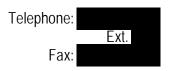
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Your ref:

Our ref: RSJ/ah/090212ferguson

25th February 2013

Children's Unit Salisbury District Hospital Salisbury Wiltshire SP2 8BJ



Northern Ireland Inquiry Into Hyponatraemia Deaths Re: Raychel Ferguson

Response to further witness statements received December 2012 and January 2013.

I received further witness statements from medical staff involved in Raychel's acute illness, written in response to specific questions posed by the Inquiry team. I was asked whether any of these would alter the conclusions of my reports written in February 2012.

In December 2012 I received statements from:

Dr Mary Butler

Dr Joe Devlin

Dr Michael Curran (2)

Dr Bernie Trainor

Dr Brian McCord

Dr Peter Crean

Dr Donncha Hanrahan.

In January 2013 I received statements from:

Mrs Marie Ferguson

Mr Raymond Ferguson

Mr Makar

Dr Gund

Dr Jamison

Mr Zafar

Dr Allen

Mr Gilliland

Dr Kelly

S/n Patterson

S/n Noble

S/n McAuley nee Rice S/n Roulston S/n Gilchrist S/n Bryce Sr Millar Dr Jeremy Johnston

Mr Zawislak

This report replaces the draft report I wrote in December 2012 in response to the first batch of statements, and incorporates my responses to all the above statements. The statements below are limited to my responses to these witness statements, and should be considered in conjunction with my original compendium report dated 13 February 2012.

1) Dr Barry Kelly

Dr Kelly was the A&E SHO who initially assessed Raychel. He elicited a typical history and examination findings consistent with appendicitis. He referred her to the surgical team and she was subsequently assessed by Mr Makar. He prescribed IV Morphine (Cyclomorph) but cannot recall whether this was on the instruction of the surgeon. He did not start IV fluids.

2) Mr Ragai Makar

Mr Makar was the surgical SHO who assessed and diagnosed Raychel as having acute appendicitis, and undertook the appendicectomy. Although he was not at registrar grade, it appears from his statement that he was well-qualified, fairly experienced and effectively functioning at registrar level. His consultant Mr Gilliland had confidence in his ability to assess and operate on a straightforward case of appendicitis without supervision (WS-044/2). It would have been common practice at the time for junior surgeons at this level to operate unsupervised..

He prescribed Hartmann's solution when he first saw Raychel in A&E but he recalls that this fluid was never given, because when she reached the ward at 22.00 on 7/6/01, she was given 0.18% saline instead. He recalls that Hartmann's was not available on Ward 6 (WS-022-2 page 6). Mr Makar prescribed the 0.18% saline himself. Although he describes why he considers Hartmann's to be preferable to 0.18% saline, he justifies giving 0.18% saline for a short period pre-operatively. He also justifies giving Raychel more than the standard maintenance quantity of IV fluid (i.e. 80 mls/hr rather than 65 mls/hr), on the basis that she may already have had a fluid deficit and in anticipation of further losses. This is reasonable: in my view 80 mls/hr was not an excessively fast infusion rate. Giving 15 mls/hr more than the standard maintenance might have been advisable to allow for extra loss of body fluid through vomiting. Mr Makar justifies the type and infusion rate of IV fluids for the pre-operative period. He does not discuss or justify continuing this fluid regime for the longer period following surgery. He did not prescribe intra- or immediate post-operative fluids for Raychel, as he considered this to be the responsibility of the anaesthetist (WS-022-2 page 11).

3) Dr Vijay Gund

Dr Gund was the anaesthetics SHO who undertook the general anaesthetic for Raychel's appendicectomy. He gave Hartmann's solution during the operation, and then prescribed it to be continued postoperatively. However he was told by his colleague Dr Jamison, who had been at Altnagelvin for longer, that standard ward practice was to use 0.18% saline after return to the ward, and so the prescription was changed. Although quite junior, he was considered competent to administer a general anaesthetic to a child unsupervised, which was usual practice at the time. Dr Gund's expectation was that the paediatric team would prescribe IV fluids beyond the immediate post-operative period.

4) Dr Claire Jamison

Dr Jamison was a more experienced anaesthetics SHO who assisted her colleague Dr Gund with the GA. She recalls little and has nothing to add to Dr Gund's account. She admits that she made a retrospective addition to the anaesthetic note about the quantity of IV fluid given during the operation, and adds that her supervising consultant Dr Nesbitt advised her to do this (WS-024/2 page 5). As stated in my compendium report at 2.j, I believe that this was justified under the circumstances.

5) Dr Mary Butler

Dr Butler was a junior paediatric SHO at Altnagelvin at the time. Her involvement was simply that she was asked to write a prescription continuing Raychel's IV fluid regime which had already been initiated. She prescribed continuing 0.18% Saline 4% Dextrose at 80 mls/hr. At WS-026/2 para 5e she admits that this rate was too fast. By standard calculations of maintenance fluid requirement, at 25 kg body weight Raychel should have been receiving 65 mls/hr.

However as stated in my compendium report at 4.b and 4.m, Dr Butler was simply following accepted practice in continuing a fluid regime started previously, and she would have seen no reason to change this. This unquestioning continuation of what had been prescribed previously is not best practice, but nonetheless occurs frequently in many situations.

Dr Butler helpfully includes, amongst other things, the Induction Booklet for paediatric SHOs from February 2001. This is mostly administrative and makes no reference at all to advice on IV fluid prescribing. This does not surprise me, as most induction guidance at the time would have looked like this. Fluids would have been considered a low priority in competition with all the many items of information that new doctors would have been expected to take on board.

6) Mr MH Zafar

Mr Zafar was the surgical SHO who saw Raychel on the surgical ward round on the morning after her operation. It was the routine practice on that unit that patients on the round were not necessarily seen by the surgeon who had done the operation. He claims that he was not aware that she had vomited earlier that morning (WS-025/2 page 8). In any event he advised the nursing staff that she should be allowed small sips of oral fluids, and that the IV infusion should be continued depending on how oral fluids were tolerated. This is fairly standard advice for any first day post-op surgical case.

His account suggests that the assessment of Raychel on the ward round was fairly brief. This is typical of surgical ward rounds, when there is often time pressure to see all the ward patients early in the morning before starting a full day's operating list. Surgical teams will often rely on a quick report from the nurses on the patient's condition without necessarily consulting all the charts.

He had no further involvement during the day of 8/6/01, but was called urgently after Raychel had a seizure at 03.15 on 9/6/01. He was unable to attend immediately because he was tied up with another seriously ill patient elsewhere. In my view, this non-attendance at that time is regrettable but not critical, as Raychel required the skills of a paediatrician, not a surgeon.

In response to questions about which team had responsibility for dealing with problems as they arose in post-op children an Ward 6, there is some confusion in his replies: on p 11 he states 'If there were any issues about Raychel's surgical condition and general medical condition, she should have been seen by Paediatrics', and then 'The surgical team should be contacted if there were any surgical issues....'. On p

18 he states 'Much of the day-to-day care of paediatric surgical patients, including prescribing, was undertaken by the paediatric team'. This is at odds with the views expressed by several other clinicians that the primary responsibility was with the surgical team unless there was a specific medical issue. This reflects the general confusion about responsibilities which is highly pertinent to this case.

7) Dr Joe Devlin

Dr Devlin was a junior house officer in surgery at Altnagelvin. Although he doesn't recall this himself, from the accounts of the nurses it appears that Raychel was not a patient under the care of his team. He was asked to help by Nurse Rice because they had been unable to contact the relevant surgical JHO, and he happened to be visiting the ward to see another patient (WS-051/2 page 15). He prescribed Ondansetron (Zofran) at about 17.30, for vomiting. He admits that he didn't consider checking her blood electrolytes then, and he didn't consider that her vomiting 'was significant enough to contact more senior doctors'. (WS-027/2 para 4 x,y, aa).

Whether this lack of action was justified depends on how severe her vomiting was considered to be, as mentioned several times in my report. In para 20 he states that he 'wasn't aware at the time that Raychel was suffering from prolonged vomiting...'

8) Dr Michael Curran

Dr Curran was also a junior house officer in surgery. He became involved around 22.00 when the nursing staff were concerned that Raychel was still vomiting. He prescribed Cyclizine (Valoid). He states that he is unable to recall whether he knew that Raychel had already received Zofran (WS-028/2 para 4c). It should have been clear from the drug prescription chart that Zofran had already been given. As I stated in my report (para 5.b), this is significant because the lack of any improvement after the first anti-emetic drug should have prompted a reassessment. Dr Curran's statement sheds no light on why this did not happen. At para 5 c he states that he 'would have believed that [the vomiting] was related to being post abdominal surgery.'

9) Dr Jeremy Johnston

Dr Johnston was the paediatric SHO on call on the night of 8/6/01, who was called immediately when Raychel had a seizure. He aborted the seizure with Diazepam. He correctly suspected an electrolyte abnormality and asked for blood tests. He describes some delay in getting the analysis done in the lab, but he correctly chased this up. As stated in my compendium report (para 6.h), I believe that he was justified in not changing the IV fluid regime until the result was confirmed.

10) Dr Bernie Trainor

Dr Trainor was the senior (middle-grade) paediatric SHO who was called at around 04.00 after Raychel had had a seizure and the low serum sodium result was known. Once the result was confirmed by a second sample, she took appropriate action in changing the IV fluids to 0.9% Saline and in reducing the infusion rate. She also, correctly, summoned Dr McCord, the duty consultant paediatrician.

11) Dr Gareth Allen

Dr Allen was the anaesthetics SHO who was called to assist with the resuscitation after Raychel collapsed on 9/6/01. He has little to add regarding Raychel's management. He is the only witness to have recalled receiving any teaching on fluid balance as an undergraduate, although not specifically on hyponatraemia.

12) Dr Brian McCord

Dr McCord was the consultant paediatrician who came in to supervise after Raychel's acute deterioration. He played little part in Raychel's immediate management, as the fluid regime had already been adjusted, she had been intubated and ventilated by the anaesthetic team, and was admitted to Intensive Care. He is unable to recall anything of relevance regarding discussions with Raychel's parents after her death.

13) Dr Peter Crean

Dr Crean was the consultant anaesthetist who supervised Raychel's management after she was admitted to PICU at the RBHSC. He gives a strong opinion that Raychel's cerebral oedema and subsequent death was primarily due to hyponatraemia induced by hypotonic fluid administration.

14) Dr Donncha Hanrahan

Dr Hanrahan was the Paediatric Neurologist at RBHSC who was only involved in the final stages following Raychel's transfer to PICU. He is of the same opinion as Dr Crean about the causes of her death.

15) Mr Robert Gilliland

Mr Gilliland was the consultant general surgeon under whose care Raychel was admitted. Much of his statement is concerned with governance rather than clinical issues. He never saw Raychel and was not directly involved in her care. He describes the role of a consultant surgeon as he perceived it at that time. He stresses that he considered Mr Makar to be entirely competent to assess cases like Raychel, to make a diagnosis of appendicitis and to carry out surgery without the need either for supervision by, or discussion with, a more senior colleague. He considers that the symptoms and signs recorded were sufficient to indicate the need for appendicectomy. Further, he did not consider it necessary for Raychel to be seen by a consultant on the ward round the following day. In my view, by the standards of the time this was acceptable practice.

He goes on to justify the later prescription of an anti-emetic by Dr Devlin at 18.00 and Dr Curran at 22.00 without a more detailed assessment, or calling someone more senior (WS-044/2 page 14). Here I disagree: as stated in my compendium report (4.j and 5.b), persistent vomiting so long after surgery should have been investigated more thoroughly.

When Raychel deteriorated acutely on 9/6/01 he considers that the consultant surgeon on-call (which was not him) should have been called. I agree, but only because of the seriousness of the situation, rather than because of the need for any surgical intervention.

Regarding whose responsibility it was to prescribe post-op IV fluids, he states specifically that it fell to the surgical pre-registration house officer (JHO). This role did not appear to be clear to all the other clinicians involved.

On page 17 (para 25 d) he discusses the issue of giving extra replacement IV fluids to allow for losses through vomiting. This was and remains common practice in patients who are having significant losses from the stomach, either through vomiting or via a nasogastric tube. This does not appear to have been considered by any of the clinicians involved with Raychel. Mr Gilliland states that: '..an estimation of the amount of vomiting and replacement of that fluid with 0.9% saline or Hartmann's would have been better management. However neither an estimate of the volume of vomiting nor the use of higher solute containing fluids was common practice in the paediatric surgical unit at Altnagelvin at that time.' The practice of replacing gastric losses ml for ml, with normal saline, rather than hypotonic solutions, was well-established long before 2001, at least in children. This is mentioned in standard textbooks used

widely at the time, e.g. Lecture Notes on General Surgery 1994 (Ref 1); Sabiston Textbook of Surgery 1997 (ref 2). However, in this case it would have required someone to make an estimate of the volume of Raychel's vomits to enable this to happen. This was not done, because none of the staff involved considered them to be large enough to justify it.

16) Mr Zawislak

Mr Zawislak was the senior surgeon on-call on 7/6/01 but he denies being called and had no involvement.

Nursing staff

I will deal with the statements from all the Ward 6 nurses collectively, as they address much the same issues. They are Staff Nurses Patterson, Noble, Rice, Roulston, Gilchrist, Bryce and Sister Millar. All of the nurses involved were aware that the standard practice on the unit was that the routine IV fluid for children was 0.18% Saline 4% Dextrose. None of them felt that they had the knowledge or authority to challenge this. None were aware of previous problems with hyponatraemia elsewhere. None felt able to give a view on the appropriateness of the type and quantity of fluid given to Raychel.

They admitted that there was incomplete recording on charts, and lack of quantification of vomit and fluid output, but in my view this is no different to what would have happened on any children's ward in the NHS at the time. S/N Noble reiterates that before Raychel's surgery she told Mr Makar that using 0.18% saline rather than Hartmann's was 'common practice', and the prescription was changed (WS-049/2 page 5).

The nurses between them comment on the vomits that Raychel was observed to have had throughout the day on 8/6/01. Most of these appear to have been recorded on the fluid chart, but the quantity is open to question. The parents recall witnessing much larger vomits than the nurses either recall or recorded at the time.

The nurses are consistent in their observations that Raychel was not sufficiently ill in herself throughout 8/6/01 to cause them concern. When the surgical JHOs were called, at 17.30 and 22.00, it was just to give symptomatic relief in the form of anti-emetic drugs, not because they were concerned about more serious complications. S/N Rice noted Raychel to be 'up and about' at around 19.30 (WS-051/2 page 19 para 12). Raychel was observed by S/N Noble to be 'coherent' and answering questions as late as 21.15 (WS-049/2 page 9). This differs markedly from the parents' account.

They also deny that the parents expressed any particular concerns to them about Raychel's general condition other than the vomiting.

Sister Millar, the senior nurse on the ward, supports all the observations and actions of her staff. She was present at the ward round, but spent much of the afternoon in her office. She describes what she would have said to the parents at the meeting after her death, but never got the opportunity. She would have said that Raychel's condition on 8/6/01 was not causing concern (WS -056/2 page 17).

Parents

The parents' account of the quantity and frequency of Raychel's vomits is considerably in excess of that reported by the nurses, throughout the day. As their memory of exact timings is vague, it is difficult to relate what they witnessed with the nurses' observations directly; however for example some time between 12.00 and 15.00 Mrs Ferguson reports 'two kidney trays full of vomit' (WS-020-1 page 10). None of the nurses reported this quantity of vomit. The parents recall that each time she vomited, they reported it to one of the nurses. Mrs Ferguson recalls that the vomit at around 17.00, before Dr Devlin prescribed for her, may have contained blood. This was not recorded or commented on by any of the staff.

More worrying is the parents' description of Raychel's behaviour and state of mind during the afternoon of 8/6/01, which is completely at odds with the nurses' descriptions. During that period Mrs Ferguson describes Raychel as 'not really taking me on at all' when spoken to by her (WS0020-1 p12 para 11 d), and 'like a zombie' (p 13). She did not want to play or speak. At 19.00 she did not respond to her friend and classmate Sarah who had come to visit (p 16 para 32). This is not normal behaviour for a 9-year-old, even immediately following surgery. In my view this behaviour was very concerning, as it may have been a sign of a decrease in conscious level, possibly due to early cerebral oedema. Also, hyponatraemia in itself, without cerebral oedema, can cause profound tiredness and listlessness. The early, subtle signs of an abnormal conscious level in a child may be very difficult to detect, and may not have been apparent to the staff at the time (see my compendium report para 4.j).

General points

1) Responsibility for prescribing fluids post-operatively

All the witnesses were asked about this. There was a divergence of views about what the policy was at the time. Some felt that it was the responsibility of the anaesthetist for the immediate post-operative period. But the duration of this period could be anything from 4 to 12 hours. Others thought that it was the responsibility of the surgical team immediately after surgery. After the post-op period some thought that the surgeons and others that the paediatricians should prescribe. No-one knew of any written protocol. This was clearly a systemic problem.

2) Awareness of and training in hyponatraemia prior to June 2001

None of the witnesses, including senior consultants, had experienced anything similar previously. None were aware of the previous cases in Northern Ireland. None were aware of the literature from 1992 or 2001. None were aware that there was any risk of hyponatraemia associated with using 0.18% saline. None had received any specific training in this area at any stage in their careers.

I do not find this surprising. If the same questions had been addressed to any group of doctors or nurses working on a children's ward at the time, I believe that the same responses would have been received.

Many described how rapidly policies changed in the aftermath of Raychel's death.

In spite of the Northern Ireland experience, life-threatening hyponatraemia was, and remains, a very rare event.

Conclusion

None of these witness statements significantly alter the conclusions of my original reports. Some of the evidence given adds further strength to my conclusions. More detail is given around some of the most critical issues; i.e. how severe the post-operative vomiting was, and how unwell the family perceived Raychel to be. They give more insight into what staff thought were the standard procedures at the time. They give no radically new insight into the sequence of events, or the causation of Raychel's critical illness.

Similarly they do not help with the more general issues about which all the witnesses were asked: these include the relationship between the paediatric and surgical teams, the lines of communication for asking for advice, the respective responsibilities of the teams in caring for surgical children, and the training given on fluid management. For all these issues, the witnesses either cannot remember or have nothing to add to previous statements.

There is nothing in these statements that would cause me to amend my original report.

Dr Robert Scott-Jupp

25 February 2013

References;

1) Lecture Notes on General Surgery 8th edition: Ed. Ellis and Calne. Pub OUP 1994. See table 6.2 page 28. 'Any additional losses should be replaced: for example, excessive drainage from a nasogastric tube....should be replaced intravenously by a similar amount of normal saline, or hyponatraemia and metabolic acidosis are likely to develop'.

2) Sabiston Textbook of Surgery 15th edition: Pub WB Saunders 1997. See p 108. 'Gl losses are usually

isotonic or slightly hypotonic and are replaced with an essentially isotonic solution'.