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IN THE CORONERS COURT FOR NORTHERN IRELAND

BEFORE CORONER J McCRISKEN

THE INQUEST TOUCHING UPON THE DEATH OF RAYCHEL ZARA FERGUSON

VERDICT FOLLOWING AN INQUEST INTO THE DEATH OF RAYCHEL FERGUSON

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[1] Before I begin to deliver my verdict with respect to the death of Raychel Ferguson, I want to give appropriate thanks to those Coroners Service, Court Service and court security staff who assisted with preparations for this inquest. I was represented by Coroners Counsel, Mr Chambers BL. My legal advisor was Ms Laverty. For the Properly Interested Persons (PIPs), Ms Gallagher BL appeared for the Western Health and Social Care Trust ('the Trust') instructed by Ms Astbury, Solicitor, from the Directorate of Legal Services. Mr Boyle K.C appeared for Nurse Noble, Nurse Gilchrist, Nurse McAuley, Nurse Roulston, Nurse Brice and Nurse Kirk ('the Nurses') along with Mr Molloy BL, Ms Smyth BL and Ms Graham BL instructed by the Royal College of Nursing. Mr Coyle BL appeared for Mr and Mrs Ferguson ('NoK') instructed by Mr Doherty, Solicitor, of Elev8law.

[2] Whatever verdict I deliver here today, will not change the fact that Mr and Mrs Ferguson lost their young daughter, Raychel, and their grief shall continue to weigh heavily on them for the rest of their lives. This has been compounded by knowing that Raychel's death was avoidable. As outlined by O'Hara J, (as he is now) in the Report of the Inquiry into Hyponatraemia-related Deaths ('the Inquiry'), errors were made by those charged with caring for Raychel. Lessons that should have been learnt following the death of Adam Strain and Lucy Crawford were not. The Ferguson family have spent the last 22 years attending various legal hearings and fighting to get answers which they deserve to have.

[3] This verdict must be read in conjunction with the Inquiry Report. At the outset, I agreed to admit the entirety of the Inquiry Report pursuant to Rule 17 of the Coroners (Practice and Procedure) Rules (Northern Ireland) 1963 ('the 1963 Rules'). This allowed not just those factual matters already established following the Inquiry, but also those conclusions reached by the Inquiry, to be considered during the

inquest. My verdict, therefore, borrows heavily from those factual matters contained within the Inquiry Report.

[4] I also considered expert reports provided to the Inquiry, and heard oral evidence, from the following witnesses:

1. Dr Haynes
2. Dr Makar
3. Nurse Noble
4. Nurse Gilchrist
5. Nurse McAuley
6. Nurse Roulston
7. Nurse Bryce
8. Nurse Kirk
9. Mr Zafar
10. Dr Crean
11. Mr Fulton
12. Dr Curran
13. Dr Gilliland
14. Mr and Mrs Ferguson

Relevant law

[5] Rule 15 of the 1963 Rules governs those matters to which inquests shall be directed and provides that:

> "The proceedings and evidence of an inquest shall be directed solely to ascertaining the following matters, namely:
>
> (a) Who the deceased was;
>
> (b) **How, when and where the deceased came by his death;**
>
> (c) … The particulars for the time being required by the Births and Deaths Registration (Northern

> Ireland) Order 1976 to be registered concerning the death." [My emphasis]

[6] Rule 16 goes on to say that:

> "Neither the Coroner nor the jury shall express any opinion on questions of civil or criminal liability …"

Application of article 2 of the European Convention of Human Rights ('ECHR').

[7] Article 2 ECHR provides, so far as is relevant, that "Everyone's right to life shall be protected by law." It is established law that this provision has a substantive aspect, governing the ways in which the state should act to protect life, and a procedural aspect, which imposes an obligation on the state to provide for investigation as to whether a death may have resulted from a breach of the substantive obligations imposed by article 2. The precise content of the substantive obligations and of the procedural obligation under article 2 varies depending on the circumstances of a particular death.

[8] In Northern Ireland, it is established law that, where necessary, to avoid a breach of any Convention rights (within the meaning of the Human Rights Act 1998), the purpose mentioned in Rule 15(b) (above) is to be read as including the purpose of ascertaining how and *in what circumstances* the deceased came by their death. An expanded verdict may be required to satisfy the procedural requirement of article 2, including, for example, a conclusion on the events leading up to the death, or on relevant procedures connected with the death. In practice, in a non-article 2 inquest, a verdict should be a brief, neutral, factual statement; it should not express any judgment or opinion. By contrast, a verdict in an article 2 inquest, known as an expanded verdict, may be judgmental.

Relevant Law

[9] In the case of *R (Morahan) v HM Assistant Coroner for West London [2021] EWHC 1603 (Admin*) *('Morahan'),* Popplewell LJ set out the distinct article 2 duties imposed on ECHR States.

> "(1) There is a **negative duty** to refrain from taking life without justification (see, for example, Rabone v Pennine Care NHS Foundation Trust [2012] 2 AC 72 at paras 12 and 93). This arises not only at a state level but more commonly, in practice, at an operational level, and includes cases where an individual dies at the hands of an agent of the state, such as a police shooting. This may be labelled the negative operational duty.

(2) There is a **positive duty** to protect life which has two aspects:

(a) There is a duty to put in place a legislative and administrative framework to protect the right to life, involving effective deterrence against threats to life, including criminal law provisions to deter the commission of offences, backed up by a law enforcement machinery for the prevention, suppression and sanctioning of breaches of such provisions; and in the healthcare context having effective administrative and regulatory systems in place (Van Colle v Chief Constable of the Hertfordshire Police [2009] 1 AC 225 at para 28, Rabone at paras 12 and 93). This is the **framework duty**, of which the latter aspect is sometimes referred to as a systems duty.

(b) There is a duty, first articulated in Osman v UK [1998] 29 EHRR 245, to take positive measures to protect an individual whose life is at risk in certain circumstances. This is the **positive operational duty**. In R (L(A Patient)) v Secretary of State for Justice [2009] 1 AC 588, Lord Walker of Gestingthorpe observed at paragraph 89 that there is often no clear dividing line between this operational duty, and the systems duty below the national level.

(3) There is an **investigative duty** to inquire into and explain the circumstances of a death. As I explain below, there are two different investigative duties which have a different scope and different juridical basis. One is a **substantive duty** to investigate every death as an aspect of the framework duty; the other is a procedural obligation which arises only in some cases and is parasitic on the possibility of a breach by a state agent of one of the substantive operational or systems duties. When the latter arises, it is a duty of enhanced investigation, to initiate an effective public investigation by an independent official body. This is the **enhanced investigative duty**."

[10] The court in *Morahan* went on to discuss four cases from which 'authoritative assistance' was derived in identifying whether a health care trust owed a positive operational duty to a deceased person – (i) *Rabone v Pennine Care NHS Foundation*

Trust [2012] 2 AC 72 ('Rabone'), (ii) Lopes de Sousa Fernandes v Portugal (2018) 66 EHRR 28 ('Lopes'), (iii) Fernandes de Oliveira v Portugal (2019) 69 EHRR 8 ('Fernandes') and (iv) R (on the application of Maguire) (Appellant) v His Majesty's Senior Coroner for Blackpool & Fylde and another (Respondents) ('Maguire').

[11] In the *Lopes* case, the Grand Chamber of the ECtHR was concerned with a case of alleged medical negligence in relation to physical illness. The applicant complained under article 2 of ECHR about the death of her husband in hospital because of a hospital-acquired infection and of carelessness and medical negligence. The Grand Chamber restated the principles that the ***operational duty*** did not apply to mere medical negligence in such cases save in two "very exceptional circumstances", firstly "a specific situation where an individual patient's life is knowingly put in danger by denial of access to life-saving emergency treatment"; and secondly "where a systemic or structural dysfunction in hospital services results in a patient being deprived of access to life-saving emergency treatment and the authorities knew or ought to have known about the risk and failed to undertake the necessary measures to prevent the risk from materialising, thus putting the patients' lives, including the life of the particular patient concerned, in danger."

[12] Relevant to the issue of the applicability of article 2 in this case, at paragraph 168 and 169 the court, in *Lopes*, said:

> "In cases where allegations of medical negligence were made in the context of the treatment of a patient, the Court has consistently emphasised that, where a Contracting State has made adequate provision for securing high professional standards among health professionals and the protection of the lives of patients, matters such as an error of judgment on the part of a health professional or negligent coordination among health professionals in the treatment of a particular patient are not sufficient of themselves to call a Contracting State to account from the standpoint of its positive obligations under Article 2 of the Convention to protect life…
>
> …To date, in cases concerning medical negligence, the court has rarely found deficiencies in the regulatory framework of member States…"

[13] The United Kingdom Supreme Court (UKSC) in the recent case of *Maguire* agreed with the 'meticulous' first instance judgment of Popplewell LJ in the case of *Morahan* (above), the United Kingdom Supreme Court was asked to examine the different levels at which aspects of the article 2 procedural obligation might apply. As Lord Sales put it:

> "…there is no simple monolithic form of procedural obligation which applies in every case. Rather, the procedural obligation applies in a graduated way depending on the circumstances of the case and the way in which in a particular context the state may be called upon to provide due accountability in relation to the steps taken to protect the right to life under article 2."

[14] The redress procedural obligation arises where there is no relevant compelling reason giving rise to the 'enhanced procedural obligation', but there is still a possibility that a substantive article 2 obligation has been breached, and so the state should provide a means by which a person complaining of possible breaches can raise that complaint, have it investigated and obtain redress for any breach. The UKSC, in *Maguire,* held that a combination of an inquest that can determine the cause of death (without any requirement of an expanded verdict) and the availability of a civil claim for damages for negligence will often satisfy this obligation.

[15] The redress procedural obligation has typically been applied in cases involving possible breaches of article 2 in the context of provision of medical services, where it is alleged there has been negligence by medical practitioners *(Calvelli and Ciglio v Italy, Grand Chamber judgment of 17 January 2002).*

[16] I commenced this inquest on the basis that it was possible that article 2 would require an expanded verdict at its end, while recognising that during the inquest matters in dispute might be sufficiently ventilated and clarified so that article 2 would no longer require such a verdict.

[17] A substantial body of United Kingdom case-law has held that in relation to cases of arguable medical negligence in a National Health Service (NHS) hospital (as Altnagelvin was), the enhanced procedural obligation does not apply and the state's procedural obligation (in the form of the basic procedural obligation and the redress procedural obligation) is satisfied by a combination of the holding of an inquest to determine the cause of death, without any requirement of an expanded verdict, and the availability of a civil claim for damages for negligence.

[18] In the case of *R (Humberstone) v Legal Services Commission* ([2010] EWCA Civ 1479;) the court held that instances of individual negligence should not be treated as indicating a breach of the systems duty, and it will be the coroner, as the decision-maker who examines the facts in detail, hears the evidence and has to decide what form of verdict should be given at an inquest, who is best placed and has the primary responsibility to decide whether an arguable breach of either duty has been established.

[19] In *Powell v United Kingdom ((2000) 30 EHRR CD362)* it was established that although the applicant's son died of natural causes, there was an allegation that this could have been prevented if doctors had taken effective action at an earlier stage. The court, at p364 said:

> "The court accepts that it cannot be excluded that the acts and omissions of the authorities in the field of health care policy may in certain circumstances engage their responsibility under the positive limb of article 2. However, where a contracting state had made adequate provision for securing high professional standards among health professionals and the protection of the lives of patients, it cannot accept that matters such as error of judgment on the part of a health professional or negligent co-ordination among health professionals in the treatment of a particular patient are sufficient of themselves to call a contracting state to account from the standpoint of its positive obligations under article 2 of the Convention to protect life. In the court's opinion, the events leading to the tragic death of the applicants' son and the responsibility of the health professionals involved are matters which must be addressed from the angle of the adequacy of the mechanisms in place for shedding light on the course of those events, allowing the facts of the case to be exposed to public scrutiny - not least for the benefit of the applicants."

[20] In the case of *Calvelli* (cited above), involved allegations of death occurring because of medical negligence. In this case, the Grand Chamber of the European Court of Human Rights (ECtHR) referring to the systems duty, said:

> "Those principles apply in the public-health sphere too. The aforementioned positive obligations therefore require States to make regulations compelling hospitals, whether public or private, to adopt appropriate measures for the protection of their patients' lives. They also require an effective independent judicial system to be set up so that the cause of death of patients in the care of the medical profession, whether in the public or the private sector, can be determined and those responsible made accountable …"

[21] In *Cavelli*, the ECtHR concluded that it was the redress procedural obligation which applied, not the enhanced procedural obligation. The family of the deceased was able to bring civil proceedings alleging negligence and, following Powell, this

was sufficient to lead the European court to conclude that there was no violation of article 2.

[22] With regards to the systems duty, the Grand Chamber of the ECtHR noted in *Lopes* that in cases concerning medical negligence it had rarely found deficiencies in the regulatory framework of states. At para 168 the court said:

> "In cases where allegations of medical negligence were made in the context of the treatment of a patient, the court has consistently emphasised that, where a contracting state has made adequate provision for securing high professional standards among health professionals and the protection of the lives of patients, matters such as an error of judgment on the part of a health professional or negligent coordination among health professionals in the treatment of a particular patient are not sufficient of themselves to call a contracting state to account from the standpoint of its positive obligations under article 2 of the Convention to protect life."

[23] Importantly, for this inquest, the court provided further guidance:

> "On the basis of this broader understanding of the states' obligation to provide a regulatory framework, the court has accepted that, in the very exceptional circumstances described below, the responsibility of the state under the substantive limb of article 2 of the Convention may be engaged in respect of the acts and omissions of health care providers.
>
> The first type of exceptional circumstances concerns a specific situation where an individual patient's life is knowingly put in danger by denial of access to life-saving emergency treatment. It does not extend to circumstances where a patient is considered to have received deficient, incorrect or delayed treatment.
>
> The second type of exceptional circumstances arises where a systemic or structural dysfunction in hospital services results in a patient being deprived of access to life saving emergency treatment and the authorities knew about or ought to have known about that risk and failed to undertake the necessary measures to prevent that risk from materialising, thus putting the patients' lives,

> including the life of the particular patient concerned, in danger."

Submissions from Properly Interested Persons.

[24] In a written submission on behalf of the NoK, Mr Coyle BL says, firstly, that Raychel's death:

> "…did not arise by 'mere' medical negligence; wrong choices in treatment and/or omission[s]. It was caused by a systemic failure to disseminate known risks and information, which the Royal Victoria Hospital had attended to, by revising its procedure on the use of Solution 18, some six months before Raychel's death. The medical literature identified the risk of continued use of Solution 18 in children in the published (and widely disseminated) paper by Arieff in 1992. Raychel was knowingly put in danger. There was a specific risk to [her] life; it was not abstract or theoretical. The Western Trust and Royal Group of Hospitals, were aware of [or had the means of knowledge]; they both had a special responsibility to protect Raychel against that specific risk happen. It did as we know occur. This known and appreciated risk to life lead to Raychel's completely avoidable death due to hospital acquired hyponatremia, as per Doctor Haynes' evidence, to this inquest."

[25] Secondly, in terms of the issue of systemic failures the NoK assert:

> "There was a catastrophic systemic failure in disseminating the pertinent known information to other pediatric centres [such as Altnagelvin] regarding the dangers of infusing Solution 18 post-operatively. Moreover, the Royal Victoria Hospital [being the center of local excellence] was aware of at least three other cases [albeit with different etiology], of three child deaths from hyponatremia, in the years immediately before Raychel Ferguson's death. The risk of hyponatremia and its potential catastrophic effect was therefore well appreciated, it had been disseminated and was widely available."

[26] Thirdly, in respect of the application of the enhanced procedural obligation the NoK say:

> "…there was a clear breach of Article 2 in that the Osman type duty owed to Raychel. This has automatically triggered the enhanced procedural obligation upon receipt of the evidence at her inquest."

[27] Fourthly, in relation to the recent judgment of Maguire and its application to the present inquest the NoK say:

> "…the logical outflow of the Supreme Court's decision in Maguire, is that expanded findings, is how in Northern Ireland the state is obligated to deal with the breach of the positive obligation to protect life, in respect of a known and already apprehended real risk, in this inquest. Raychel's inquest examined the highly exceptional circumstances, [as Lord Sales set out in Maguire] which concerned because of '….a structural issue linked to the regulatory framework.' Raychel's death was not due to the denial of life-saving treatment by 'mere' negligence. It was significantly more serious. The actions and omissions which lead to Raychel's death at the Royal Victoria Hospital were deliberate and persistent; these were the continued use of Solution 18 by Altnagelvin post-operatively."

[28] Finally, in conclusion the NoK say:

> "…Raychel's is an exemplar instance for the enhanced procedural obligation, with the necessary deployment of extended findings, to thereby set fully out the utterly avoidable reasons for this child's death. Only that fulfills (sic) the duty to protect life in this instance, for the reasons given above upon the evidence, which has been received in this inquest."

[29] Mr Boyle KC, writing on behalf of the Nurses, takes a different view to the NoK and says that in accordance with *Maguire* and the circumstances of this inquest, the enhanced procedural obligation does not arise automatically and therefore I should consider whether there is, in law, an arguable breach of the systemic or operational duty. As to whether on an individual, or even cumulative role of healthcare staff, it can be arguable in a healthcare case there is a breach of the systemic duty, Mr Boyle KC reminded me of the UKSC emphasis on this point from the case of *Fernandes*:

> "157 … Further, as stated in Fernandes, para 168, negligent coordination among health professionals in the

> treatment of a patient is not sufficient to call a state to account from the point of view of its positive obligations under article 2."

[30] Accordingly, the Nurses say it would be wrong in law to conclude that based on the actions or omissions of the Nurses, there was an arguable breach of the systemic duty. Mr Boyle KC directed me to the UKSC observations at paragraphs 159–160 as to the rarity and limited circumstances of a systemic breach in a healthcare case such as this.

[31] In relation to the State's 'operational duty', Mr Boyle referred to the judgment of Lord Sales in *Maguire* when, having considered the relevant authorities including *Rabone, Fernandes, Morahan and Oliveira*, he observed:

> "…As regards the enhanced procedural obligation in the context of the operational duty, it is only if the appellant can show that there was an arguable breach of the operational duty, targeted on a specific risk to Jackie's life which was known or which ought to have been known, that this obligation will be triggered."

[32] Mr Boyle KC continued this point by referring directly to the facts of *Maguire*, a case, he said, arguably on even more extreme facts than the current case:

> "None of the healthcare professionals involved was on notice that Jackie's life was in danger, so as to engage the Osman operational duty."

[33] The Nurses say that the same is true here. None of the staff were on such notice {that Rachel's life was in immediate danger) and then failed to act in a way which would give rise to an arguable breach of the operational duty. Accordingly, in relation to any acts or omissions on behalf of the Nurses it is submitted on their behalf that it would be wrong in law to conclude that an expanded form of verdict is required.

[34] On behalf of the Trust, Ms Gallagher BL submits that the evidence, as has been heard during the inquest, does not demonstrate a violation of the art 2 systems duty. She says the Trust made adequate provision for securing high professional standards among its health professionals and the protection of the lives of patients. As in *Powell*, it should not be held that errors of judgment on behalf of individual health professionals or a negligent co-ordination among said professionals in the treatment of a particular patient are sufficient of themselves to violate their article 2 responsibilities.

[35] Ms Gallagher continues by referring to other similarities between this case and *Powell* – Mrs Ferguson brought a civil claim on behalf of Raychel against the Trust that settled in 2014. Both Mr and Mrs Ferguson and their three sons settled civil claims against the Trust post mediation in 2019. No proceedings were issued in respect of those claims and at no stage have any civil claims been brought against individual health professionals.

[36] In relation to the administration of Solution 18 and the assertion by the NoK that such practice constituted a real and immediate danger to Raychel's life, Ms Gallagher says that it is accepted that the use of Solution 18 at that time, per se, was not dangerous. It continued to be used in paediatric wards across the UK for some time after Raychel's death. The Trust, therefore, did not administer Solution 18 to paediatric patients in the knowledge that it could be harmful.

[37] Referring to the Inquiry, Ms Gallagher submits that the fact that there has been a Public Inquiry into Raychel's death has already afforded full, public scrutiny into the circumstances of her care, subsequent death and the related governance actions taken by the Trust. Therefore, she says, requiring a coroner to provide an expanded form of narrative findings is unnecessary.

Discussion

[38] There was no disagreement between the PIPS that the central issue regarding article 2 applicability, to be decided was whether, in all the circumstances, the enhanced investigative element of the positive operational duty applies in this inquest. The Nurses and Trust say that this enhanced investigative duty does not apply automatically since the circumstances of Raychel's death relate to actions of individual members of medical or nursing staff and not State level systemic issues. They say, in accordance with *Maguire* and *Morahan*, the enhanced investigative duty, therefore, only applies in the two "exceptional circumstances" outlined by the court in *Lopes*, and neither are relevant here. In contrast, the NoK say that Raychel's death occurred, not because of "mere negligence" but by a "systemic failure to disseminate known risks and information." This systemic failure, say the NoK, relates to the failure of the Belfast Trust to share information regarding the potential dangers of using Solution No 18 in children, following the death of Adam Strain in 1995. Mr Coyle BL, on behalf of the NoK, says, in his written submission, that the enhanced procedural obligation is triggered automatically in this case and, as a result, an expanded verdict is required.

[39] The Grand Chamber of the ECtHR in *Lopes* made it clear that this duty will not apply automatically in cases concerning "mere medical negligence" unless "very exceptional circumstances" exist. In *Lopes*, the Grand Chamber also took the opportunity to clarify the issue of the application of article 2 to deaths occurring in a healthcare setting. Firstly, the Grand Chamber examined two scenarios in which the

Court had previously found breaches of article 2 – (1) denial of health care and (2) failure to provide emergency care in the context of pre or post-natal care.

[40] In terms of denial of health care, the Grand Chamber accepted that it had previously held that an issue may arise under article 2 where it is shown that the authorities of a Contracting State have put an individual's life at risk through the denial of the health care which they have undertaken to make available to the population generally. The Grand Chamber then discussed some cases on this issue:

> "Until recently, the type of cases which were examined by the Court with reference to the aforementioned principle concerned applicants who were claiming that the State should pay for a particular form of conventional treatment because they were unable to meet the costs it entailed …or that they should have access to unauthorised medicinal products for medical treatment. The Court did not find a breach of Article 2 in any of these cases, either because it considered that sufficient medical treatment and facilities had been provided to the applicants on an equal footing with other persons in a similar situation or because the applicants had failed to adduce any evidence that their lives had been put at risk. In this connection the Court reiterates that issues such as the allocation of public funds in the area of health care are not a matter on which the Court should take a stand and that it is for the competent authorities of the Contracting States to consider and decide how their limited resources should be allocated, as those authorities are better placed than the Court to evaluate the relevant demands in view of the scarce resources and to take responsibility for the difficult choices which have to be made between worthy needs.
>
> The Court found a procedural violation in the case of Panaitescu v Romania (no. 30909/06, 10 April 2012) where it considered that the State had failed to prevent the applicant's life from being avoidably put at risk by not providing him with the appropriate health care as ordered by the national courts. This was a very exceptional case which concerned the refusal of the domestic authorities to provide the patient with a particular, costly cancer drug free of charge, in circumstances where the domestic courts had found that the individual in question had such an entitlement."

[41] The Grand Chamber then focussed on recent cases concerning a failure to provide emergency medical care in the context of pre- or post-natal care:

> "A substantive violation of article 2 was found in the context of denial of health care in Mehmet Şentürk and Bekir Şentürk … where the first applicant's wife, who was pregnant, died in an ambulance because of the doctors' refusal to carry out an urgent operation owing to her inability to pay medical fees. In this connection the Court held that it was not disputed that the patient had arrived at the hospital in a serious condition and that she required emergency surgery, failing which there were likely to be extremely grave consequences. While the Court did not want to speculate on the chances of survival of the first applicant's wife had she received medical treatment, it considered that the medical staff had been fully aware that transferring the patient to another hospital would put her life at risk. In this regard it took note that domestic law did not have any provisions in this area capable of preventing the failure to give the patient the medical treatment she had required on account of her condition. The Court therefore considered that the first applicant's wife, victim of a flagrant malfunctioning of the relevant hospital departments, had been deprived of the possibility of access to appropriate emergency care.
>
> In the case of Asiye Genç … the applicant's new-born baby died in an ambulance after being refused admission to a number of public hospitals owing to a lack of space or adequate equipment in their neonatal units. The Court, considering that the State had not sufficiently ensured the proper organisation and functioning of the public hospital service, or more generally its health protection system, held that the applicant's son had been the victim of a dysfunction in the hospital services, as he had been deprived of access to appropriate emergency treatment. It emphasised that the baby had not died because there had been negligence or an error of judgment in his medical care, but because no treatment whatsoever had been offered. The Court therefore concluded that there had been a refusal to provide medical treatment, resulting in the patient's life being put in danger.
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> In Elena Cojocaru … the applicant's pregnant daughter, who was suffering from a serious pre-natal condition,

died after a doctor at the public hospital had refused to perform an emergency C-section and she was transferred to another hospital, 150 km away, without a doctor's supervision. The new-born baby died two days later. The Court found that the circumstances in that case constituted a failure to provide adequate emergency treatment since, irrespective of the reason, the patient's transfer had delayed the emergency treatment she needed. The apparent lack of coordination of the medical services and the delay in administering the appropriate emergency treatment attested to a dysfunction in public hospital services.

The case of Aydoğdu, cited above, concerned the death of a premature baby due to a combination of circumstances, notably on account of a dysfunction in the health system in a particular region of Turkey. In that case the Court considered that the authorities responsible for health care must have been aware at the time of the events that there was a real risk to the lives of multiple patients, including the applicant's baby, owing to a chronic state of affairs which was common knowledge, and yet had failed to take any of the steps that could reasonably have been expected of them to avert that risk. The Court noted that the Government had not explained why taking such steps would have constituted an impossible or disproportionate burden for them, bearing in mind the operational choices that needed to be made in terms of priorities and resources. It therefore held that Turkey had not taken sufficient care to ensure the proper organisation and functioning of the public hospital service in this region of the country, in particular because of the lack of a regulatory framework laying down rules for hospitals to ensure protection of the lives of premature babies. The Court, noting that, apart from the negligent behaviour of the medical staff, there was a causal link between the baby's death and the above-mentioned structural problems, held that the baby had been the victim of negligence and structural deficiencies. This had effectively prevented her from receiving appropriate emergency treatment and amounted to a refusal to provide medical treatment, resulting in the patient's life being put in danger.

> The predominant features which stand out in the aforementioned cases - apart from the case of Elena Cojocaru which follows the line taken in the Chamber judgment in the present case - clearly demonstrate that the Court has distinguished these cases, where there is an arguable claim of a denial of immediate emergency care, from cases which concern allegations of mere medical negligence…Thus, the approach adopted in those cases cannot be transposed to cases where the allegations concern mere medical negligence. These cases are, in the Court's view, exceptional ones in which the fault attributable to the health-care providers went beyond a mere error or medical negligence. They concerned circumstances where the medical staff, in breach of their professional obligations, failed to provide emergency medical treatment despite being fully aware that a person's life would be put at risk if that treatment was not given (see Mehmet Şentürk and Bekir Şentürk, cited above, § 104). 184. Moreover, as observed by the United Kingdom Government, the Court's approach, particularly in the case of Aydoğdu, cited above, is akin to the test which it applies when examining the substantive positive obligation of the State to undertake preventive operational measures to protect an individual whose life is imminently at real risk. In Aydoğdu the failure to provide emergency medical treatment resulted from a dysfunction in the hospital services in that particular region, a situation of which the authorities were or ought to have been aware but which they had failed to address by undertaking the necessary measures to prevent the lives of patients being put at risk. In this regard the Court emphasises that the dysfunctioning of the hospital services referred to in Aydoğdu and Asiye Genç, both cited above, did not concern negligent coordination between different hospital services or between different hospitals vis-à-vis a particular patient. It concerned a structural issue linked to the deficiencies in the regulatory framework."

[42] The Grand Chamber in *Lopes* went on to outline the *"very exceptional circumstances"* under which the substantive limb of article 2 ECHR may be engaged in respect of the acts and omissions of health-care providers:

> "The first type of exceptional circumstances concerns a specific situation where an individual patient's life is

knowingly put in danger by denial of access to life-saving emergency treatment… It does not extend to circumstances where a patient is considered to have received deficient, incorrect or delayed treatment.

The second type of exceptional circumstances arises where a systemic or structural dysfunction in hospital services results in a patient being deprived of access to life-saving emergency treatment and the authorities knew about or ought to have known about that risk and failed to undertake the necessary measures to prevent that risk from materialising, thus putting the patients' lives, including the life of the particular patient concerned, in danger... The Court is aware that on the facts it may sometimes not be easy to distinguish between cases involving mere medical negligence and those where there is a denial of access to life-saving emergency treatment, particularly since there may be a combination of factors which contribute to a patient's death. However, the Court reiterates at this juncture that, for a case to fall into the latter category, the following factors, taken cumulatively, must be met.

Firstly, the acts and omissions of the health-care providers must go beyond a mere error or medical negligence, in so far as those health-care providers, in breach of their professional obligations, **deny a patient emergency medical treatment despite being fully aware that the person's life is at risk if that treatment is not given**… [My emphasis]

Secondly, the dysfunction at issue must be objectively and genuinely identifiable as systemic or structural in order to be attributable to the State authorities and must not merely comprise individual instances where something may have bee**n dysfunctional in the sense of going wrong or functioning badly**.

Thirdly, there must be a link between the dysfunction complained of and the harm which the patient sustained.

Finally, the dysfunction at issue must have resulted from the failure of the State to meet its obligation to provide a regulatory framework in the broader sense indicated above."

[43] It seems to me, that the circumstances of this inquest centrally concern allegations of ether individual or collective medical negligence involving the actions, or inactions, of medical staff. Accordingly, I am not satisfied that the operational duty applies automatically.

[44] That being the case, I should then consider if the "very exceptional circumstances", described in Lopes, apply. I am not satisfied that they do. Firstly, the court in Lopes required "a specific situation where an individual patient's life is knowingly put in danger by denial of access to life-saving emergency treatment." Any submission that the medics or nurses caring for Raychel knowingly put her life in danger by denying her life-saving emergency treatment is bound to fail. That is not what was disclosed by the evidence, during the enquiry of this inquest.

[45] Secondly, in the alternative, according to *Lopes*, there must exist:

> "a systemic or structural dysfunction in hospital services results in a patient being deprived of access to life-saving emergency treatment and the authorities knew or ought to have known about the risk and failed to undertake the necessary measures to prevent the risk from materialising, thus putting the patients' lives, including the life of the particular patient concerned, in danger."

[46] In this case, there were systems in place for training medical and nursing staff, for managing fluid therapy, for observing a patient post-operatively and for sharing information between Trusts. What has become apparent following the Inquiry, and this inquest, is that these systems were not utilised properly by certain staff members – they were dysfunctional or functioned badly, to use the words of the Grand Chamber in *Lopes*. In correspondence to the Nursing and Midwifery Council, Mr Ferguson, asserted that Raychel's death was because of the negligent actions of staff and not systemic failings. The Inquiry Report, similarly concluded, that although there were shortcomings in clinical governance, leadership and consultant engagement, responsibility for what happened to Raychel was collective among certain healthcare staff.

[47] Applying the guidance set out above to Raychel's care I am satisfied that a series of individual human errors resulted in Raychel's death rather than any serious systemic or structural failures of the type envisaged in *Lopes*. Counsel for the NoK, in his oral submission on this issue, urged me to accept that there had indeed been a systemic failing by the Belfast Trust, following the death of Adam Strain, in not sharing the learning regarding the dangers of Solution 18 along with a Study by Arieff published in 1992, which warned of the dangers of hyponatraemia following the administration of hypotonic solutions in children. I am satisfied, however, that although learning from Adam Strain's death could, and should, have been shared

more widely it was not done because of any inherent systemic issue. Even in 1995 the systems existed to share this learning. They may not have been as immediate or comprehensive as our modern electronic forms of communication, but systems existed such as conferences, seminars, journal articles and paper-based learning materials.

[48] Accordingly, I am not satisfied that "very exceptional circumstances" exist the that would require me to give an expanded verdict to comply with the enhanced investigative duty pursuant to article 2. It seems to me that it is the redress obligation which applies. As outlined, at paragraph 14 above, the redress procedural obligation arises where there is no relevant compelling reason giving rise to the 'enhanced procedural obligation', but there is still a possibility that a substantive article 2 obligation has been breached. By a combination of a Public Inquiry and inquest the State has provided a means by Mr and Mrs Ferguson could complain of possible breaches of article 2, have it investigated and obtain redress for any breach. As the UKSC held in *Maguire,* a combination of an inquest that can determine the cause of death (without any requirement of an expanded verdict) and the availability of a civil claim for damages for negligence, which I have been told has already been settled here, will often satisfy this obligation.

[49] According to the court in *Morahan*, (cited above) my verdict should comprise of a factual narrative answering those questions set out by Rule 15. In this inquest there is no difficulty in determining who the deceased was; when and where she came by her death or in recording the particulars required by the 1976 Order. The substantial issue to be considered, now, relates to "how" Raychel came by her death – the medical cause of death. The standard of proof required is the civil standard, that is, the balance of probabilities.

Verdict

[50] Raychel Ferguson was born on 4 February 1992, the fourth child and only daughter of Raymond and Marie Ferguson. In June 2001 Raychel was 9 years old and in her Primary 5 year at St Patrick's Primary School, Pennyburn, Derry.

[51] On Thursday 7 June 2001, Raychel went to school as usual. She was reportedly in good spirits and won a medal in her school sports day. Later, at about 16.30hrs she began to complain of stomach-ache. Despite this, she played in and around the family home and ate normally. However, she continued to complain, and Mrs Ferguson eventually made up a bed for her on the sofa. Her primary concern at that time was not that Raychel was in pain, but that she looked grey. Things did not improve, and Mrs Ferguson decided to take Raychel to the Altnagelvin Area Hospital ('Altnagelvin'). She put her in the car and set off, collecting Mr Ferguson on the way. They arrived at the hospital shortly after 19.00hrs. Mr Ferguson thought

Raychel looked grey and unwell. He carried her into the Accident and Emergency Department ('ED').

[52] Raychel was seen in ED at 20.00hrs by Senior House Officer ('SHO') Dr Barry Kelly. Dr Kelly made a record of his examination in the medical notes. He noted a history of sudden onset abdominal pain from about 16.30hrs and increasing thereafter. Nausea was noted with "pain on urination." Pain was found to be maximal over 'McBurney's Point' with clinical signs of tenderness in the right iliac fossa. Based on these findings, Dr Kelly noted his suspicion as "Appendicitis? Surgeons." He arranged for blood and urine tests, referred Raychel for surgical assessment, and gave her cyclimorph (a morphine medication) to ease her pain. This appears to have been effective as Mrs Ferguson thought her "back to normal after the injection." Dr Kelly referred Raychel to another SHO, Mr Makar, who specialised in surgery.

[53] Upon request, Mr Makar saw Raychel and examined her on Thursday evening. He noted his examination in the record. He found tenderness at the right iliac fossa with guarding and mild rebound. He noted normal blood test results and ordered a repeat urine test.

[54] Mr Makar concluded that Raychel had "acute appendicitis/obstructed appendix" and obtained Mrs Ferguson's written consent to surgery. Raychel was admitted to Ward 6 at 21.41hrs to fast and receive fluids in preparation for an appendectomy. Mr Makar was to perform the operation himself.

[55] Altnagelvin had only one children's ward, Ward 6. It served both surgical and medical patients. Surgical patients were children admitted in relation to surgery and medical patients were those otherwise admitted for paediatric treatment. The ward could accommodate 43 children but on 8 June 2001, there were 23. Most patients would normally have been medical cases. Paediatricians were employed on Ward 6 to care for the medical patients. However, because there were no paediatric surgeons at Altnagelvin, children were operated on by general hospital surgeons and cared for on Ward 6 by the general surgical staff. The nurses, some of whom were trained childrens' nurses, cared for both the medical and the surgical patients.

[56] The on-call surgical consultant for the night of 7 June was Mr Robert Gilliland. He was not consulted about the decision to operate. The Ferguson family have issues with the decision to operate but since, as is set out below, the procedure is not implicated as a cause of Raychel's death, and my primary focus is on identifying an accurate cause of death, an examination of the circumstances as to how it came about are outside the scope of the inquest.

[57] Having decided to operate, Mr Makar prescribed intravenous fluids to be administered pre-operatively. His initial prescription was for the isotonic solution known as Hartmann's. However, he changed this prescription to Solution No.18 after a discussion with Staff Nurse Ann Noble because she assured him that Solution No.18 was the accepted intravenous ('IV') fluid for use on Ward 6. Evidence

considered at inquest confirmed that Solution No.18 was the IV fluid of choice on Ward 6 and had been for about 25 years. Mr Makar amended his prescription, not only because of ward practice, but also because he knew that the anaesthetic team would, in any event, make separate prescription for fluids intra-operatively and direct Raychel's fluids thereafter.

[58] Rates were calculated with reference to patient weight using a set formula. Mr Makar prescribed 80mls per hour which was more than the 65mls indicated by formula and more than was necessary even allowing for a possible deficit. In fact, Raychel was to receive only 60mls before the anaesthetic team assumed responsibility for her fluids and changed the prescription.

[59] Upon Raychel's admission onto Ward 6 Staff Nurse Daphne Patterson downloaded a computerised pro-forma episodic care plan ('ECP') for Raychel's abdominal pain. By so doing, Staff Nurse Patterson automatically became Raychel's nominal 'named nurse.' The ECP was designed to be regularly updated and adjusted to a patient's ongoing needs to guide nursing care. It was used to communicate accumulated patient information in print-out form at handover. In connection with Raychel's IV fluid therapy, the plan directed that nurses should:

> "(i) "Observe/record urinary output"
>
> (ii) "Check the prescribed fluids, set rate & flow as prescribed, inspect infusion rate hourly, encourage oral fluids [and] record.
>
> (iii) "Encourage parental participation in care."

[60] Mr and Mrs Ferguson, having left the hospital believing that Raychel would not have surgery unless her condition deteriorated, then received a call that the operation was to proceed. They managed to return before Raychel was taken to theatre. Mrs Ferguson accompanied Raychel to the operating theatre with Staff Nurse Fiona Bryce. Raychel seemed "a bit nervous." She was anaesthetised by Dr Vijay Gund who was assisted in part by Dr Claire Jamison. Mr Makar performed the operation.

[61] The operation started at 23.40hrs and finished about 00.20hrs. Raychel received IV Hartmann's solution intra-operatively. There is no record of precisely how much she received. In addition, Dr Gund noted "Hartmanns 1 L" which, the Inquiry found, was a potentially misleading entry because it is most improbable that Raychel received a full litre of Hartmann's during surgery. It was thus that after Raychel's death, Dr Jamison was asked to, and did, make "Retrospective note dated 13/6/01. Patient only received 200mls of noted fluids below when in theatre. Litre bag removed prior to leaving theatre." This was signed by her and countersigned by Dr Geoff Nesbitt, Consultant Anaesthetist and Clinical Director in Anaesthesia and Critical Care. Dr Haynes, considered that that "the anaesthetic administered by Dr Gund (including the fluid administered during the operation) was entirely appropriate and cannot be faulted."

[62] Raychel took a little longer than expected to regain consciousness after surgery but was ready to be returned to the ward by about 01.30hrs. Post-operatively Mr Makar recorded that the appendix was "mildly congested" with an "intraluminal fecalith." Accordingly, while the appendix was not inflamed, it was not normal.

[63] After the operation, and while Raychel was still in the recovery room, Dr Gund gave his prescription for Raychel's initial post-operative fluids. He prescribed Hartmann's Solution to continue at the same rate as pre-operatively, 80mls per hour.

[64] Upon Raychel's return to Ward 6, the anaesthetic team ceded control of Raychel's fluids. The Inquiry found that there was then no prescription or clinical protocol to guide the post-operative management of Raychel's fluid therapy. Without any reference to her post-operative needs, she was re-subjected to her pre-operative fluids.

[65] Raychel was sleepy when she returned to the ward, opening her eyes only briefly for her parents. They stayed with her until about 06.00hrs when Mrs Ferguson left. Mr Ferguson recalled Raychel waking at about 08.00hrs in relatively good form. Staff Nurse Patterson "helped Raychel sit up in bed and... told Raychel and her dad, [that] she was doing very well." Mr Ferguson went to buy her a colouring book. Raychel vomited shortly after 08.00hrs.

[66] After that, she was well enough to get out of bed and sit colouring. The IV drip attached to her arm was infusing Solution No.18 at 80ml/hr. Raychel was the only child on the ward to have undergone surgery overnight. At approximately 08.00hrs – 08.30hrs Staff Nurse Noble made a hand-over of Ward 6 to Sister Elizabeth Millar. Sister Millar allocated Staff Nurse Michaela McAuley as Raychel's principal carer. Between 08.30hrs and 10.00hrs a surgical SHO, Mr M H Zafar, conducted the morning ward round with Sister Millar. Following this ward round, as Raychel was displaying clear signs of recovery, Mr Zafar directed a routine and gradual reduction of intravenous fluids with staged encouragement to take fluids orally.

[67] When Mr Zafar and Sister Millar were taking their leave of Raychel, Mr Makar arrived to enquire after her. He spoke briefly to Mr Ferguson. Mr Makar confirmed that *"Raychel was sitting up... she was pain free at that time."* Neither Sister Millar nor the doctors had any concerns at that time. In fact, Mr Ferguson telephoned his wife at about 09.30hrs and told her not to hurry to the hospital because Raychel was up and about.

[68] Fluid balance charts record information to guide fluid management. The Inquiry found deficiencies in the way in which Raychel's fluid balance was recorded on Ward 6. The Inquiry concluded that neither the frequency nor quantity of urinary output was properly recorded. Similarly, the quantification of vomit in the record

was uncertain. A shorthand was devised on Ward 6 to record vomit quantity using the '+' sign. Unfortunately, this had not always been explained allowing nurses to interpret "vomit ++" as indicating anything from small to large. Additionally, individual incidents of vomiting were not accurately recorded. The Inquiry found that there was likely an under recording of incidents of Raychel vomiting. The Inquiry, further, found a lack of due attention to fluid documentation.

[69] Raychel's fluid balance chart for 9 June records nine vomits in the 15 hours between 08.00hrs and 23.00hrs. In addition, the Inquiry concluded, there were, at the very least, three additional vomits.

[70] Over the course of Friday, Raychel who had started her day contentedly colouring-in, became very ill. She stopped passing urine, became increasingly lethargic, vomited repeatedly, failed to respond to anti-emetics and vomited coffee grounds.

[71] In terms of Raychel's appearance and demeanour the Inquiry did not accept the nursing evidence that Raychel was well and presenting no real cause for concern. The Inquiry concluded that Staff Nurse McAuley was probably wrong when she said that shortly before 20.00hrs she saw Raychel "up and about, walking in the corridor" and pointing things out to her brothers. As the Inquiry was able to hear evidence in full, from several important witnesses on this issue I do not intend to arrive at any factual finding on this matter.

[72] Dr Mary Butler was on Ward 6 when Raychel's litre bag of Solution No.18 had almost emptied. She was asked by Staff Nurse McAuley to prescribe a replacement. Dr Butler did so without investigating any further and probably without even seeing Raychel. She told the Inquiry that she believes that she probably made some basic enquiries and if so, would probably have been told that according to the chart, Raychel had vomited twice. This would not have caused her concern at that time. Had she been concerned, she would have contacted a surgical SHO or spoken to her paediatric registrar, which she did not.

[73] Dr Butler assumed that the rate prescribed for the fluids had been properly calculated and accordingly issued a repeat prescription for Solution No.18.

[74] At about 15:00 Sister Millar was alerted to Raychel's vomiting and contact a surgical JHO for an antiemetic. Her evidence, which was accepted as accurate by the Inquiry, was that she tried repeatedly over the next 2-2½ hours to get a junior surgical doctor to come to Ward 6 but without success. Eventually Sister Millar saw Dr Joseph Devlin, a junior doctor, and directed that he be asked to "give Raychel an anti-emetic."

[75] When Dr Devlin attended Raychel at 18.00hrs he gave the anti-emetic as indicated. Dr Devlin recalled that Raychel vomited when he was with her, but he did not record this in the records.

[76] At about 22.00hrs Staff Nurse Gilchrist 'bleeped' Dr Curran because of Raychel's continued vomiting and he attended. He could not recall any conversation but believes he must have been told where to find Raychel and the medication he was to prescribe and administer. Dr Curran told the Inquiry that he was not asked to assess Raychel's condition and that no concern was expressed to him about coffee ground vomiting or deterioration - he was only asked to administer an anti-emetic which was a routine request.

[77] Raychel's vomiting intensified between 21.00hrs and 23.00hrs hours. Mr Ferguson was by then increasingly alarmed by Raychel's condition and told nurse Noble that Raychel was complaining of a sore head and was bright red in the face. Nurse Noble said she would come and give Raychel a paracetamol and did so a short time later.

[78] At 21.15hrs Staff Nurse Gilchrist recorded of Raychel "colour flushed → pale, vomiting ++ c/o headache" and at about 21.30hrs, Mr Ferguson telephoned his wife to voice his frustration and concern.

[79] Mrs Ferguson returned at 22.00hrs to find Raychel very restless and with something trickling from the side of her mouth. Dr Haynes told this inquest that Raychel was, by that stage, increasingly threatened by an excessive infusion of hypotonic fluid in the context of Syndrome of Inappropriate Anti-Diuretic Hormone (SIADH) and prolonged vomiting.

[80] Further vomiting was noted at 23.00hrs and 00.35hrs on Saturday morning. Mr and Mrs Ferguson eventually left the hospital at about 00.40hrs They did so because they had been reassured by nursing staff that Raychel had settled and would sleep for the night. Soon thereafter, Raychel became restless again and was noted as possibly "behaving funny? confused." This was reported to Staff Nurse Noble by Staff Nurse Bryce. Raychel then vomited again. Staff Nurse Bryce described her as being "a little unsettled."

[81] At 03.00hrs, Auxiliary Nurse Elizabeth Lynch alerted Staff Nurse Noble to the fact that Raychel was fitting. She was found in a tonic state lying in a left lateral position with her hands and feet tightly clenched. She had been incontinent of urine. Staff Nurse Noble immediately sought the help of the nearest doctor who was Dr Jeremy Johnston, a paediatric SHO on Ward 6.

[82] Dr Johnston administered diazepam rectally and then intravenously. This quieted the seizure, but Raychel was unresponsive, and oxygen was given. Her vital signs were assessed and in the absence of raised temperature, Dr Johnston became concerned that there might be a critical underlying cause. He identified electrolyte abnormality as the principal differential diagnosis and directed a Urea & Electrolyte ('U&E') test. He further requested an Electrocardiogram (ECG), chased up blood results and maintained Raychel's airway.

[83] Staff Nurse Noble telephoned Mr and Mrs Ferguson at about 03.45hrs. At about 04.00hrs hours, Dr Johnston asked Dr Bernie Trainor, the SHO in paediatrics to swap roles so that Dr Trainor could go to Raychel. It was then that the results of the blood test came back recording a sodium level of 119mmol/L, demonstrating acute hyponatraemia. This was lower than Dr Trainor had ever seen. She asked for a repeat test because the result was so abnormal, she felt it could be wrong.

[84] Raychel's oxygen saturation levels were dipping. She was transferred to the treatment room. Dr Trainor telephoned the on-call consultant paediatrician, Dr Brian McCord who came as quickly as he could. Raychel suffered a respiratory arrest and Dr Aparna Date, anaesthetist, attended. Raychel was intubated and her fluids adjusted to restrict the rate and increase the sodium. Mr and Mrs Ferguson were with her.

[85] When Dr McCord examined Raychel at 05.00hrs on 9 June, her pupils were fixed and dilated. The Inquiry concluded that at that stage her condition was almost certainly irretrievable. Dr McCord noted "marked electrolyte disturbance with profound hyponatraemia" and arranged a CT scan.

[86] The CT scan was thought to suggest sub-arachnoid haemorrhage with evidence of cerebral oedema. Dr Nesbitt, Consultant Anaesthetist arrived and discussed the scan via image linking with neurosurgeons at the Royal Victoria Hospital ('RVH'). They suggested that there was "possibly a subdural empyema (an area of infection)" for which surgical intervention might have been possible.

[87] A second and enhanced CT scan was sought to exclude the possibility of sub-dural empyema and haemorrhage. It was performed at 08.51hrs by Dr Cyril Morrison, Consultant Radiologist, who reported that "a sub-dural empyema [is] excluded." He discussed it with Dr Stephen McKinstry of the RVH who considered that "the changes were in keeping with generalised brain oedema" (swelling due to increased fluid content) and that there was no evidence of haemorrhage.

[88] The decision was taken at 09.10hrs to remove Raychel to Paediatric Intensive Care Unit ('PICU') in Belfast. Raychel arrived at the RVH at 12.30hrs. She was formally admitted under the care of Dr Peter Crean, Consultant in Paediatric Anaesthesia and Intensive Care. She had no purposeful movement. Her serum sodium level was then 130mmol/L and her diagnosis "? Hyponatraemia." Dr Dara O'Donoghue assessed her as having "coned with probably irreversible brain stem compromise." She was admitted for "neurological assessment and further care."

[89] Drs Crean and Hanrahan performed the first brain stem death test at 17.30hrs on 9 June and noted brain death. Their second test of 09.45hrs the following morning confirmed no evidence of brain function. Raychel was pronounced dead at 12.09hrs, on 10 June 2001.

Cause of Death

[90] The World Health Organisation (WHO) provides international guidance for death registration – known as ICD-10. This guidance recommends that for registration and classification purposes the cause of a death is split into two sections – Part 1 - is used for diseases or conditions that form part of the sequence of events leading directly to death. The immediate (direct) cause of death is entered on the first line, 1(a). There must always be an entry on line 1(a). The entry on line l(a) may be the only condition reported in Part I of the certificate, but, where there are two or more conditions that form part of the sequence of events leading directly to death, each event in the sequence should be recorded on a separate line -1(b), 1(c) and so on. Part 2 is used for conditions that do not belong in Part 1 but whose presence contributed to the death.

[91] The Senior Coroner, at the conclusion of the original inquest found that the cause of Raychel's death was:

> "1(a) Cerebral oedema
>
> *Due to*
>
> (b) Hyponatraemia."

In his findings, Senior Coroner Leckey, said that:

> "…The hyponatraemia was caused by a combination of inadequate electrolyte replacement in the face of severe post-operative vomiting and water retention resulting from the inappropriate secretion of ADH (Anti-Diuretic Hormone)."

The Attorney General for Northern Ireland issued a direction pursuant to section 14(1) of the 1959 Act because, inter alia, he considered that the Senior Coroner had not been furnished with all relevant materials when he heard the original inquest.

[92] In examining those conditions which potentially contributed to Raychel's death I have considered material from the following:

"1. Dr Simon R Haynes, Consultant in Paediatric Cardiothoracic Anaesthesia and Intensive Care.

(a) Report dated 14 December 2011.

(b) Supplementary Report dated 22 January 2013.

(c) Oral Evidence to the Inquiry.

(d) Oral evidence to this Inquest.

2. Dr Robert Scott-Jupp, Consultant Paediatrician.

(a) Report dated 29 November 2011.

(b) Supplementary Report dated 13 February 2012.

(c) Written response to witness statements dated 25 February 2013.

3. Dr Wellesley Forbes, Consultant Neuro-radiologist.

(a) Report dated 8 December 2011.

4. Professor Finella Kirkham, Professor of Paediatric Neurology and Consultant Paediatric Neurologist.

(a) Report dated 8 February 2012.

(b) Supplementary report (undated)

5. Dr McKinstry, Consultant Neuroradiologist.

(a) Statement dated 4 August 2011.

6. Dr Brian Herron, Consultant Neuropathologist.

(a) Post-mortem report dated 11 June 2001.

(b) Statement dated 21 June 2005.

7. Dr Edward Sumner, Consultant Paediatric Anaesthetist.

(a) Report dated February 2002.

(b) Statement dated 7 July 2005."

Dr Haynes

[93] In his original report to the Inquiry, (14 December 2011) Dr Haynes said that the cause of hyponatraemia was twofold:

> "… Firstly, the administration of hypotonic fluid (i.e., fluids containing low electrolyte concentrations, thus exerting less osmotic pressure than blood) results in a dilutional effect, diluting the serum sodium, and secondly because of the effect of anti-diuretic hormone (ADH) … Which is released from the posterior pituitary as part of the response to trauma or surgery. The amount of ADH released is variable but can be inappropriately and idiosyncratically large… When the syndrome of inappropriate ADH production occurs (SIADH) excessive

> free water (i.e., water not containing solute) is retained by the kidneys thus diluting the serum sodium concentration. Despite hyponatraemia developing because of SIADH, salt is still lost in significant quantity in the urine, a process sometimes referred to as desalination. Many factors can stimulate SIADH … These include trauma (including surgery)."

[94] In his original report, in relation to the causes of post-operative vomiting in Raychel's case, Dr Haynes said that post-operative vomiting is one of the most frequent causes for complaint from parents. He said that at least 40% of children aged three and over will vomit during the post-operative period – twice as many as adults. According to Dr Haynes, post-operative vomiting and nausea is more common following certain operations – including an appendicectomy and becomes more likely the longer the operation. Post-operative vomiting related to anaesthetic and operations usually settles within the first six hours but, according to Dr Haynes, (in his first report) it is not infrequently troublesome for up to 24 hours. He said that in his opinion a component in the initiation of Raychel's vomiting was the drugs given during the anaesthetic. He also said that handling of the intestines during surgery can stimulate nausea and vomiting. Dr Haynes noted that Rachel had become progressively debilitated and drowsy over the course of 8 June, she was initially mobilising, but latterly drowsy and non-communicative. It was his opinion that this debility in association with persistent vomiting was related to the on-set of hyponatraemia caused partly by electrolyte loss in vomit and partly by SIADH.

[95] When he gave evidence to this inquest, Dr Haynes said that most post-operative nausea and vomiting are attributable to the anaesthetic or the procedure but, in children, this vomiting would cease within six hours and certainly within 12 hours. In Raychel's case, Dr Haynes said that any vomiting up to approximately 14.00hrs on 8 June could be attributable to the surgery but after 14.00hrs it is likely that this vomiting was because of an evolving low sodium concentration in her bloodstream, hyponatraemia then developed and caused the vomiting to persist.

[96] In terms of SIADH, Dr Haynes originally told this inquest that in his opinion Raychel was "probably unlucky" in that she possibly was producing or was "one of those people" who produced a particularly inappropriately large amount of ADH which would have compounded the dilutional hyponatraemia caused by the administration of hypotonic fluids. He said there was no way of identifying any one individual who may have a problem with ADH secretion but as a medic it must be assumed that it could happen to anyone. When he gave evidence to the Inquiry, Dr Haynes, was consistent in saying that likely during the morning of 8 June 2001 Raychel would have experienced SIADH because of the surgery.

[97] When Dr Haynes was asked, at this inquest, for his opinion on the cause of Raychel's death, however, he said he would exclude any post-operative vomiting or SIADH as a part of the cause of death. He told this inquest, it was his opinion, that it is more likely that the protracted vomiting which Raychel suffered from was a consequence of low serum sodium. Dr Haynes said that the mention of inappropriate ADH as a cause of death, in his opinion, is speculative. However, when pressed on this issue he said that SIADH may well have been present, and would have increased Raychel's vulnerability, but its effect would have been amplified by the administration of hypotonic intravenous fluid. When Dr Haynes was asked for his opinion on the formulation of a cause of death, he said that the primary cause of death was brainstem death caused by cerebral oedema, caused by hyponatraemia, caused by the administration of hypotonic intravenous fluids.

Dr Scott-Jupp

[98] I also considered a report written by Dr Robert Scott-Jupp, a Consultant General Paediatrician which was prepared for the Inquiry. When considering the cause of cerebral oedema in Raychel's case, Dr Scott-Jump said the following:

> "I would guess that the seizure itself caused a vicious cycle that hastened her deterioration. It is impossible to say how much of the vomiting that preceded the seizure was due to normal post-operative vomiting and how much was due to increasing cerebral oedema. There were no clearly diagnostic signs of raised intracranial pressure until after the seizure (i.e., reduced conscious level, bradycardia and hypotension). Any seizure can result in increased swelling of the brain, as the cerebral metabolic activity increases, and the blood supply is unable to keep up with the demand. The brain cells need more oxygen at a time when it is relatively lacking in the blood supply, and hypoxic brain cells can swell rapidly. Normally, this recovers extremely quickly, but if the brain had already started to become oedematous because of the hyponatraemia, the seizure would have rapidly made it worse. The seizure would also have worsened the inappropriate ADH secretion which is with hindsight assumed to be part of the cause of Raychel's hyponatraemia. The seizure could therefore have been both an effect and a cause of her rapid deterioration. Once cerebral oedema progressed above a certain level, "coning" i.e., herniation of the brainstem through the foramen magnum at the base of the skull, would have occurred in the situation would have become irrecoverable."

Dr Sumner

[99] Dr Sumner prepared a report for the benefit of Senior Coroner Leckey in 2001. Although, of course, Dr Sumner did not have the benefit of those reports and statements made for the purposes of the Inquiry, he was furnished with statements from those medics and nursing staff who had treated Raychel as well as reports from Dr Herron and Dr Loughrey. In conclusion Dr Sumner made the following comments:

> "1. Raychel was a previously fit and healthy little girl suffering from mild appendicitis.
>
> 2. Post operative vomiting is very common indeed and has a variety of causes notably as a reaction to anaesthetic agents particularly the opioids such as fentanyl and morphine but also after interference with the peritoneum. Vomiting is also a sign of rising intracranial pressure. Raychel was given antiemetic drugs but suffered very severe and prolonged vomiting. We know this because of the presence of "coffee grounds" which is a sign of gastric bleeding and also the petechiae seen on her neck from straining.
>
> 3. It has been known for many years that after surgery there is an accumulation of fluid in the extravascular space and that some degree of fluid restriction is necessary post operatively for 24 to 48 hours. This is known to be caused by the inappropriate secretion of antidiuretic hormone (ADH)…
>
> 4. Vomiting causes a severe loss of both water and electrolytes. Sodium and acid loss from the stomach in the vomiting and as a compensatory mechanism the kidneys in trying to conserve sodium allow a net loss of potassium. If these dual electrolyte losses are not replaced with normal saline… A state of hyponatraemia will develop acutely…
>
> 5. There is no doubt that Raychel suffered severe and prolonged vomiting. In my opinion there should have been fluid supplements administered, probably as early as 1030 on 8 June after large vomit. It would also have been very prudent to check the electrolytes on the evening of that day, as the vomiting had not settled down by that stage…
>
> 7. The brain is very sensitive indeed to acute changes in serum sodium levels and cerebral oedema from

> hyponatraemia with catastrophic consequences is very well documented in the medical literature. Although the skull is a rigid structure, as the brain swells, the intracranial pressure does not rise at once because CSF and blood are displaced from the cranium, but when this mechanism cannot cope, then the pressure rises rapidly, and the brain is forced down into the foramen magnum - a situation known as coning. At this stage there would be seizures and vomiting with the rise in intracranial pressure followed by changes to the pupils and loss of consciousness. Brain death follows if steps to reduce the cerebral swelling are not taken immediately as intracranial pressure exceeds that of the blood supply. Raychel's clinical course vividly illustrates this.
>
> …To conclude and summarise, I believe that Rachel died from acute cerebral oedema leading to coning as a result of hyponatraemia. I believe that the state of hyponatraemia was caused by a combination of inadequate electrolyte replacement in the face of severe post-operative vomiting and water retention always seen post operatively from inappropriate secretion of ADH."

Dr Herron

[100] On 11 June 2001, Dr Herron conducted a post-mortem examination on the body of Raychel. Dr Herron concluded as follows:

> "[Raychel]…had her appendix removed on 07/06/01 and developed seizures on 09/06/01. At autopsy she had cerebral oedema and aspiration pneumonia from which she died. Specialist opinion was sought as to the likely cause of the cerebral oedema and a report is enclosed. The summary of this was that the oedema was caused by rapid fall in plasma sodium concentration as a result of net sodium loss, coupled with hypotonic fluid administration in a situation (i.e., post operative state +/- vomiting) were a normal physiological response inhibited the effective excretion of the excess free water. The abnormality of sodium balance and thus the cerebral oedema which led to her death was thought to be caused by three main factors: - 1. Infusion of hypotonic fluids, 2. Profuse vomiting, 3. Antidiuretic hormone (ADH) secretion.
>
> Established changes related to sodium imbalance such as central pontine myelinolysis were not seen possibly due

to the short time period between her deterioration and death. The relative contribution of these factors are unknown and as a combination they led to the brain swelling which eventually led to her death."

[101] The expert report referred to by Dr Herron was produced by Dr Clodagh Loughrey, a Consultant Neuropathologist. Her conclusions are replicated below:

> "I believe that in this case the fall in plasma sodium concentration and thus extracellular fluid toxicity was caused by a combination of three main factors:
>
> 1. Infusion of hypotonic parenteral fluids (No. 18 solution contains 31mmol Na in 1 Litre 4% glucose solution, one fifth the concentration of plasma);
>
> 2. Profuse vomiting in the post-operative period. Although vomitus contains 70 – 100 mmol of sodium/L, which is relatively less than plasma (at 140mmol/L), if the ECF volume is replaced as in this case with fluids containing very little sodium the net effect is a significant stoploss with little or no water deficit;
>
> 3. Anti-diuretic hormone (ADH) secretion, known to be associated with stress (e.g., surgery), vomiting and pain, is likely to have been a major contributor to the overall picture by inhibiting excretion of excess free water.
>
> The relative contributions of these factors will remain unknown. Normally administration of generous volumes of hypotonic fluids will result in a brisk diuresis, and certainly this will be noted by most healthy people who can tolerate drinking large amounts of dilate fluids without consequence. However, in this case, excess ADH secretion for the reasons mentioned above might have resulted in a net year-round positive fluid balance and an inappropriately concentrated urine. Urine osmolarity was indeed inappropriately high in the sample taken after the seizure… and the low urea notable in the post seizure serum samples, relative to that on admission, might indicate relative water access as a consequence of ADH action. However, whether this was a cause or effect of the cerebral oedema cannot be judged and no plasma or urine samples are available from the post-operative but pre-seizure. Unfortunately, no record of fluid balance was

> apparent. A low urinary output might have given an early sign of evolving problems.
>
> In summary, I believe that the cerebral oedema which he noted at autopsy was caused by rapid fall in plasma sodium concentration as a result of a net sodium loss coupled with hypotonic fluid administration in a situation where a normal physiological response inhibited the effective excretion of the excess free water."

[102] There was no doubt among the experts that the immediate cause of Raychel's death was cerebral oedema or brain swelling which was confirmed by both a CT scan and subsequent post-mortem neuropathological analysis. This cerebral oedema had caused brain stem death. All the experts agreed that Raychel's primary cause of death was cerebral oedema, only Dr Haynes thought that the term "brain stem death" should be entered at part 1(a) with "cerebral oedema" at part 1(b). I do not agree with the opinion of Dr Haynes on this issue. In my view, brain stem death, describes the outcome of cerebral oedema, and is not a cause of death per se. Therefore, I will record the terminal event, in accordance with the WHO guidance, as - 1 (a) Cerebral Oedema.

[103] Further, I am satisfied, on balance, that the cerebral oedema was due to hyponatraemia. The weight of expert opinion also supports this conclusion, and I will, therefore, enter at 1 (b) Hyponatraemia.

[104] I heard a great deal of evidence related to the causes of hyponatraemia. I consider that in Raychel's case there are three potential causes of hyponatraemia:

1 – Infusion of hypotonic (low saline content) fluids.

2 – Anti-diuretic Hormone Secretion.

3 – Vomiting.

[105] In terms of the role of ADH secretion, I have considered those expert views outlined above. Dr Haynes, who at one point was dismissive of the role of ADH secretion in the fatal sequence, finally conceded that excessive or inappropriate ADH secretion may well have been present which would have made Raychel more vulnerable to the effects of hypotonic fluid therapy.

[106] I note that in the paper by Arieff, relied upon and considered at the Inquiry, it concluded that the hyponatraemia seen in the sixteen children who formed part of the analysis:

> "…seems to have been caused by extensive extrarenal loss of electrolyte containing fluids and intravenous replacement with hypotonic fluids in the presence of antidiuretic hormone activity."

[107] I am satisfied that following, and because of, Raychel's surgery there was excessive or inappropriate ADH activity or secretion – referred to as SIADH. I am also satisfied that SIADH secretion on its own would not have led to Raychel developing hyponatraemia. In other words, if Raychel had not been given hypotonic fluids, she would not have become hyponatraemic based on inappropriate ADH secretion alone.

[108] In terms of the role of postoperative vomiting, I have considered the views of the experts outlined above. All consider that there would have been a degree of postoperative vomiting caused by factors like – anaesthetic agents and the surgery - but that at some point, probably after lunch into early afternoon of 8 June, this vomiting was because of a developing hyponatraemia. Dr Haynes suggested that by 14.00hrs any vomiting that occurred could not reasonably be attributed to the surgery and I agree with him.

[109] The Inquiry report (at page 129) set out details of the vomiting that occurred before 14.00hrs.

(i) "Vomit" around 08:00

(ii) "Large vomit" around 10:00

(iii) "Vomited ++" around 13:00

[110] Accordingly, I am satisfied that Raychel suffered from a degree of post-operative vomiting which would have adversely affected her sodium balance. Sodium was being lost through vomit which was not being adequately replaced. I am not satisfied that the vomiting can be accurately described as "profuse" or "severe" but nonetheless it has contributed to Raychel's condition.

[111] The NoK asked that I consider using the term "hospital acquired hyponatraemia" in the cause of death to record that Raychel suffered from hyponatraemia while a patient in hospital – that the condition was iatrogenic. They say that this term is frequently used to differentiate where a person may have contracted an infection like pneumonia. While it is correct to say that medics will often complete a cause of death and use terms like "community acquired" or "hospital acquired" in relation to infection, there is a specific rationale for doing so, in terms of infectious diseases. Guidance from the Department of Health on completing a death certificate says:

> "It is important to identify, if possible, the source of a (Health Care Associated Infections) HCAI as either Community Acquired or Hospital Acquired. This will allow Trusts to identify learning to inform and underpin continuous improvement. Therefore, it is incumbent on clinical staff, when completing a MCCD for patients who require the entry of an infection, for example COVID-19, into either Part I or II, that they qualify the entry with

where the infection originated – from the Community, the Hospital environment (probable or definite) or as Indeterminate."

[112] It would not be usual to include the source in other circumstances. For example, if a person died as a result of a fall, the death certificate would not contain details of the location of the fall, care home, at home, hospital etc. I see no reason that I should include this information in Raychel's cause of death.

[113] I consider that there were three causes of hyponatraemia – (i) inappropriate infusion of hypotonic fluids, (ii) SIADH secretion following surgery and (iii) post-operative vomiting. Although they all warrant inclusion at part 1 (c) I am completely satisfied that an inappropriate infusion of hypotonic saline (Solution No 18) played the most significant part in Raychel developing hyponatraemia which lead to her death.

[114] Accordingly, the cause of death will be recorded as:

1 **(a)** **Cerebral Oedema**.

due to or as a consequence of

(b) **Hyponatraemia.**

due to or as a consequence of

(c) **Inappropriate infusion of hypotonic fluids, Syndrome of Inappropriate Anti-diuretic Hormone (SIADH) secretion following surgery and post-operative vomiting.**