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Strictly Private & Confidential
Mr Justice O'Hara
Chairman to the Inquiry into Hyponatraemia related Deaths
Arthur House
41 Arthur Street
Belfast
BT1 4GB

Our ref: RMcM/RMcA/M389
Your ref:

23rd May 2013

BY E-MAIL ONLY

Dear Sir,

Re: Our Client – Dr James F Kelly

We write, further to previous correspondence, and upon receipt of the report of Dr Roderick MacFaul, Governance Expert to the Inquiry, dated 25th April 2013.

We note that the Brief to Dr MacFaul (paragraph 147) states that the Inquiry has been advised by the GMC that an outstanding complaint remains against Dr Kelly. We appreciate that this Brief is dated April 2012, and therefore precedes the cancellation, by the GMC, of proceedings against Dr Kelly, as outlined in the decision of the Investigation Committee Member, Professor Roger Green, provided to you on 4th October 2012.

You will note from the decision of Professor Green, that he refers on page 4 (paragraph 11), to the report of Dr Mike Durkin, whom he refers to as *"an experienced Medical Director from another Trust."* Mr Green sets out a number of points made by Dr Durkin in his determination, and concludes his summary of the report by stating *"in his opinion the actions of Dr Kelly did not fall below the standard expected of a reasonably competent Medical Director when the time of the incident is considered."*

We wish to draw the decision of Professor Green to your attention for two reasons:

1. Firstly, to remind the Inquiry that the complaint against Dr Kelly is no longer outstanding. We invite the Inquiry to notify such experts who continue to labour under this continued false impression, most notably Dr MacFaul, to be informed of Professor Green's decision, so that they can make such correction(s) to their report(s) as they think fit; and
2. Secondly, that as a Medical Director, we consider that Dr Durkin is of the ideal background to comment on the reasonableness of Dr Kelly's actions in the aftermath of the death of Lucy Crawford, judged by the standards of the time. More so, we submit, than Dr MacFaul, who does not have experience of ever having held such a position.

We therefore wish to put you on notice that we are likely to seek to rely on Dr Durkin's report during the course of the Inquiry. However, we recognise that if Dr MacFaul is to have the contents of Dr Durkin's report put to him, he needs to see it, as do you, and as do all other Interested Parties in the interests of fairness to all. We therefore append a copy of the report for your consideration in advance of the start of the resumed Oral Hearings next week.

We recognise that the Witness Protocol (at paragraph 2.6) makes it plain that it is for the Inquiry to decide who to call to give oral evidence. But we think it right to invite you to consider, in accordance with paragraph 2.1 of the Protocol, whether Dr Durkin is a person with information likely to be of relevance to the Revised Terms of Reference and the List of Issues, in light of the totality of the material the Inquiry has already received. We submit that he plainly is such a person, and, as such, is someone you may wish to consider calling to give live evidence.

Finally, we feel we ought to provide an explanation for why you are receiving this correspondence the week before the Oral Hearings in Raychel Ferguson (Preliminary) are due to begin. The reason is that we only received the (lengthy) report of Dr MacFaul earlier this month, the Consolidated Report by Advisors dated 15th May 2013 even more recently, and the Opening note for this segment of the Inquiry yesterday. We consulted carefully with Counsel earlier this week about the issues raised in the first two documents and have, therefore, only very lately been able to come to a firm view that Dr Durkin's report is likely to be of assistance to the Inquiry, in providing some balance in the scrutiny of Dr Kelly's actions, whereas hitherto we did not wish to inundate you with additional material on a purely speculative basis.

Yours faithfully,

Carson McDowell LLP
Transmitted electronically without signature

Enc – Report of Dr Durkin

GMC v Dr James Kelly
Fitness to Practise Panel Hearing – Date TBC

Introduction

I have been asked to give an expert opinion in relation to the actions taken by Dr James Kelly, Geriatrician and Medical Director of the Sperrin and Lakeland Health and Social Care Trust, Northern Ireland ("the Trust") following the death of LC, a patient at Erne Hospital, Enniskillen, Northern Ireland in April 2000.

The purpose of the instruction was to provide a report to the GMC which is investigating a complaint made in relation to Dr James Kelly. A case had been listed to be heard by a Fitness to Practise Panel which would consider whether his fitness to practise is impaired to a degree that would justify action on his registration.

I was provided with the letter of instruction 2 March 2011 and a set of documents (bundle 1) referenced by Ms Hannah Eldridge, acting on behalf of the GMC:

1. Letter of instruction from Dr Fee to Dr Quinn dated 21 April 2000
2. Copy of the documents that Dr Quinn was provided with by Mr Fee
   a. Anonymised hospital records of Lucy Crawford
   b. Summary post mortem report dated 17 April 2000
   c. Final post mortem report dated 12 June 2000
3. Report by Dr Quinn dated 22 June 2000
4. Report by Moira Stewart dated 26 April 2001
5. Good Medical Practice (2000), although stated as (2006) in letter of instruction.

On reviewing the above documents I believed that there were further documents that I required in order to complete this report:

- A job description for Dr James Kelly, outlining his role and responsibility as Medical Director
- The management structure of the Trust
- The medical leadership and directorate structure of the Trust
- The Clinical Governance structure of the Trust
- Relevant Reports to the Board and Executive Team
- Minutes of the Clinical Governance Committee

As a result of this further enquiry on 9 May 2011 I was provided with copies of 52 further documents as referenced by Ms Hannah Eldridge in two further bundles.

These bundles were accompanied by a letter referenced April 14 2011 RMcM/EH/M389, which detailed a response from Roger MacMillan on elements that he believed were pertinent to this expert report.

A copy of the transcript of a conversation between a television reporter and Dr Quinn was referenced as being with the above documents in the first letter of instruction (2 March 2011) but was not included as that element was subject to another expert report. I was subsequently given access to a copy of this transcript.

Background

The background to the actions taken by Dr Kelly and the subsequent complaint are outlined in the letter of instruction of 2 March 2011 from Ms Hannah Eldridge.

I have no further amendments to make on this chronology of events other than to refer to the letter RMcM/EH/M389 which provides further commentary particularly relating to the LC post-mortem findings, the decision to nominate Dr Quinn to write a report, the findings and report by Dr Moira Stewart and its availability to the family of LC, and the Coroners' Service to Northern Ireland.

Opinion

1. **Should Dr Kelly have notified the Coroner that LC had not died of natural causes?**

It would have been normal practice for the death of a patient who has not died of natural cause to be reported (or referred) to the Coroner. This is a duty which is not solely that of the Medical Director for the organisation within which the death occurs or even of the relevant doctor with responsibility for the particular case. This is outlined in the attached image which sets out[1] the responsibility to report death other than of natural cause to the Coroner within 28 days. It would have been usual however for the death to have been reported to the Coroners' Service by the doctor in charge of the case at the place of death. I believe therefore that the responsibility to report the death was that of the medical team at the place of death of LC; I would have also expected that a discussion and file note should have taken place between the receiving medical team at the Royal Belfast Hospital for Sick Children and the referring team at Erne Hospital to agree the next steps which would have included who would make the referral to the Coroner.

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[1] img-519083456-0001.pdf

2. **Should Dr Kelly have made enquiries to see if Dr Quinn had previously had interaction with the Trust?**

I understand from the documents provided that, Mr Mills, Chief Executive, instructed Mr Fee, Director of Acute Services at the Trust and Mr Trevor Anderson to investigate this case. I understand that this decision followed discussion between Mr Mills and Dr Kelly. It was decided that Mr Fee should proceed to seek a review of the care given to LC. The documents provided included the terms of reference for the review and the instruction letter from the Trust signed by Mr Fee to Dr Quinn, Consultant Paediatrician at Altnagelvin Area Hospital, Londonderry.

I would have expected that the leadership of any clinical investigation would be taken up by the Medical Director, unless any stated conflicts of interest precluded such leadership. If there were any such conflicts then the usual practise would be for another Executive Director or the Director of Nursing to take such a leadership position. It would also be normal practise to enquire as to whether any conflicts of interest would preclude the choice of reviewer. In reviewing the documentation I could no find evidence that the concern that any conflict of interest had been raised or whether any conflicts had been stated by Dr Kelly, Mr Mills, Mr Fee, Dr Anderson or Dr Quinn.

It is my opinion that Dr Kelly should have made enquiry and sought confirmation from Mr Fee whether there were any issues that would have precluded Dr Quinn from carrying out the review because of any previous dealings with the Trust that would have rendered his review prejudicial or without sufficient expertise.

This finding however should be seen in the context of the time however when sparse guidance on the duties of the reviewer or commissioner of such a review to ensure through due diligence methodology that any actual or perceived conflicts of interest was in place.

3. **If enquiries had revealed that Dr Quinn had previously had interaction with the Trust, would Dr Quinn be considered an independent expert for the purposes of writing the report?**

In my view there are two issues within this question.

Firstly whether or not Dr Quinn had any material interactions that would prevent him from acting as an independent reviewer; and secondly whether or not Dr Quinn had sufficient expertise to be designated as having the capability of an expert. I am not in a position to give an opinion as to whether Dr Quinn had the capability of an expert reviewer.

It is my opinion that previous interaction by Dr Quinn with the Trust would not of itself have prevented him from being considered either as a reviewer or as an independent expert with regard to providing a written report of a review of a clinical case.

However it should be seen as essential that before any such review is undertaken a full disclosure of any interactions that may be seen as conflicts of interest should have been made by Dr Quinn. As stated above it should also be incumbent of the Trust through its officers, in this case, Mr Fee who was designated as the Trust lead for the investigation, to ensure whether any such conflicts or questions of capability were present or had ever been present and that a written record of such was made.

This does not however absolve Dr Kelly as Medical Director who should have ensured that he was satisfied that there were no reasons of capability or probity that would have prevented Dr Quinn from acting as the independent expert reviewer and if there were any concerns he should have raised these with Mr Fee or Mr Mills.

I could find no evidence or documentation to confirm that Dr Kelly had documented a record of any such concerns and this should have been in place. This may be seen as a failing in current times but it was not unusual at that time although good practice would confirm that Dr Kelly should have confirmed any conflicts.

I note that it has been recorded that members of the Western Health and Social Services Board (Dr W McConnell, Director of Public Health, Dr Colin Hamilton, Consultant in Public Health Medicine and Mr Martin Bradley, Chief Nurse) were also advised of the involvement of Dr Quinn as an external opinion and I could find no record relating to concerns relating to previous interactions with the Trust.

4. **Whether Dr Kelly failed to identify that Dr Quinn's Report was flawed**
    a) **because the report failed to identify that hyponatraemia as a probable cause of LCs death or,**
    b) **for any other reason**

The four page report by Dr Quinn dated 22 June 2000 provided a review of the case notes pertaining to the care provided to LC on 12 April 2000.

Dr Quinn was asked to write a report to answer the questions as set out in the instruction letter from Mr Fee, namely what his opinion was relating to:

1. The significance of the type and volume of the fluid administered
2. The likely cause of the cerebral oedema

3. The likely cause of the change in the electrolyte balance ie. Was it likely to be caused by the type of fluids, the volume of fluids used, the diarrhoea or other factors

I note on page 2 of his report that Dr Quinn confirms a low sodium measurement at or around 0300h with a consequent decision to administer normal saline. In a subsequent paragraph 3 on page 2 Dr Quinn makes reference that he was made aware of a Pathologist report that states significant pneumonia and cerebral oedema were present.

The post-mortem report of 17 April 2000 by Dr M D O'Hara provided states in the clinical summary that the sodium measured at Erne Hospital was in the hyponatraemic range of 136-126. It also states that the CT scan of April 13 2000 at Royal Belfast Hospital for Sick Children identifies obliteration of basal cisterns. It determines a Clinical Diagnosis of dehydration and hyponatraemia; it also confirms cerebral oedema with acute coning and brain stem death. The Clinical History was provided by Dr Caroline Stewart, Specialist Registrar, Paediatrics, RBHSC.

These findings were not referenced in the report by Dr Quinn who in his report states:
"I find it difficult to be totally certain as to what occurred to Lucy at or around 0300a.m. or indeed what the ultimate cause or her cerebral oedema was"

I am surprised that Dr Quinn does not state whether he has read or utilised the information from the post-mortem other than to acknowledge being made aware of the Pathologist report. I believe that this would have been important contextual information for Dr Kelly who although the Medical Director, as a Geriatrician would not have been expected to have the current practice of infant fluid resuscitation to hand and as such may not have seen the registrars statement as pertinent.

On reviewing the documentation provided and including materials provided by Mr McMillan I understand that Dr Kelly discussed the findings of the report with Dr Quinn and with Mr Fee. it also states that he discussed the findings with Dr Halahakoon, Lead Paediatrician, and Mrs E Traynor, a Senior Paediatric Nurse for the unit at Erne Hospital.

I could find no reference that Dr Kelly or Mr Fee, or indeed any other person had questioned the capability or findings of the report by Dr Quinn. It would appear from the documentation provided that the main concern at the time was related to the clinical abilities of members of the paediatric team rather than the cause of death of LC.

At the time of the report by Dr Quinn I understand that there was a lack of knowledge of the pathophysiology of cerebral oedema and the role of

intravenous fluids in infants and as such the failure of the report to identify that hyponatraemia was a probable or possible cause of death was not due to a failure of Dr Kelly to scrutinise the report by Dr Quinn. It is of note that the Specialist Registrar states coexisting conditions within the clinical summary of dehydration, hyponataemia and cerebral oedema.

Although Dr Kelly may have requested a more thorough case review by Dr Quinn it would not be reasonable to conclude that Dr Kelly failed to identify that Dr Quinn's Report was flawed because the report failed to identify that hyponatraemia as a probable cause of LCs death.

Guidance on the compilation and formulation of evidence to provide expert reviews was immature at the time. It has since become good practice to use guidance as provided by the National Patient Safety Agency with regard to Root Cause Analysis[2] and the Incident Decision Tree[3].

5. **Whether Dr Kelly acted appropriately by not disclosing a copy of the report by Moira Stewart received on 26 April 2001 to**
   a) **LCs family and,**
   b) **the Coroner**

It has been and will always be important to share information concerning any element of a patient's pathway and specifically any investigative findings with the patient and with their permission with certain family members, or those granted power of attorney. In this case it would have been important to share the findings of Dr Stewart with the family of LC, and with the Coroner.

It was often the case that the advice given to Trusts and medical practitioners by the legal profession acting to protect their interests failed to recognise the importance of sharing information.

In 2005, the National Reporting and Learning Service issued guidance on communicating with patients when things go wrong. This was published through the Central Alert System[4] and was subsequently re-launched in 2009 as the initiative Being Open[5] by the NPSA with an action date of November 2010.

[2,3] https://report.npsa.nhs.uk/rcatoolkit/course/iindex.htm

[4] http://www.nrls.npsa.nhs.uk/resources/?entryid45=59792

[5] www.nrls.**npsa**.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=65172

At the time however in 2000 it was not uncommon for information to be withheld from patients and their families. I believe that this was unreasonable on the part of the Trust and therefore Dr Kelly and that this report should have been shared with the family and the Coroner.

Not below the standard at the time

6. Whether Dr Kelly failed to adequately investigate LC's death

I have considered the documentation provided, reviewing the reports provided by Dr Quinn, the preliminary findings of the post-mortem by Dr O'Hara, the report by Dr Stewart for the Royal College of Paediatrics and Child Health, and chronologies provided by Dr Kelly.

From the documentation provided Mr Fee was tasked with the leadership of the investigation into the death of LC. He was to work with Dr Anderson. The report was shared with Dr Kelly who had the opportunity to discuss the report with Dr Quinn.

It is my opinion that Dr Kelly made reasonable efforts to investigate the cause of death of LC and that he did not fail to adequately investigate the death of LC. It is my opinion however from the documentation provided that there appeared to be more enquiry into the capability of the paediatric medical team following the report as opposed to whether or not it provided sufficient detail to provide for a root cause analysis of the death of LC.

7. Whether Dr Kelly should have taken any further action on receipt of the report

From the materials provided and given the rudimentary state of clinical governance systems and processes at the time of the report I am of the opinion that Dr Kelly acted reasonably with regard to the further actions that he took between April 2000 and October 2002 following the report made by Dr Andrew Boon and Dr Moira Stewart.

It is recorded that he made a written update to the Western Health and Social Services Board following receipt of the report in May 2000. It is recorded that he discussed the findings of the report with senior members of the clinical team at Altnagelvin Hospital.

A further review into the case was undertaken by Dr Moira Stewart, on behalf of the Royal College of Paediatrics and Child Health and I understand from the materials provided that Dr Kelly raised the issue of fluid regimes relating to the

use of intravenous fluids in infant resuscitation were raised with the Chief Medical Officer for Northern Ireland.

It is apparent that he shared the findings of published materials on this matter with staff at Altnagelvin Hopsital.

My opinion from the materials provided is that Dr Kelly acted reasonably after he had received the report by Dr Quinn. I also believe from the materials provided that he acted reasonably following receipt of the two reports on behalf of the RCPCH by Dr Moira Stewart, and by Dr Andrew Boon and Dr Moira Stewart.

8. If Dr Kelly had dealt with the investigation differently, could this have led to RF receiving a more appropriate treatment plan

I do not believe it is possible for me to give an opinion as to whether RF would have received a more appropriate treatment plan if Dr Kelly had dealt with the investigation differently.

At the time of this case the systems and processes of clinical governance were in their infancy. *(G Scally and L J Donaldson: Clinical governance and the drive for quality improvement in the new NHS in England, BMJ (4 July 1998): 61-65)*[6] *(Halligan A, Donaldson LJ. Implementing clinical governance: turning vision into reality. British Medical Journal 2001; 322: 1413-1417)* [7].

There was little evidence of a systematic method of incident reporting and it was probable that there was no systematic approach to the rapid spread of learning from such serious incidents.

I make reference to the use of the tools of such above but these were not in practice at the time of these incidents in Northern Ireland.

[6] http://www.bmj.com/content/317/7150/61.full

[7] http://www.bmj.com/content/322/7299/1413.full

Conclusion

It is my opinion that the actions taken by Dr Kelly did not fall below that expected of a reasonably competent Medical Director. I make this opinion based on the documentation provided regarding this case and also on the basis that the systems and processes of clinical governance were in their infancy and that the methodological approach to investigate clinical incidents and carry out root cause analyses into such were not in place at that time.[8]

Dr M A Durkin
22 August 2011

[8] http://www.gmc-uk.org/Management_for_doctors_2006.pdf_27493833.pdf