clinical governance and it should be seen as a medium to long-term objective.*"

It carried on[16]:

> "*It is also very pertinent to ask how well current mechanisms for learning from experience appear to support NHS organisations in improving the quality and safety of the care they provide.*"

. Unsurprisingly the Report concluded[17] that "*there were a number of serious weakness"*, and went on to say, "*To some extent this situation may reflect both the culture of devolved responsibility and competition under the internal market which occurred at Regional level during the same period"*. This is recognition that, the 1990s in the NHS, had been an era when market solutions had been tried in an attempt to drive down costs by creating autonomous health care Trusts. The market was also suppose to drive up quality due to the fact that commissioners would move towards better performing Trusts. The direct oversight of quality was to be contract driven arising from the relationship between Commissioners and providers. Externally imposed governance structures were largely directed to the stewardship of public funds. The key idea was that if a function could be devolved to Trusts, it should be devolved. This "free market" model may have worked well in some economic settings. Whether it operated efficiently in the health care setting is at the heart of the Inquiry's current consideration.

30. In any event it will be recalled that the 2000 Donaldson Report led to the formation of the National Patient safety Agency which started work in December 2001. This was followed by a 2001 document "*Doing less harm*" and the NPSA 2004 publication "*Seven Steps to Patient Safety*" which set out the mechanisms for reporting. It is instructive to see how

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[15] para 4.3
[16] in the same paragraph
[17] para 4.18

well the NPSA system worked. The answer is given in the National Audit Office's Report in 2005[18]. It stated[19]:

> *"The roll out of the National Patient Safety Agency's National Reporting and Learning System has taken two years longer than originally envisaged. By 31 December 2004 all trusts had the technology to link to the system but many still had to map details from their local system to the national system. By the end of March 2005, some 170 acute, ambulance and mental health trusts had reported 79,220 incidents (a further 6,122 incidents were reported by primary care trusts making a total of 85,342 patient safety incidents reported to the National Reporting and Learning System up to March 2005)."*

31. If one takes these three months it would suggest that around 300,000 adverse events would be reported per annum. This is just over one third of the Donaldson Report's 2000 estimate of the number of adverse incidents that occurred annually.

32. In Northern Ireland the first guidance as to adverse incident reporting came in July 2004, in the form of *Circular HSS (PPM) 06/2004*, *Reporting and follow-up on serious adverse: incident interim guidance.* The substantive guidance was issued by means of *Circular HSS (PPM) 02/2006, Reporting and Follow-up on Serious Adverse Incidents, March 2006.* Additional guidance was subsequently issued by the DHSSPS, *How to Classify Adverse Incidents and Risk, Guidance for Senior Managers Responsible for Adverse Incident Reporting and Management, April 2006.* It is acknowledged that the Department was behind England and Wales in issuing guidance due, largely, to the setting up of the new devolved Government arrangements in Northern Ireland and the stop-start nature of the same. Some comfort can be derived from the fact that Northern Ireland worked rapidly to close the gap. This can be seen from the fact that the NPSA published its first national learning report in July 2005. The equivalent learning report in Northern Ireland was published by the Department in June 2006.

33. It is clear that, in all regions, this was a work in progress. Perhaps it will also be so. Sir Liam Donaldson issued a Report in 2006[20] on the progress made since his 2000 Report. He wrote:

> *"important and necessary steps have been taken on the journey to improve patient safety across the NHS. There is much greater awareness among clinicians, managers and policymakers that patients are not as safe as they should be. We have seen an unprecedented*

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[18] Building a Safer Place for Patients: Learning to Improve Patient Safety

[19] Executive Summary, para 17, Main Report para 2.11

[20] Safety First (2006) – Dept of Health

growth in the number of voluntary reports from healthcare staff about their safety concerns. Much effort and debate has gone into defining the types of intervention necessary to reduce risks and improve safety. At times, within NHS organisations we have seen glimpses of potentially exciting safety projects and initiatives that carry the seeds of the large-scale change that is needed to genuinely put 'safety first'. However, the pace of change has been too slow. We are still unable to assure NHS patients that all organisations are learning from experience in ways that prevent harm to future patients. This, however, is a challenge for all developed countries – the NHS is not unique in this respect. Indeed, most countries recognise that they have for too long failed to give priority to patient safety compared to other areas of healthcare.

34. When one looks at the totality of the regimes in place throughout the United Kingdom, any suggestion by Professor Scally that Northern Ireland was significantly lagging in the introduction of clinical governance and adverse incident reporting arrangements is not borne out. Indeed Professor Scally does not appear to have many of the key documents to hand[21]. It may be that Professor Scally had an idea that the picture in Northern Ireland was not limited to METL 2/93 in that he attaches an important caveat to his conclusions: "… i*n the absence of evidence to the contrary …*"[22].

35. Professor Scally goes on to criticise the professional leadership within the Department and the Chief Medical Officer in particular. What is not stated is that neither the CMO nor CNO had direct policy responsibility for quality or clinical governance within the Department at the relevant time. Both Officers, and the CMO in particular, would have a professional advisory role in ensuring that this remained central to Departmental policy and the strategic direction for the health service as set by the Department. What does appear from the report 2000 report, "*Confidence in The Future*," is that the then CMO was actively seeking to progress this agenda by recommending that a framework of clinical governance in the health service including primary care be established "*as a matter of urgency*."

36. The challenge facing the NHS throughout the United Kingdom and the ongoing nature of the task is underlined by the Inquiries in England into Harold Shipman, Beverley Alit, the Bristol Royal Infirmary and the Mid-Staffordshire Trust. In 21 July 2013 the Secretary of State for Health, Jeremy Hunt gave a speech[23] where he discussed what he

[21] see Appendix to his instructions for the list of documents that were provided to the Professor.
[22] Para 54 of his report of 23 October 2013
[23] www.gov.uk/government/speeches/the-silent-scandal-of-patient-safety

referred to as "*the silent scandal of patient safety*". He considered the many of the matters set out above and concluded by saying:

> *"The lesson of recent tragedies is that the NHS must never again be silent about patient safety - because it matters too much. It matters to each one of the million people who have given their professional lives to the NHS. And it matters to each one of the millions of patients they care for every year. A change of this magnitude will not be instant, nor will it be easy. But it is possible. And our NHS should aspire to nothing less"*

Concluding Remarks

37. The foregoing is a brief tour though just some of the issues facing this Inquiry. It is replete with detail of reports, circulars and recommendations. Despite this, can I say, on behalf of the Department, that we are acutely aware that at the heart of this Inquiry lie the short lives and tragic deaths of little children whose parents put their fate in the hands of the Health Service. Nothing can replace the lost years that lay ahead of each child. Nothing can make up for the immeasurable and enduring suffering of their families and all whose own lives were touched by those children. While nothing that we can do could ever make up to the slightest degree for that loss and suffering, it is hoped that the very fact of the existence of this Inquiry and the detailed examination of the questions posed, do provide some assurance that there is a commitment to find out what went wrong. Perhaps, more to the point, the sincere hope of the Department is that this Inquiry will move us towards a situation where mistakes in healthcare, if they can never be totally excluded, become increasingly rare. We owe these children, and their families, no less.