SHERIFFDOM OF GLASGOW AND STRATHKEVLIN AT GLASGOW

[2025] FAI 41

GLW-B367-24

DETERMINATION

BY

SHERIFF J MCDONALD

UNDER THE INQUIRIES INTO FATAL ACCIDENTS AND SUDDEN DEATHS ETC (SCOTLAND) ACT 2016

into the death of

SOPHIA EVANGELINE SMITH

Glasgow 24 September 2025

DETERMINATION

The Sheriff, having considered the information presented at the Inquiry, determines in terms of section 26 of the Inquiries into Fatal Accident and Sudden Deaths etc. (Scotland) Act 2016 ("the Act") that :

1. In terms of section 26(2)(a) of the Act : Sophia Evangeline Smith died at 1748 hours on 11 April 2017 within the neonatal intensive care unit at the Royal Hospital for Children, Glasgow. She was 12 days old at the time of her death.

2. In terms of section 26(2)(b) of the Act : there was no accident which resulted in Sophia's death and accordingly there is no finding in terms of section 26(2)(d)

3. In terms of 26(2)(c) of the Act: the causes of Sophia's death :

    a. Pulmonary haemorrhage

b. Cardiomyopathy

c. Trisomy 21 (Down Syndrome)

d. Persistent pulmonary hypertension of the new-born (PPHN)

e. Subsequent post mortem examination established that Sophia had an active blood stream infection caused by methicillin sensitive Staphylococcus aureus producing Panton- Valentine Leucocidin (PVL-MSSA); this played a material role in her decline and death.

4. In terms of section 26(2) (e) of the Act: there were no precautions which (i) could reasonably have been taken; and (ii) had they been taken, might realistically have resulted in Sophia's death being avoided.

5. In terms of section 26(2) (f) of the Act: there was no evidence of any defects in any system of working which contributed to Sophia's death.

6. In terms of section 26(2) (g) of the Act: the foregoing are the principal facts relevant to the circumstances of Sophia's death.

a. The infection which contributed to Sophia's death was not related to the built hospital environment and was not associated with the new build hospital at Queen Elizabeth University Hospital campus, Glasgow.

b. PVL-MSSA is a rare strain of Staphylococcus aureus, which is both virulent and aggressive. Vulnerable patients, such as extremely ill neonates like Sophia, are particularly at risk from serious harm or death. Clinicians who treat such patients should be particularly vigilant, with a view to providing

early and proactive antibiotic and anti- toxin therapy, such as clindamycin, which might realistically prevent future deaths.

Recommendations

The Sheriff, having considered the information presented at the Inquiry, makes the following recommendations in terms of section 26(1)(b) of the Act:-

1. Weekly screening of vulnerable neonates in intensive care is a useful early warning of Staphylococcus aureus colonisation. This can inform clinical decisions with regard to possible infection and antibiotic therapy. NHSGGC should review the existing protocol in order to ensure that it is properly complied with at all times. Other Health Boards should consider adopting a similar screening process.

2. Public Health Scotland should disseminate information on; (a) the risks associated with PVL-MSSA; (b) the difficulties of diagnosis; (c) the advantages of early antibiotic and anti-toxin therapy, and; (d) the learning described by Dr Jonathan Coutts in his evidence, to other neonatal clinical teams throughout Scotland.

Preliminary matters

1. The death of a child must be the most painful experience that any parent can endure; it goes against the natural order of life and can shatter core beliefs and expectations. The intense grief, sorrow and sense of loss is a burden that is borne by parents for the rest of their natural lives. Sophia's birth and tragic death has impacted not only on the lives of her parents but that of her siblings who were looking forward to

welcoming a new member to their family. I, again, offer my deepest sympathy and condolences to the family of Sophia.

2. The purpose of this Inquiry is to understand what happened to Sophia and what might be done in the future to avoid such tragedy. Mr and Mrs Smith participated in the Inquiry in a dignified manner, in what must have been incredibly difficult circumstances, and I pass on to them my utmost thanks and respect.

3. The Inquiry was assisted by the Advocate Depute and Procurator Fiscal for the Crown, Senior Counsel and Counsel, and their instructing agents, for Mr and Mrs Smith and the Greater Glasgow Health Board. To each, I extend my thanks for the manner in which the Inquiry was conducted and am grateful for the agreement of evidence in this case which allowed the Inquiry to focus on the disputed areas of the evidence.

4. Evidence in cases of this nature is specialised and complex, sometimes resulting in the evidence being difficult to follow and/or understand but the presentation of the evidence in this case by the Advocate Depute was such that these difficulties did not arise and as such the writing of this determination has been assisted greatly. It is hoped that such an approach allowed Mr and Mrs Smith to understand fully all of the circumstances that led to the tragic death of their daughter.

5. The representatives of the participants of the Inquiry provided full and considered submissions which I considered fully; I have not repeated these or summarised them in this determination but where relevant I have referred to them in the discussion section.

6. There are a number of issues that this Inquiry set out to address. The Crown set out their submissions in chapters and proposed conclusions. In their submissions, Senior Counsel for Mr and Mrs Smith and Counsel for Greater Glasgow Health Board endorsed this approach and addressed the evidence and each conclusion. Senior Counsel for Mr and Mrs Smith largely agreed with the Crown's assessment and conclusions and the only substantive matter where Counsel for the Health Board diverged was in relation to the role that the infection played in the role of Sophia's death. I have aimed to address the areas where conflict arises and have detailed my assessment of the evidence within this determination and stated my conclusion.

7. Appendix 1 sets out the details of the participants, the witnesses led and the dates of the preliminary hearings and the Inquiry Hearings.

8. The court directed that a glossary of medical terms and definition of acronyms be provided to assist the Inquiry and those having an interest in the proceedings. These are produced as Appendix 2 and 3 respectively.

Legal framework

1. This Inquiry was held under the Fatal Accidents and Sudden deaths etc. (Scotland) Act 2016 ("the Act). Sophia's death was not reported to the Procurator Fiscal and her death was brought to the attention of the Crown by a letter from Solicitors representing Mr and Mrs Smith in 2020. As a result, Sophia's death was investigated under the direction of the Crown as part of a wider investigation into patient deaths and infections at Queen Elizabeth University Hospital (QEUH). In 2023, no link between

Sophia's death and the other patient deaths being investigated at Royal Hospital for Children (RHC) /QEUH was established and a separate report relating to the circumstances of Sophia's death was submitted to Crown Counsel.

2. The Lord Advocate instructed a discretionary Fatal Accident Inquiry in terms of section 4 of the Act be held. The First Notice was lodged on 1 February 2024.

3. In terms of section 1(3) of the Act, the purpose of the Inquiry is to establish the circumstances of Sophia's death and to consider what steps (if any) could be taken to prevent other deaths in similar circumstances.

4. Section 26 of the Act sets out the matters to be covered in the determination. These include setting out findings on the following:

a. when and where the death occurred;

b. when and where any accident resulting in the death occurred;

c. the cause or causes of the death;

d. the cause or causes of any accident resulting in death;

e. any precautions which-

i. could reasonably have been taken, and

ii. had they been taken might realistically have resulted in the death, or any accident resulting in the death, being avoided;

f. any defects in any system of working which contributed to the death or any accident resulting in death;

g. any other facts which are relevant to the circumstances of the death.

They also include setting out such recommendations (if any) in relation to:

a. a. the taking of reasonable precautions;

b. the making of improvements to any system of working

c. the introduction of a system of working

d. the taking of other steps

which might realistically prevent other deaths in similar circumstances.

5. The Procurator Fiscal represents the public interest in investigating, arranging and conducting an Inquiry. An Inquiry is inquisitorial and not adversarial, it is not their purpose to establish civil or criminal liability.

Factual background

[1] Theresa and Matthew Smith are Sophia's parents. Mr and Mrs Smith had eight children and Sophia, at the time of her birth, was their ninth child. They are both experienced parents.

[2] Sophia Evangeline Smith was born at 37 + 6 weeks weighing 3.22 kilos at the Royal Alexandra Hospital (RAH) on 31 March 2017 at 2353 hours. Delivery was normal.

[3] Mrs Smith was concerned immediately when Sophia was born that something was wrong and spoke of the midwife rubbing Sophia and moving her onto her side. Sophia required to be face mask ventilated then began to breathe on her own. Sophia's oxygen saturation remained below the normal range and she was taken to the Special Care Baby Unit (SCBU) and incubated. The oxygen levels suggested possible cyanotic

heart disease. A blood sample was taken at 0245 hours on 1 April 2017 to be analysed for infection.

[4] Dr Brian Kelly, consultant Paediatrician, spoke with Mrs Smith and arranged for Sophia to be transferred to the Queen Elizabeth University Hospital (QEUH) campus to have a cardiac assessment at the regional cardiac centre.

[5] QUEH campus comprises a combination of new buildings and buildings retained from the old Southern General Hospital. The new buildings are principally the Royal Hospital for Children (RHC) and a co-joined adult hospital, the QEUH that opened in 2015.

[6] The Neonatal Intensive Care Unit (NICU) was built in 2009. It is connected to the main new build RHC via an aerial walkway and does not share a water supply with the new buildings which comprise the QEUH campus. The NICU is a large neonatal unit that treats premature babies, babies with congenital abnormalities or babies that require surgical or specialist medical care.

[7] Sophia was taken by ambulance to the NICU at QEUH on 1 April 2017, arriving at around 0500 hours. She was sedated, intubated and mechanically ventilated within an hour of arrival. Mr and Mrs Smith arrived separately once Mrs Smith had discharged herself from the RAH at around 0630 hours. Ear, rectal, throat and umbilical swabs were taken from Sophia at 0642 hours in order that they could be analysed for signs of infection.

[8] On 1 April 2017, Dr Lesley Jackson and Dr Dhulippa Ananad, consultant neonatologists took responsibility for Sophia's care when she was admitted to the NICU.

An echocardiogram established that Sophia did not have cyanotic heart disease. There was, however, a thickening of the heart muscle with severe persistent pulmonary hypertension of the new-born (PPHN) and Sophia was found to have Trisomy 21 (Down syndrome).

PPHN

[9] PPHN is a condition where the new-born's circulation reverts to a fetal pattern, bypassing the lungs. Before a baby is born, a baby does not need to breathe, as oxygen is provided from the umbilical cord and the placenta. When a baby takes their first breath or cries, the lungs fill with air instead of fluid. When the lungs fill, the blood vessels which take blood from the heart to the lung dilate and oxygen is carried from the lungs, back to the heart, and pumped to the brain and the rest of the body. The blood pressure inside the lungs and blood vessels at this point is low. If a problem arises at around the time of birth which interferes with this process the blood vessels may not open up properly and the pressure inside them remains high. As a result of the blood vessels not opening up, blood cannot get into the lungs to pick up oxygen and the body does not have enough oxygen for the brain and other organs.

[10] Following the initial supportive treatment that had been provided, Sophia's treatment in the NICU was escalated. She was placed on high frequency ventilation, inhaled nitric oxide was commenced and vasoactive and inotropic medication was prescribed.

[11] The admission samples taken at QEUH and the samples taken at RAH were tested and were negative for signs of infection but as a precaution against neonatal sepsis, Sophia was started on intravenous (IV) antibiotics (benzyl penicillin and gentamicin). IV access was via an umbilical venous catheter (UVC) using aseptic technique; this was replaced later in the morning of 1 April 2017, again using aseptic technique, to a better position. This UVC was used over the following days for admission of infusions including adrenaline, dopamine and milrinone to improve heart function, vecuronium to muscle relax, sildenafil to reduce pulmonary blood pressure and morphine and midazolam for sedation. The UVC was removed on 6 April 2017.

[12] On 3 April 2017, Dr Patel, consultant neonatologist took over responsibility for Sophia's care, Sophia remained on high frequency ventilation and needed multiple vasoactive or inotropic medication to support her blood pressure and to encourage blood to flow to her lungs.

[13] On 5 April 2017, Dr Patel discussed with Mr and Mrs Smith that Sophia still required high levels of support, with particular focus on trying to maintain her oxygen levels. Dr Patel noted that Sophia was receiving 70% oxygen which is a very high level (for clarity, over 40% is considered high). He advised Sophia's parents that he hoped that, with time, Sophia's condition would improve over the next few days and weeks.

[14] At 1615 hours on the 5 April 2017, a peripherally inserted central catheter (PICC) line was inserted. A PICC line is a long thin line inserted into a vein, in Sophia's case via the saphenous vein in her left foot and extended through her main vein to a position proximate to her heart. It allows medicines to be administered to the patient and can

also be used to draw blood. The insertion of the PICC line was performed using a full aseptic technique and skin disinfection.

[15] On 7 April 2017, Dr Jonathan Coutts, consultant neonatal and respiratory paediatrician took over Sophia's care. There was still no understanding as to what the primary cause was for the PPHN and this was the focus of her treatment. Sophia was taken off the adrenaline and muscle relaxant medication.

[16] On 8 April 2017, the antibiotic therapy was discontinued and Sophia was moved from high frequency ventilation to conventional ventilation. Although these were all signs of Sophia improving, she remained a very sick baby and was still receiving 66% oxygen.

[17] By the 9 April 2017, Sophia needed less support but remained on medication to provide cardiac support and encourage blood to her lungs. Although the ventilator was providing less support Sophia still required 45% oxygen.

10 April 2017

[18] On the morning of 10 April 2017, Lorna McSeveney, a senior charge neo natal nurse, was the nurse assigned to care for Sophia. She noted on the commencement of her shift at 0730 hours that Sophia was stable. However, throughout the day Sophia's oxygen requirement on the ventilator increased. Mr and Mrs Smith noticed a change in Sophia's presentation, Mrs Smith describing Sophia as progressing from "pale, to ghost white to almost translucent". This was brought to the attention of staff but no note was made of these concerns within the medical records.

[19] Between 1400 hours and 1500 hours on 10 April 2017 there was an increasing need for oxygen and Dr Coutts increased the nitric oxide and ordered a chest x-ray. The x-ray revealed changes in the right upper lobe of the lung and prompted investigation, the position of the endotracheal tube also appeared low on the x-ray. Dr Coutts performed a bronchoscopy at 1650 hours and observed that Sophia had fresh blood in her right upper lung. This is an unusual finding in a term baby and is seen more commonly in acutely sick premature babies. Dr Coutts concluded that Sophia was suffering a pulmonary haemorrhage.

[20] The pulmonary haemorrhage was treated by increasing the pressure on the ventilator and at 2316 hours on 10 April 2017, blood was taken for possible causes to be identified, including a non-specific test for infection known as C reactive protein (CRP). Antibiotics (Gentamicin and Vancomycin) were commenced.

11 April 2017

[21] On 11 April 2017, at around 0145 hours Sophia's condition further deteriorated. Medical notes record that the chance of Sophia surviving were low due to the pulmonary haemorrhage. At around this time, on the advice of a neonatologist and an Extracorporeal Membrane Oxygenation (ECMO) surgeon a decision was made to place Sophia on an ECMO machine. This is a life support system that temporarily takes over the function of the heart and/or lungs, allowing them to rest and potentially heal. It ensures optimal oxygen delivery to the organs but is not a treatment for any underlying

condition. Sophia was commenced on ECMO at 0400 hours but her general condition did not improve.

[22] At 0547 hours on 11 April 2017, a blood culture was taken from the ECMO circuit. The Procurator Fiscal was notified by Dr Coutts at around 1645 hours that Sophia was likely to die shortly and he obtained agreement from the Procurator Fiscal that all medical lines could be removed to allow Mr and Mrs Smith time with Sophia. Dr Coutts had contacted the Procurator Fiscal to confirm that the Crown had no interest in having a post mortem examination carried out on Sophia; had they wished one then the invasive medical lines would not have been removed.

[23] After the call with the Procurator Fiscal, Dr Coutts spoke with Mr and Mrs Smith and explained Sophia's worsening condition. Following this discussion it was decided that intensive care support would be stopped and the ECMO machine was switched off; all tubes except the cannula were removed from Sophia allowing Mrs Smith to hold her. Sophia's heart began to cease to function and she died in her mother's arms at 1748 hours.

[24] On 11 April 2017, at 1935 hours, Dr Coutts discussed with Mr and Mrs Smith the notification of death and discussed whether they would consent to a post mortem examination. Dr Coutts was keen that a post mortem examination take place due to the uncertainty of the initial cause for the PPHN and it would possibly answer the question of whether any diagnosis had been missed. Mr and Mrs Smith agreed and provided their consent to a post mortem examination , which would be limited to Sophia's chest and abdomen.

[25] The death certificate issued by Dr Jonathan Coutts on 13 April 2017 gave the cause of death as:

1. pulmonary haemorrhage
2. cardiomyopathy

   Trisomy 21 (Down Syndrome)

   Persistent pulmonary hypertension of the new-born (PPHN)

   At the time of the death certificate being issued the results of the ante mortem and post mortem laboratory tests were not known.

[26] On 11 April 2017, the two ante mortem blood samples, referred to in paragraph 20 and 22 above, were received by the QEUH laboratory at 1153 hours and were processed the following day. The samples were analysed and were found to be positive for Staphylococcus aureus (SA). These results were reported verbally at a microbiology meeting on 13 April 2017 and confirmed in a final report on 14 April 2017. These two samples were sent to the Scottish Staphylococcus aureus reference laboratory for further analysis.

[27] SA is a type of bacterium commonly found living on the skin, and in the nose and throat. Around one third of people carry it quite harmlessly. People carry many different strains of SA, some causing more infections than others

Post mortem examination and laboratory results

[28] On 18 April 2017, a hospital post-mortem examination was conducted by Dr Dawn Penman, consultant forensic paediatric pathologist. The Final Summary of findings in the post – mortem report stated:

> "Early neonatal death (2 weeks of age); Trisomy 21 (diagnosed postnatally); Dysmorphic appearance; Ventricular myocardial thickening; severe sepsis; multiple foci of recent myocardial infarction; bilateral diffuse pulmonary haemorrhage; septic pulmonary vasculitis; no further anatomical abnormalities."

[29] Post mortem, samples of heart blood and lung fluid were obtained on 18 April 2017. These were sent to the Scottish Staphylococcus aureus reference laboratory for further analysis.

[30] On 25 April 2017, the Scottish SA reference laboratory confirmed that the ante-mortem samples, taken from Sophia on the 10 and 11 April 2017 were methicillin sensitive Staphylococcus aureus, Panton-Valentine leucocidin toxin positive. (PVL-MSSA).

[31] On 16 May 2017, the post mortem samples, taken from Sophia on 18 April 2017, were confirmed as PVL-MSSA. The isolates in the ante and post mortem samples were of the same type.

PVL-MSSA

[32] Methicillin sensitive staphylococcus aureus (MSSA) is a Gram-positive bacterium, genetically distinct from other forms of staphylococcus aureus (SA). Some

strains of SA, including MSSA, can produce a toxin known as Panton-Valentine leucocidin (PVL).

[33] PVL-MSSA is a rare strain of Staphylococcus aureus which is both virulent and aggressive. Vulnerable patients, such as very ill neonates like Sophia, are particularly at risk from serious harm or death. PVL-MSSA can be transmitted by having skin-to-skin contact with a carrier of PVL-MSSA or by contact with an item or surface that has PVL-MSSA on it from someone else. PVL-MSSA is known to be more likely to cause infection than other strains of SA. The PVL toxin is associated with necrotising pneumonia.

[34] All SA, including PVL-MSSA, can cause skin infections, but they are also associated with more serious infections of the lungs, blood, joints, and bones. They can cause harm if they get an opportunity to enter the body. This can occur spontaneously following asymptomatic colonisation (the presence of microorganisms, such as bacteria, on a body surface, such as the skin, where there are no signs or symptoms of disease or infection in a person). The risk is, however, increased where there are breaks in the skin, or invasive medical treatment such as central lines or catheters.

[35] Transmission of PVL-MSSA is usually by direct contact between human carriers or from contaminated surfaces. Bacteria can colonise the skin and remain until it has the opportunity to enter the blood stream.

[36] Since March 2020, PVL-MSSA has been placed on the Mandatory NHS Scotland Alert Organism/Condition list. This is a nationally agreed list used to establish and maintain local surveillance systems, allowing prompt monitoring and follow up of infectious diseases that pose a significant risk to public health.

[37] There were no other cases of the same type of PVL-MSSA found in Sophia within the NICU at RHC in the 6 months before or after she was nursed there.

Communications

[38] Following Sophia's death, Mr and Mrs Smith were trying to obtain more information about Sophia's death. Mrs Smith made a number of calls to speak with Dr Coutts. He spoke to Mrs Smith (date unknown) and advised her that PVL-MSSA had been identified in the samples taken from Sophia. At that time, he explained that this organism may have played a role in Sophia's death. This call must have taken place after the results were confirmed from the Scottish Staphylococcus aureus reference laboratory on 16 May 2017 and before the meeting with Mr and Mrs Smith on 9 June 2017.

[39] On 9 June 2017, Dr Coutts met with Mr and Mrs Smith within the chapel at the RHC to discuss the results of the post mortem examination. At this meeting, he explained the medical terminology used within the post mortem report and sought to answer any questions that Mr and Mrs Smith had. Carl Davis (ECMO surgeon) and Nurse McSeveney were also present at this meeting.

[40] Following from this meeting, Mr and Mrs Smith sought a copy of Sophia's post mortem examination report. It was a number of months before a copy of the report was received. Dr Coutts explained in his evidence that if such a request is made, then he would always seek permission from the Pathologist who has written the Report and that is what happened here. The report could not therefore be handed over at the meeting.

[41] On 1 August 2017, Mrs Smith wrote a letter of complaint to Greater Glasgow and Clyde Health board (NHSGGC) once the post mortem examination report had been received. In this letter Mrs Smith stated that both she and Mr Smith had consented to a post mortem examination of Sophia in the hope that it could shed some light on how Sophia died. She indicated that Sophia's death had come as a shock as they believed that Sophia had been improving. Mrs Smith states that the post mortem examination has not answered their questions and listed a number of questions that both she and her husband wanted answered [Appendix 4]

[42] Mrs Smith provided "notes" in relation to the questions that she asked, setting out her reasons for asking them. She concluded the letter by stating that Sophia had contracted PVL "at some point during the time [Sophia] was in your hospital" and that "we were not told about it at any stage but now know it is what killed her. We need some answers to these questions".

[43] NHSGGC's letter of response was dated 10 October 2017. In it, Mr and Mrs Smith are advised that their complaint has been investigated by a Mrs C Brady who had spoken to Dr Coutts and a Dr French (consultant paediatric pathologist). Each question is answered and Mr and Mrs Smith were offered a meeting with Dr Coutts if there were "remaining concerns". In his evidence Dr Coutts confirmed that he did not draft the letter of reply and that he had not "signed it off". The letter provided by NHSGGC did not provide a comprehensive response to the questions raised by Mr and Mrs Smith.

[44] In January 2019, Mr and Mrs Smith made email contact with Jeanne Freeman, the then Scottish Cabinet Secretary for Health, regarding Sophia's treatment and their experience. Fiona McQueen, the Chief Nursing Officer at the time, was passed this correspondence and corresponded with Mrs Smith. As a result of their communications, a meeting was arranged for 19 March 2019.

[45] On 19 March 2019, a meeting at QUEH attended by Mr and Mrs Smith, Dr Coutts, Jennifer Rodgers (Chief Nurse Paediatrics and Neonates, NHSGGC), an adviser from the Patients Advice Service and the Lead Complaints Manager NHSGGC, took place. At this meeting ,Dr Coutts advised Mr and Mrs Smith that he was of the view that the PVL-MSSA infection had played a role in causing the PH

[46] In preparation for this meeting, Mr and Mrs Smith prepared a list of questions in advance [Appendix 5]. The adviser from the Patients Advice Service made a note of the meeting and despite being given an assurance that verbatim notes would be taken, they were not. Mrs Smith had to bring to the Parent Advice Service's attention the omissions that had been made. An amended note of the meeting was issued on 2 April 2019.

Discussion and Recommendations sought

[1] In dealing with the recommendations sought by the Crown and Senior Counsel for Mr and Mrs Smith I propose to adopt the approach that the Crown have in their presentation of their submissions, and commended by parties, namely chapters of evidence. Counsel for NHSGCC did not ask that the Inquiry make any recommendations.

[2] It is important to acknowledge that the Act sets out the legal framework under which I can make recommendations.

[3] Section 26(1) (b) and (4) of the 2016 Act empowers the Inquiry to make such recommendations, if any, as the Inquiry considers appropriate as to: (a) the taking of reasonable precautions; (b) the making of improvements to any system of working; (c) the introduction of a system of working and (d) the taking of any other steps, which might realistically prevent other deaths in similar circumstance.

[4] Any recommendation that I make must be based on the evidence which is before the Inquiry and must be made, on the balance of probabilities, that there is a real or likely possibility that other deaths in similar circumstances will be prevented. I agree with the submissions made by both the Crown and NHSGCC that section 26(1) (b) and (4) is not sufficiently wide as to permit me to make recommendations which cannot be said to have any bearing on the realistic prevention of other deaths in similar circumstances.

[5] In that regard, I have found that many of the recommendations sought on behalf of Mr and Mrs Smith by their Senior Counsel are recommendations that I have no statutory authority to make. I do, however, consider that where what has been raised by Senior Counsel on their behalf would be of assistance in the treatment of neonates in NICU it is appropriate that I note my observations and I have done so throughout this determination. I have collated these as Appendix 6.

The Circumstances of Sophia's Death

[6] I have set these out in paragraphs 1 to 22 above. I am satisfied that there was no gap or deficiency in the level of care that Sophia received. There was a clear decision making process in place. There were regular reviews of how Sophia's condition was progressing and these were documented. This was evident from the parole evidence of both Dr Coutts and Nurse McSeveney and the contemporaneous medical and nursing records available to the Inquiry.

[7] Professor Peters, in his evidence, commented that when he considered the medical notes to assist preparation of his report, that they were "easy to follow" explaining that there was a clear narrative, which included reasons why decisions were being made. The medical records included the interpretation of results and there was clear details setting out the care plan for Sophia's treatment. All of this allows me to conclude that Sophia was subject to a high level of care and treatment.

[8] For the family in relation to this chapter, Senior Counsel raises the failure to note the concerns raised by Mr and Mrs Smith to a nurse on the 10 April 2017 regarding Sophia's presentation. Both Mr and Mrs Smith brought to the attention of the nurse the fact that Sophia's colour had changed - she was getting paler. There is no note of these concerns within the records but I accept that the concerns were raised.
Nurse McSeveney did not think that she was the nurse to whom the concerns had been raised but accepted that as an experienced nurse, "it was folly to ignore a mother's intuition" when it came to concerns being raised regarding a baby.

[9] Dr Coutts, in his evidence, stated that when handovers between staff are done that this occurs "face to face" and that although he would look at notes and observations he, as a consultant, would not necessarily look at the nursing notes but would rely on direct communications. This of course raises the issue that if there is no record of parental observations made then these observations will not be brought to the attention of anyone and will be known only to the person spoken to directly. Dr Coutts agreed that it was important to encourage communication and that such communication could be noted on the nursing chart. He stated that it was important that parents understood that they "were parents, not visitors".

[10] The evidence of both Dr Coutts and Nurse McSeveney was such that they recognised that the concerns and observations of parents can be important and relevant and I make the following observation:

Observation 1:

Parents of a child in a neo natal setting are hyper vigilant of any change in the presentation of their child, be that material or not. This was clearly exhibited by the evidence of Mr and Mrs Smith who devoted their time and energy to ensuring that Sophia had her parents by her side throughout her life. In a neonatal setting, observations and concerns expressed by parents regarding a change in their child's condition or presentation should be captured in medical notes to allow other medical personnel dealing with the child to be aware of the parental concerns.

Did the PVL-MSSA Infection play a material role in the death?

[11] The Advocate Depute, in his submissions sets out the evidence of each of the relevant witnesses in this chapter: Dr Martin Connor, a retired consultant microbiologist, Professor Mark Peters, Professor of Paediatric Intensive Care at Great Ormond Street Hospital, London, Dr Dawn Penman, consultant paediatric pathologist and Dr Jonathon Coutts, consultant neonatal and respiratory paediatrician . I do not propose to repeat their evidence but will refer to it when necessary.

[12] This question, whether the PVL-MSSA infection played a material role in Sophia's death, is the most significant point where parties disagree, albeit there is not significant divergence. The Crown and Senior Counsel for Mr and Mrs Smith both submit that the infection did play a material role in Sophia's death. Counsel for the NHSGGC, whilst accepting that Sophia was suffering from PVL-MSSA submits that the extent to which it contributed to Sophia's death cannot be determined on the evidence before this Inquiry.

[13] To understand the role of the infection in Sophia's death it is necessary to consider the evidence from each of the expert witnesses and the role that each has played in considering this question. Both Dr Connor and Professor Peters provided their opinions in relation to the role of the infection from the detailed medical records, results and reports. Neither had the benefit of observing Sophia. Professor Peters acknowledged that his examination of the medical papers provided an "imperfect picture" of clinical events as they unfolded. Both he and Dr Connor accepted that the clinicians would be the individuals to defer to on clinical matters. Dr Coutts had the

advantage of observing Sophia in life and Dr Penman performed the post mortem examination.

[14] There is no doubt that Sophia's health deteriorated in the afternoon of 10 April 2017, which led Dr Coutts to perform the bronchoscopy. During this procedure, he found fresh red blood in Sophia's right lung, which was an unusual finding in a term baby (which Sophia was). This finding led Dr Coutts to conclude that Sophia was suffering from a pulmonary haemorrhage. At 2316 hours on the 10 April 2017, a blood culture was taken from Sophia's vein with a further one being taken from the ECMO circuit at 0547 hours on 11 April 2017. These two blood cultures when later tested provided positive results for PVL-MSSA being present in Sophia's blood stream. Dr Connor opined that this meant that Sophia had an active infection in her blood stream at the time of her deterioration.

[15] There was no pathological finding of necrotising bacteria in Sophia's lungs at the post mortem examination and Dr Coutts opined that its absence meant that Sophia's decline could be explained by the PPHN alone. Professor Peters opined that given Sophia's PPHN was unresolved (and had been so for 10 days) her chances of survival were poor and his evidence was that Sophia's death could be explained by PPHN alone. Both, however, expanded on the role of the infection in their evidence.

[16] Dr Coutts when commenting on the absence of necrotising bacteria in Sophia's lungs stated that he did not regard the infection as not being important. In his evidence, he was asked by the Advocate Depute in re-examination whether the infection had

played a role in the overall decline of Sophia and answered, "Did the infection play a material role in the overall decline? On balance of probabilities , yes"

[17] In Professor Peters' evidence, he was of the view that Sophia's decline did not follow the pattern which he would have expected had it been due to the infection and he was of the opinion that the pulmonary haemorrhage was explained by the PPHN alone. He accepted, however, the hypothesis put to him that even if the pulmonary haemorrhage was not driven by the infection, Sophia's ability to recover was affected, albeit he could not quantify that, "Does it make death more likely? Yes, it does, but given this was the expected trajectory I suspect that it is a very small, negligible increase in risk". He was then specifically asked about the pathological findings and whether or not they meant that Sophia was more unwell and answered, "Yes. I hesitate because I am not that familiar with post mortem results in children. I don't disagree with the principle". When put to him that the infection had played some role, he agreed stating, "Yes either the cause of the pulmonary haemorrhage or the decline". Ultimately, Professor Peters was of the view that the role of the infection was "negligible".

[18] Professor Peters' evidence was invaluable in understanding Sophia's complex medical picture; he commended the level of care and treatment that Sophia had received throughout her life. It is hoped that his evidence was of great assistance to Mr and Mrs Smith in understanding the plight of their daughter.

[19] Dr Penman carried out the post mortem examination on 18 April 2017 and observed and described "an overwhelming, relatively recent sepsis" which, in her opinion, was likely to have mediated Sophia's terminal decline and death. Her evidence

was that the infection was material and it was the reason why Sophia got "more unwell". It was put to her that Professor Peters had opined that the infection was "negligible" which she disagreed with stating, "I saw it".

[20] The Crown are correct to say that the question for the Inquiry to determine is not whether the infection caused the pulmonary haemorrhage but rather did the infection play a material or significant contribution to Sophia's death? On the basis of the evidence I heard I cannot say that the pulmonary haemorrhage was caused by the infection, there are too many other factors in play to be able to conclude this and I am not satisfied that I can, on the balance of probabilities, state this. However, having regard to the evidence of both Dr Coutts and Dr Penman, I am satisfied that although the infection was not the immediate cause of death, it did make a material contribution to Sophia's decline and death.

Could the PVL-MSSA infection have been prevented?

[21] In dealing with this chapter consideration of section 26(2) (e) of the 2016 Act is paramount. This section requires that a two-stage test must be considered before any finding can be made - was there any reasonable precaution that could have been taken [to avoid the death] and if the precaution had been taken it might it *realistically* (my emphasis) have prevented the death.

[22] There is no dispute that Sophia was at an increased risk infection due to a number of factors: her age, her complex medical condition, the length of time that she had spent in the NICU and the necessary use of invasive devices. Infection is a known

complication of neonates requiring intensive care and it does not imply defective line insertion or line care. There was evidence before the Inquiry that such devices are a necessary medical tool that brought with their use a risk of infection. Sophia had four possible routes for the PVL-MSSA infection to enter her bloodstream: the cannula on each hand, the arterial line in her right foot, and the PICC line in her left leg.

[23] It was the opinion of Dr Connor that the PICC line was the likely route of the infection into Sophia's body. He explained that due to the superficial positioning of the arterial and cannula lines, there was a less likely risk of blood infection from them. He also stated that the outward blood pressure associated with the arterial line meant that infection by this route was less likely.

[24] The PICC line is often associated with infection and Dr Connor's opinion that it was the route of the infection was supported by the finding of a thrombus in the central vena cava (the main vein), which Professor Peters opined could be linked to the infection. It was also a finding of the post mortem examination that the signs of infection appeared to be emanating from the blood stream rather than the respiratory system, again consistent with the PICC line being the most likely route for the infection.

[25] The evidence that I heard and the submissions made by the Crown (unchallenged by parties) allow me to conclude that the PVL-MSSA entered Sophia's bloodstream via her PICC line. It, however, cannot be established that the PVL-MSSA infection entered Sophia's blood stream at the time of the line insertion. Dr Connor's evidence was that the process of skin colonisation can occur at any time and infections

can occur even if aseptic techniques are used. It will never be possible to eliminate the risk of infection in intensive care settings – all that can be done is to reduce risk.

[26] In relation to this chapter, parties are largely in agreement with the Crown analysis and conclusions that they make, however there a number of matters Senior Counsel on behalf of Mr and Mrs Smith have asked that I take cognisance of when considering if the infection could have been prevented. These relate to a number of concerns in relation to some of the areas of practice within the QEUH relating:

a. The use of a bank nurse within NICU during Sophia's care. It is not clear when this was, Mr Smith stating that he believed it to be "maybe" day 6 or 7 of Sophia's admission and Mrs Smith believing it to be "on about" day 9.

b. Hand hygiene; and

c. Antibiotics and screening.

The bank nurse

[27] A bank nurse is a registered nurse who is not a permanent employee but is a nurse who provides short term or ad-hoc staffing to a hospital.

[28] Mr and Mrs Smith both describe a bank nurse treating Sophia and both formed the opinion that she was "out of her depth". Her communication was poor and she had asked Mrs Smith where the arterial line was. The bank nurse had contact with the PICC line at Sophia's left heel. Mr and Mrs Smith raised their concerns regarding the bank nurse with a senior nurse at the time.

[29] Nurse McSeveney in her evidence stated that was unaware of any concerns being raised regarding the bank nurse. She confirmed in her evidence that any bank nurse working within NICU would have the relevant experience of neonatal intensive care nursing. I accept Mr and Mrs Smith's perception of the bank nurse as being less experienced than the other nurses dealing with Sophia's care are but there was no evidence before me which would lead me to conclude that the care provided by the bank nurse was the root cause of the infection and to conclude this would be entirely speculative.

Hand hygiene

[30] The Health Environment Inspectorate for Healthcare Improvement Scotland (HIS) carry out announced and unannounced inspections of NHS hospitals and services. All inspections involve a physical inspection of clinical areas and discussions with staff members at the inspected hospital. These inspections cover hand hygiene. Not every area of a hospital is inspected during the course of an inspection.

[31] Prior to inspections taking place, the relevant NHS health board completes a self-assessment which is submitted to HIS for review. During inspections, HIS undertake physical inspection; assess compliance with standard infection control precautions; and have discussions with senior staff, operational staff, services users, and service users' carers. After inspections are carried out feedback is provided to the hospital or senior staff at the hospital.

[32] Parties agreed within the joint minute before the court the results of the inspections at the QEUH campus from the HIS over a period from 2016 – 2019.

[33] The Royal Hospital for Children was inspected by HIS in September 2016, January 2019 and November 2019 (a follow up to the inspection in January 2019). NICU was inspected as part of the Inspections in January 2019 and November 2019. There was no non-compliance with standard infection control observed or reported within NICU during these Inspections.

[34] There was evidence before the inquiry from hand hygiene audits in April 2017 which supported the assertion that standards in NICU were high and exceptions were rare.

[35] Mr and Mrs Smith in their evidence drew the Inquiry's attention to their concerns regarding the hand hygiene practices of staff and of others visiting the NICU. It is completely understandable that the behaviour of others, and their perceived lack of compliance with the hygiene requirements, is something that would cause any parent of a child in NICU concern.

[36] The Inquiry heard evidence from Nurse McSeveney that nurses would not necessarily wash hands between each patient interaction and that disinfectant wipes were used, thus the action of not physically washing ones hands did not mean that hand hygiene was not being followed.

[37] Senior Counsel for Mr and Mrs Smith raised a number of matters in his submissions with regards to hand hygiene, including seeking NHS Scotland to undertake a review of adherence to hygiene protocols in neonatal and other high

dependency units across Scotland, the aim of such an exercise being that results would be collated to determine whether there was any general or local failure to implement and enforce hygiene in these particularly vulnerable units. I am not satisfied this is necessary and take the view that I could not, in any event, make such a determination on the basis of the evidence before me.

[38] It is difficult to ensure 100% compliance with hand hygiene but I am satisfied that standards were high and as such the Inquiry does not need to address this matter further. There are two points that I would highlight as being relevant in my decision making process. Firstly, there was no evidence before the Inquiry that linked the PVL-MSSA infection that Sophia was suffering from to any lapse in hand hygiene practice and I accepted Dr Connor's evidence that the absence of any similar cases meant that staff transmission was less likely. Secondly, since Sophia's death in 2017, awareness of hand hygiene amongst the public and professionals alike has developed and advanced due to the outbreak of the Coronavirus SARS- 2 pandemic. I did not accept the suggestion from Senior Counsel on behalf of Mr and Mrs Smith that there was a need for an increase in posters and printed material to deliver the message of the importance of hand hygiene - the world has moved on since April 2017 in that regard.

[39] There were two other matters, relating to hygiene in general in the NICU raised by Mr and Mrs Smith in their evidence and I wish to address these. There was evidence from Mrs Smith that people visiting NICU (other parents and visitors) had their mobile phones in NICU and were using them. In such an environment, there must be a control of what people introduce to that environment. It is surprising that items such as mobile

phones are permitted. Such items are reservoirs for bacteria and can contaminate hands and surfaces. Bacteria on phones can spread to vulnerable neonates through contact, and the frequent handling of phones by families, combined with a lack of any disinfection brings the risk of creating a major pathway for hospital-acquired infections.

[40] Evidence was also given by Mr and Mrs Smith that visitors to NICU often entered the unit wearing their outside clothing despite advice being given that outer garments should be removed and left outside. I have no reason to doubt their recollection of these events and, as I have previously noted, they would have been hyper vigilant to the goings on of those coming in and out of the unit. I did not hear any evidence as to how this was monitored or what preventative measures were in place.

[41] With regard to these issues, phones and clothing, I make the following observations:

Observation 2:

In a neonatal setting, there should be implementation of regular and thorough cleaning of mobile phones using appropriate disinfectants. Hospitals should develop and enforce clear local policies regarding mobile phone use in NICU areas and educate visitors to NICU on the risks and importance of phone hygiene. The use of mobile phones in close proximity to high-risk patients should be avoided to ensure that the risk of any bacterial spread is reduced.

Observation 3:

In a neonatal setting, visitors should be aware and reminded of the risk of infection that wearing outdoor clothing brings and there should be strict monitoring of any breaches of this requirement by staff, ensuring that lockers/ cloakrooms are used.

Antibiotics and screening

[42] When Sophia arrived at NICU on 1 April 2017, her admission samples were negative for signs of infection. As a precaution against neonatal sepsis, intravenous antibiotics were administered. The Inquiry heard evidence that in neonates the signs of sepsis can be difficult to spot and that antibiotics are, sometimes, given to prevent rather than treat an infection.

[43] There was evidence before the Inquiry in relation to how infection is detected and it is clear that there are a number of factors in play in such detection. Ultimately, I am satisfied that when the decision was made to discontinue antibiotics to Sophia on 8 April 2017, there were no clinical signs of infection and that the decision to discontinue antibiotics was, in all the circumstances, reasonable. There was also, at this time, no concerns regarding the appearance of the invasive lines.

[44] In NHSGGC babies admitted to NICU are swabbed on admission and should thereafter be swabbed weekly; these are similar to the swabs taken on admission. These swabs are capable of detecting SA colonisation .Sophia should have been swabbed by 10 April 2017. She was not. There was no reason provided to the Inquiry why this was

not done and understandably, this has led Mr and Mrs Smith to wonder if an opportunity was lost which would have saved Sophia.

[45] Dr Coutts gave evidence that whilst neither infection nor PVL-MSSA would be detected on these swabs, the detection of a SA colonisation could be. In his evidence, he stated that had a weekly screening result returned a positive result, Sophia would have been placed back on antibiotics and whilst this may have improved Sophia's condition, he could not say if this would have resulted in Sophia's survival.

[46] I consider a weekly screening swab would be a precaution which could reasonably have been taken but I must then move to the second part of the test as set down in the Act: "had they [the precaution] been taken, might [they] realistically have resulted in the death being avoided". The test that I must apply is whether the precaution "might realistically" have prevented the death and I have concluded that it would not in Sophia's case.

[47] Had the weekly swab been taken, neither Dr Coutts nor Nurse McSeveney could say when Sophia would have been swabbed: it would have been in the first week but they may have been taken when Sophia was not colonised. If the swabs had detected the SA colonisation resulting in further antibiotics being administered, the expert evidence before me spoke of a theoretical possibility of improvement and I am not satisfied that Sophia's death might realistically have been avoided.

[48] I was invited by the Advocate Depute to recommend that NHSGGC should review their protocol in relation to the weekly screening of neonates. Counsel for NHSGCC in her submissions on this matter, indicated that this was in hand and that

NHSGGC were already in the process of reviewing the operating procedure for neonatal microbiology surveillance taking account of Health Protection Scotland's evidence based screening guidance. This review was due to be completed by 31 July 2025 and its findings were not known to the Inquiry.

[49] The Advocate Depute in his submissions stated that notwithstanding this review, it was appropriate that a recommendation was made, Senior Counsel for Mr and Mrs Smith agreed.

[50] The evidence in relation to the weekly screening of neonates in the NICU was that it provided early warning of SA colonisation which, if a positive test was returned would result in additional antibiotic therapy. Both Dr Coutts and Professor Peters stated antibiotic therapy has more chance of being effective the earlier it is given.

[51] I agree with the Advocate Depute's submission that the weekly screening of vulnerable patients resulting in earlier antibiotic therapy has a realistic bearing upon patient treatment and outcomes, particularly in neonates where there is a real risk of death from infection. In these circumstances I am satisfied that it is appropriate that a recommendation is made.

Recommendation 1:

Weekly screening of vulnerable neonates in intensive care is a useful early warning of Staphylococcus aureus colonisation. This can inform clinical decisions with regard to possible infection and antibiotic therapy. NHSGGC should review the existing

protocol in order to ensure that it is properly complied with at all times. Other Health Boards should consider adopting a similar screening process.

[52] Both the Crown and counsel for NHSGCC asked that an explicit finding be made to the effect that Sophia's death was not related with the new build hospital in order to restore public confidence and allay any anxiety that the public may have about the safety of the NICU. It would be appropriate to do so in terms of section 26(2)(g): any other facts which are relevant to the circumstances of the death

[53] Senior Counsel for Mr and Mrs Smith demurred from the wording offered by the Crown and NHSGCC in this regard and asked that in my determination I state that there "*was no evidence before this inquiry* [my emphasis] that the infection came from the built up environment, nor that it was associated with the new build at QUEH campus". He explained that Mr and Mrs Smith were parties to the Scottish Hospital Inquiry where questions remained in relation to the neonatal unit and how it was affected by the wider hospital environment. His submission was that if I were to state in this determination that the infection did not come from the built environment nor that it was associated with the new build QUEH campus, I may prejudice Mr and Mrs Smith's position at the Scottish Hospital Inquiry.

[54] I do not know what the terms of reference are for the Scottish Hospital Inquiry nor what impact, if any this determination will have on Mr and Mrs Smith's position within that Inquiry. More importantly, I do not accept that there was "no evidence before this Inquiry" on this point.

[55] Firstly, it was agreed within the joint minute signed by all parties that:

> "61. In February 2021, the case was transferred to the Health and Safety Investigations Unit (HSIU) at COPFS to be considered alongside and as part of the ongoing investigation of environmental Gram-negative bacterial and fungal infections in four patients who died at RHC and QEUH between 2017 and 2019, and the built environment of the new-build hospital.
>
> 62. The said investigation found no evidence that Sophia's infection was associated with any of the other infections being investigated, or the built environment of the new-build hospital at QEUH campus."

[56] It was also agreed within the joint minute that:

> "8. The NICU was built in 2009. It is part of the retained estate and was not built at the same time as the new RHC and QEUH, which opened in 2015. It is connected to the main new-build RHC via an aerial walkway. It does not share a water supply with the new buildings which comprise QEUH campus."

and:

> "58. [……] Sophia was never nursed within the new-build hospital."

[57] In considering the joint minute and the other available evidence before me, I have concluded that the PVL-MSSA infection did not come from the built up environment and was not associated with the new build hospital at QEUH campus Glasgow.

[58] The fact that Sophia's case was an isolated incident, there being no similar cases or an outbreak of PVL-MSSA in the NICU 6 months prior to and 6 months after Sophia's death or elsewhere, further supports that the infection was less likely to have been as a result of staff transmission. I am satisfied based on the evidence that there were no deficiencies on part of NHS GGC, which caused the infection and agree that a finding in terms of section 26(2) (g) is appropriate.

[59] Dr Coutts told the inquiry that until he had treated Sophia, he had never come across PVL-MSSA in his career. He agreed that it was rare and a virulent and aggressive infection with the potential to cause significant harm and death. After Sophia's death, as a direct result of his experience of treating Sophia and his learning thereafter, he was able to advise the treating clinicians of two neonates to provide antibiotic therapy and to include clindamycin anti-toxin.

[60] The Advocate Depute invited the Inquiry to recommend that NHS Scotland should disseminate information to neonatal clinicians throughout Scotland in relation to the dangers of PVL-MSSA and the treatments available. Senior Counsel for Mr and Mrs Smith and Counsel for NHSGGC agreed with this proposal. Counsel for NHSGGC pointed out in her submissions, that any such recommendation in this regard should be directed to Public Health Scotland as they are the NHS Board responsible for disseminating public health information and advice at a national level. I am grateful to her for this information and am satisfied that this is a recommendation that I can make and do so.

Recommendation 2:

Public Health Scotland should disseminate information on; (a) the risks associated with PVL-MSSA; (b) the difficulties of diagnosis; (c) the advantages of early antibiotic and anti-toxin therapy, and; (d) the learning described by Dr Jonathan Coutts in his evidence, to other neonatal clinical teams throughout Scotland.

Communications

[61] In the First notice, the Inquiry was tasked to address three heads of communication between Mr and Mrs Smith and NHSGGC:

a. Communication in NICU between the staff and Mr and Mrs Smith regarding the serious nature of Sophia's condition

b. Whether the issuing of the death certificate was premature ; and

c. Was there any deliberate attempt to withhold information relevant to Sophia's death.

[62] In relation to (b) and (c) above, I am satisfied based on the evidence before the Inquiry that both can be answered in the negative.

[63] In his submissions , Senior Counsel acting on behalf of Mr and Mrs Smith has stated that the evidence that has been led before the Inquiry is such that Mr and Mrs Smith feel that the main source of their grievance is how their concerns regarding Sophia were handled by NHS management as opposed to the matters identified at (a) to (c) above.

[64] Senior Counsel on behalf of Mr and Mrs Smith has drawn to the Inquiry's attention a number of issues that arose not only at the time of Sophia's death but in the years following it. I acknowledge and understand that this chapter is one that has caused Mr and Mrs Smith perhaps the greatest frustration and the fact that some 8 years later, until this Inquiry, Mr and Mrs Smith had unanswered questions is unacceptable.

[65] It should not have been the case that the Inquiry was the vehicle for Mr and Mrs Smith to gain the answers and explanations that they have been looking for since

Sophia's death. It cannot be underestimated that at a time of the most imaginable grief and heartache that communication is key and there have been examples during this Inquiry where this has been lacking.

[66] Mr and Mrs Smith were kept informed of Sophia's condition whilst she was in the NICU. Dr Coutts held a number of meetings with Mr and Mrs Smith during his treatment of Sophia and following her death.

[67] In dealing with (a) above, I make the following comments. Mr and Mrs Smith both made comments throughout their evidence that sometimes language was used which appeared "flippant". Senior Counsel for Mr and Mrs Smith put a particular comment to Dr Coutts in his evidence, namely that in discussing Sophia's condition and reasons for it, Dr Coutts used the term that it was "just bad luck". Dr Coutts did not recall making such a remark and doubted that he had. He said that he would be "disappointed" if he sounded flippant during his discussions with Mr and Mrs Smith and apologised, in court, to them if that had been their perception.

[68] Mr and Mrs Smith found themselves in a scenario that by its very nature was distressing and upsetting – it is difficult to comprehend how they must have felt. They found themselves in an unfamiliar environment surrounded by medical equipment and medical terminology. Every single word uttered by a nurse or Doctor would have been incredibly important to them and understanding what is being said is critical. On a number of occasions in their evidence, they both spoke of being "confused" "dumbfounded and shocked", no doubt reflecting the state of anxiety that they were in. It is recognised that the nurse or Doctor in that situation walks a very fine, and difficult,

line when they speak with a parent advising the parent of their child's condition. Dr Coutts, in his evidence spoke of how training is provided to enable "bad news" to be shared but went on to say "bad news is bad news, it will always be bad news".

[69] Mrs Smith provided examples of phrases being used by one of the Doctors in relation to Sophia, "she's walking out of the woods" and "she's out of the danger of death zone". These provided her with hope, making the rapid decline and death of Sophia even more devastating and leaving Mr and Mr Smith in a situation where they had so many questions. It is understandable that those treating Sophia would wish to provide words of reassurance to Mr and Mrs Smith but those words need to be chosen with care and used appropriately.

[70] The overall impression that I gained in relation to the communication between Mr and Mrs Smith and NHSGGC was that it at times it was poor but generally, it was good. It is clear that when it was poor however, this clearly affected Mr and Mrs Smith and added to their grief. Much of the criticism of the communication being unsatisfactory follows upon Sophia's death and arises at a time when Mr and Mrs Smith were trying to understand what happened to their daughter.

[71] The letter dated 10 October 2017 from the NHSGGC Complaints Department to Mr and Mrs Smith (replying to their letter dated 1 August 2017) failed to provide comprehensive answers to the questions raised by Mrs Smith. Dr Coutts gave evidence that a draft of the letter had been sent to him. On considering it, he had made suggestions re the wording of it. The letter which was sent to Mr and Mrs Smith was however not "signed off" by him, nor had it been changed in accordance with his

suggestions and had in fact been added to (the paragraph referring to the post-mortem examination had been added). Dr Coutts gave evidence that he spoke with the Complaints Department and expressed his "distress" at the letter and stated in his evidence that it made him wonder, "How many other [such] documents are sent to families?"

[72] The Minute sent to Mr and Mrs Smith following upon the meeting on 19 March 2019 was wrong. Despite being given the assurance that verbatim notes were being taken by the representative from the Parent Advice and Support Service, they were not. The Minute sent omitted an opinion provided by Dr Coutts in relation to the potential source of Sophia's infection. This was a particularly sensitive omission given that it related to the infection and had been noted in the meeting notes retained by NHSGCC and Dr Coutts.

[73] The correspondence between Mrs Smith and the chief nursing officer, Fiona McQueen which was pivotal in arranging the meeting on the 19 March 2019 contained an email dated 12 February 2019 from Mrs Smith to Ms McQueen. Within this email, Mrs Smith expresses her shock and surprise that during a telephone conversation, Ms McQueen raised the question of litigation and compensation for Sophia's death. It is accepted that Ms McQueen offered an "unreserved apology" for her comments on litigation but the hurt had been caused.

[74] The occurrences of miscommunication, not limited to what is noted above, resulted in Mrs and Mrs Smith, quite understandably, distrusting the process. I agree with Senior Counsel's submissions that although Mrs Smith in her letter , dated

1 August 2017, states that a complaint is being made, what is being sought is answers. The response issued on 10 October 2017 is responding to a "complaint" and is guarded and defensive.

[75] Dr Coutts made an insightful observation in his evidence and indicated that whilst parents have every right to complain, what would be manifestly more constructive would be for parents to be able to have answers. His feeling was that the way in which the complaints procedure worked moved the process away from addressing the concerns raised. A culture where families and management are working together to acknowledge a situation rather than becoming adversarial should be encouraged. It is reasonable to assume that where a complaint is made against someone that a defensive approach is taken and openness and transparency are lacking.
Dr Coutts indicated that his opinion was that where matters escalated to complaints, parents often did not get the information they were seeking.

[76] Taking into account the issues in this case surrounding communication, the following observations are made:

Observation 4:

Where a clinician has been asked to comment in relation to the concerns of a family where they have lost a child, it essential that what is sent to the family properly reflects the clinician's opinion and is approved by the clinician whose views have been sought. There should be no omissions or additions made once the clinician has approved the communication that is to be sent to the family.

Observation 5:

Any communications with families of deceased children should be accurate and sensitive. Where concerns are raised regarding the treatment of a child who has died, there should be a collegiate approach taken, in the first instance, to try to ascertain the truth and to address the concerns raised by the family.

Post Mortem Procedures

[77] Although post mortem procedures were not an issue that featured in the First notice a number of issues arose in the evidence before the Inquiry that I wish to address. These relate to the post mortem examination report and the presentation of Sophia after the post mortem examination had been carried out.

[78] As a result of a conversation with Dr Coutts, Mr and Mrs Smith agreed that a post mortem examination, limited to the examination of Sophia's chest and abdomen, would be carried out. Their desire for this to be done was to see if answers could be found in relation to the cause of Sophia's death with the hope that it might help other families and assist the medical professionals in understanding what had happened to Sophia. They are to be commended for their reasoned approach and compassion in this decision in the most difficult circumstances.

[79] The post mortem examination was carried out by Dr Dawn Penman consultant forensic paediatric pathologist and was instructed by Dr Coutts in an email setting out questions that he was seeking answers to in a quest to find out more information in

relation to Sophia's death. The purpose was twofold – to allow him a greater understanding of Sophia's death and to provide any additional information to Mr and Mrs Smith. Dr Penman was aware that the report would be discussed with the family.

[80] The Inquiry was told by Dr Penman in her evidence that there are different types of post mortem reports. There is a medical legal post mortem report which is usually instructed by the Procurator Fiscal in their role to investigate suspicious or unexplained deaths. In such cases, there is no known cause of death and the pathologist is aiming to provide the cause of death. In a hospital request for a post mortem, which Sophia's was, it is instructed by a clinician who will ask questions to assist with the understanding of the cause of death and will often discuss the findings with the family.

[81] Dr Penman stated that the resulting reports are different: the hospital report is much more technical and uses medical terms throughout whereas the medico- legal report is more "understandable to the lay man". The resultant report in relation to Sophia, due to the type of report it was, was difficult for a layperson to understand. It fell to Dr Coutts to explain the report to Mr and Mrs Smith, although I noted from Mrs Smith's evidence that when she received a copy of the post mortem report she "worked very hard …by researching all the medical terms it contained so that I could understand it fully". Mrs Smith's desire to understand what was being said is how every parent would feel but not every parent would have the means or ability to undertake the task that Mrs Smith did. This was another example of her resilience in these matters and how better communication would have assisted her.

[82] There is no criticism levelled at either Dr Penman or Dr Coutts with regards to their actions in relation to the post mortem report : the writing of it by Dr Penman and the explanation and discussion of it by Dr Coutts to Mr and Mrs Smith. When Dr Penman gave evidence in the Inquiry, she was taken through the post mortem report, almost, line by line and asked to explain what was written. Her evidence was concise, clear and straightforward – the report and its findings was instantly understandable when she explained it. It is hoped that this evidence provided Mr and Mrs Smith with a better understanding of Sophia's condition. As stated earlier, however, it should not have been at this stage a number of years later at the Inquiry, that that understanding was gained.

Observation 6:

Where a clinician has requested a post mortem report, the pathologist should be aware that the next of kin will at least wish to discuss the report and may, as happened in this case, request a copy of the report. Language that is clear, simple and understandable to lay persons should be adopted in the report or a clear, simple summary should be appended to the report to be provided to the next of kin. Additionally it may be appropriate for the paediatric pathologist to attend the meeting with the bereaved relatives to assist in their understanding.

[83] In providing their consent to the post mortem examination of Sophia, Mr and Mrs Smith restricted this to an examination of Sophia's chest and abdomen. Mrs Smith

gave evidence that on seeing Sophia after the post mortem examination, Sophia had incisions that she had not expected and that they had been stitched crudely. The distress that this caused does not have to be stated. Mrs Smith also spoke of her upset at being given Sophia to hold in the mortuary with a large identification sticker attached to her chest. The image she painted in her evidence was upsetting and could have been avoided with a sensitivity fitting of the occasion.

[84] Dr Penman was asked specifically about these matters and appeared quite shocked at what was being put to her. The presentation of the child after a post mortem examination is not something that she would be involved in and would be the responsibility of the mortuary technicians.

[85] Dr Penman indicated that incisions that required to be stitched would be done by the mortuary technicians and that she would not have expected them to be done in the manner described by Mr and Mrs Smith.

[86] Dr Penman in her evidence explained that what was described in the affidavit of Mr Smith regarding the incisions made to Sophia, related to repairs to clinical incisions and were not demonstrative of the extent of the post mortem examination. It appeared to me that this was the first time that this information had been given to Mr and Mrs Smith and was just another example of how communication at the outset could have made their understanding of the process much easier and less upsetting.

[87] Both Mr and Mrs Smith, in my opinion, did not seem to have been advised of what was involved in a restricted post mortem examination (this is borne out in

Mrs Smith's letter dated 1 August 2017) and were not prepared for their meeting with Sophia after the post mortem examination had been carried out.

[88] Dr Penman's evidence was that had she been made aware of Sophia's presentation to her family as described by Mr and Mrs Smith, she would have spoken with her management.

Observation 7:

The requirement for sensitivity in preparing a baby or a child for their family following on from a post mortem examination cannot be overstated. The family should be prepared for what they are going to see with explanations provided to assist their understanding of the process.

Conclusion

[89] I express my gratitude and thanks to the Advocate Depute, Mr Mitchell KC and Miss Toner for their assistance to the court in this Inquiry. The manner in which the Inquiry was conducted by them was such that I hope Mr and Mrs Smith felt that their voices had been heard and their questions answered. I would also like to express my thanks to the court staff, my clerk and bar officer, who assisted the court and Mr and Mrs Smith during this Inquiry.

[90] My last words are offered to Mr and Mrs Smith. Their strength, dignity and resilience are remarkable; to them and each of their family members I offer them my

deepest condolences in their loss of their daughter, their sister and their grandchild, Sophia Evangeline Smith.

Appendices

1. Procedure and Participants
2. Glossary of Medical Terms
3. Draft List of Abbreviations
4. Questions in Letter of Complaint from Mrs Smith
5. List of prepared Questions by Mr and Mrs Smith for Meeting on 19 March 2019 at QEUH
6. Observations

Appendix 1

Procedure and Participants

1. The participants of the Inquiry were represented by the following Counsel and Solicitors:

Crown	Advocate Depute Mr Fyffe KC
Mr and Mrs Smith	Mr Mitchell KC
Greater Glasgow Health Board	Ms Toner, Advocate

2. The first preliminary hearing fixed for the 7 May 2024 was jointly discharged administratively for 12 weeks to allow parties time to prepare, a preliminary hearing was fixed for 20 August 2024.

3. On 20 August 2024, the Court ordered that the Crown lodge their productions with the Court, that parties exchange expert reports from their respective expert witnesses, that parties discuss and agree a joint minute of evidence and that affidavits be prepared and lodged with the Court. The 17 to 28 February 2025 were identified as the dates for the Inquiry and a further preliminary hearing was fixed for 11 December 2024.

4. On 11 December 2024, the Court ordered that parties lodge a final joint minute 14 days in advance of the Inquiry, that the Crown lodge electronic productions and that a glossary of medical terms be lodged.

5. The Inquiry commenced on the 17 of February 2024. Evidence was heard over six days. The use of affidavits and the agreement of evidence significantly reduced the length of the Inquiry. Submissions were heard on 6 May 2025.

6. The Inquiry heard from nine witnesses:

Monday 17 February 2025	Matthew Smith - Sophia's father Theresa Smith -Sophia's mother
Tuesday 18 February 2025	Lorna McSeveney Pamela Joannidis
Wednesday 19 February	Dr Martin Connor
Thursday 20 February 2025	Sandra Devine
Tuesday 25 February 2025	Dr Jonathon Coutts
Wednesday 26 February 2025	Dr Dawn Penman Professor Mark Peters

Appendix 2

Glossary of Medical Terms

Acidosis - respiratory acidosis describes a build-up of carbon dioxide caused by overproduction of acid in the blood resulting from poor lung or breathing function

Acute deterioration - a sudden reduction in physiological (physical health) status

Adrenaline infusion - used for treatment of rapidly developing life threatening problems with lung and blood vessel function

Antenatal - before birth

Antibiotic - a substance used to treat or prevent bacterial infection

Antimicrobial therapy - a course of treatment to prevent or inhibit the growth of micro organisms such as bacteria or fungi

Arterial - relating to the arteries (large blood vessels)

Auscultation of the heart - checking the sounds made by the heart with a stethoscope

AVSD - an atrioventricular septal defect is a heart defect which can cause heart failure and high blood pressure in the lungs

Bacteria - single celled living organism

Biventricular hypertrophy - a thickening of the heart walls, which affects ability to breathe

Blood cultures - a method of testing blood for the presence of micro organisms such as bacteria or fungi

Blood pressure – the term used to describe the strength with which blood is being pumped around the body

Bronchoscopy – a procedure to look directly at the airways in the lungs by inserting a narrow, lit tube through the nose or mouth and into the lung

Cardiac assessment - medical assessment of the **cardiovascular** system ie the heart and blood vessels

Cardiomyopathy – disease of the heart muscle

Central venous catheter – a narrow, flexible tube inserted into a vein to connect with a large vein through which the veins of the body can be supplied with nutrition or medication

CRP levels – C reactive protein (CRP) is a biochemical marker of, or flag indicating, infection

Colonisation – the presence of micro organisms on the body which does not cause disease or sign of infection

Congenital abnormalities – structural or functional anomalies that arise before birth

Congenital heart disease – a defect of the heart which has arisen before birth

Cyanosis – blue-purple skin colouring due caused by decreased oxygen in the bloodstream

Cyanotic heart disease – heart defect causing insufficiency of oxygen in the blood

Down syndrome – chromosomes contain the genetic information which tells the body how to grow and function. There are 23 pairs of chromosomes in every cell. Having a third copy of chromosome 21 is described as "Trisomy 21". Trisomy 21 is known as Down Syndrome or Down's Syndrome. Trisomy 21 causes health issues and learning difficulties to varying levels.

Dysmorphic appearance – a physical feature as part of a larger clinical syndrome

Environmental bacteria – bacteria found in the air, water or soil characterised by reacting to environmental factors such as temperature

Extracorporeal Membrane Oxygenation (ECMO) – a system of medical equipment which performs the function of the heart and lungs

Femoral pulse – pulse point in the area of the inner hip, the femoral pulse of a a newborn baby is checked since a weak femoral pulse may be a sign of a congenital heart malformation

Foetal medicine – the medical specialism addressing complications arising with the baby in the womb

Forensic pathology – the medical specialism which investigates cause of death by examination of the dead body

FBC – a Full Blood Count, or Complete Blood Count (CBC) is a set of tests which confirms the levels of red and white blood cells in the blood

Gram positive/gram negative – a bacterium can be gram positive or gram positive depending on the structure of its cell wall. Gram negative bacteria are more difficult to control with antibiotics

High frequency ventilation - greater than 60 breath per minute rate mechanical ventilation, used to minimise risk of lung injury

Human flora – the bacteria present normally in the human body, which includes staphylococci and streptococci

Hyperoxia test – a test used to assist to differentiate between cardiac and non-cardiac causes of cyanosis

Hypotension – low blood pressure

Immune compromised/immunodeficient – a weakened immune system causing vulnerability to disease

Incubator – a piece of medical equipment which assists control of body temperature

Inotropic drugs – medication which affects the function of the heart muscle

Intravascular catheter - a narrow, flexible tube inserted into a vein to connect with a large vein through which the blood pressure and blood gases can be monitored

Intravenous antibiotics – antibiotics administered directly into a vein to enter the bloodstream

Intubation – the insertion of a tube through the mouth or nose into the chest

Invasive indwelling catheters – a catheter which is inserted inside of the body and remains there for a period of days

Microbiology – the study of the biology of microscopic organisms such as bacteria, fungi and viruses

Mosaic Down syndrome – Mosaic Down Syndrome occurs when an extra copy of chromosome 21 is present in some but not all of the body's cells. It cannot be known how many of a baby's cells have two or three copies of chromosome 21. Mosaic Down Syndrome causes health issues and learning difficulties to varying levels.

MSSA – methicillin sensitive staphylococcus aureus. Staphylococcus infections can be a healthcare associated infection (HAI) which can complications for patients. Patients are at an increased risk if they have a compromised immune system. Staphylococcus bacteria can enter the body via medical devices that enter the body such as catheters, intravenous devices and tubes for feeding patients or enabling them to breathe.

MSSA PVL – PVL refers to Panton-Valentine Leucocidin, which is a toxin produced by some strains of staphylococcus aureus and which can cause skin infections and necrotising pneumonia

Necrotising pneumonia – severe lung infection commonly caused by staphylococcus aureus

Neo natal – relating to the newborn

Neonatal intensivist/neonatologist – a paediatrician specialising in the treatment of newborn babies

Neo natal sepsis – bloodstream infection in the newborn

Pathogen – any organism that causes disease

Persistent pulmonary hypertension of the newborn (PPHN) – pulmonary hypertension is high blood pressure in the blood vessels that supply the lungs -PPHN occurs when the baby's pulmonary arteries no not open sufficiently to enable the baby's organs to get enough oxygen

PICC – peripherally inserted central catheter, a central venous catheter inserted through the skin via a suitable vein

Pleural effusion – a build up of fluid around the lungs

Pneumonia – inflammation of the lungs

Post ductal/pre ductal saturation – oxygen levels in the lower (post) and upper (pre) extremities of the body

Post-natal – after birth P**perfusionist –** ECMO technical operator

Pulmonary haemorrhage – bleeding into the lung

Respiratory – relating to the breathing

Sepsis – a life threatening reaction to an infection

Severely deranged clotting – a symptom of severe bacterial bloodstream infection

Spa typing – a method of distinguishing differing strains of staphylococcus aureas

Staphylococcus aureus - a common bacteria which is a cause of potentially serious bloodstream infections

Sterile – free of micro organisms

Standard Infection Control Precautions (SICP) - SICP assess: (1) patient placement (2) hand hygiene (3) respiratory hygiene (4) personal protective equipment (5) safe management of care equipment (6) safe management of care environment (7) safe management of linen (8) safe management of blood and body fluid spillages (9) safe disposal of waste, and (10) occupational safety, prevention and exposure management, e.g. safe disposal of sharps.

Trisomy 21 – chromosomes contain the genetic information which tells the body how to grow and function. There are 23 pairs of chromosomes in every cell. Having a third copy of chromosome 21 is described as "Trisomy 21". Trisomy 21 is known as Down Syndrome or Down's Syndrome. Trisomy 21 causes health issues and learning difficulties to varying levels.

TBP - Transmission Based Precautions which are the precautions in addition to SICP which should be applied if patients have a known infection.

Vasoactive drugs – drugs affecting the diameter of blood vessels and hence blood pressure

Venal system – system of veins throughout the body

Ventilator – a piece of medical equipment providing a controlled supply of air

White blood cell count – a high white blood cell may indicate that the body is fighting an infection

Appendix 3

Draft List of Abbreviations

ARHAI –Antimicrobial Resistance and Healthcare Association Infection –a clinical service providing national expertise for infection prevention and control, antimicrobial resistanceand healthcare associated infection for Scotland. It is part of NHS Assure, and sits within National Services Scotland.

CRP –C-Reactive Protein

CVC–Central Venous Catheter

CXR–Chest X-Ray

ECG –Echocardiogram

ECMO–Extracorporeal Membrane Oxygenation

ET (Suction) -Endotracheal

ETT–Endotracheal Tube

FiO2–Fraction of Inspired Oxygen –the concentration of oxygen in the ventilator air provided to the patient.

HIIAT–Healthcare Infection Incident Assessment Tool

ICD–Infection Control Doctor

ICN–Infection Control Nurse

IMT–Incident Management Team

IPC–Infection Prevention and Control

IPCAT-Infection Prevention and Control Assessment Tool

IVC–Inferior Vena Cava

MSSA–Methicillin Sensitive Staphylococcus Aureus

MSSA-PVL (or PVL-MSSA)-Methicillin Sensitive Staphylococcus Aureus Panton Valentine Leukocidin

NHSGGC–Greater Glasgow and Clyde Health Board

NIPCM–National Infection Prevention and Control Manual

NICU–Neonatal Intensive Care Unit

NO–Nitric Oxide

OP (Suction) –Oropharyngeal

PAG–Problem Assessment Group

PAL–Peripheral Arterial Line

PICC–Peripherally Inserted Central Catheter2

PPHN–Persistent Pulmonary Hypertension of the Newborn

PVL–Panton-Valentine Leukocidin

QEUH–Queen Elizabeth University Hospital, Glasgow

RAH –Royal Alexandra Hospital, Paisley

RHC–Royal Hospital for Children, Glasgow

SA -Staphylococcus Aureus

SAB -Staphylococcus Aureus Bacteraemia

SaO2–Oxygen saturation-measured in arterial blood

SCN –Senior Charge Nurse

SICP –Standard Infection Control Precautions

SpO2 –Oxygen saturation –detected by pulse oximeter

ST6 –Speciality Trainee

UVC –Umbilical Venous Catheter

WCC –White Cell Count

Appendix 4

Questions in Letter of Complaint from Mrs Smith

a. How could it be stated in page 1 of the PM report that Sophia went onto ECMO on the first day?
b. Why was my daughter was examined below the waist during the post mortem?
c. Why did it take so long to diagnose Sophia's condition and put her on ECMO?
d. How could it be said in comment (PM report Page 6) that "Her pulmonary hypertension did not improve ?"

Appendix 5

List of prepared Questions by Mr and Mrs Smith for Meeting on 19 March 2019 at QEUH

a. How was our daughter infected with MSSA PVL?
b. What is the probable source of the infection?
c. How did it go unnoticed?
d. Had it been noticed, could Sophia have been saved?
e. We often see NHS campaign posters for sepsis and spotting the signs of it. How did Sophia's sepsis go unnoticed in the NICU? How did it manage to take hold so badly without being uncovered?
f. When could the sepsis have been reasonably identified? When culd it have been reasonably treated ?
g. Were there any signs that sepsis could be a risk? Were signs monitored and thereafter acted on timeously?
h. Could the MSSA PVL diagnosis have been made prior to Sophia's death?
i. Could the necrotising pneumonia have been diagnosed prior to Sophia's death?
j. Were there any steps that could have been taken?
k. When it was discovered that MRSA [sic] was the cause of Sophia's death, what action did the hospital take to protect other patients? Was the ward cleaned? Were other babies tested/treated?

Appendix 6

Observations

Observation 1

Parents of a child in a neo natal setting are hyper vigilant of any change in the presentation of their child, be that material or not. This was clearly exhibited by the evidence of Mr and Mrs Smith who devoted their time and energy to ensuring that Sophia had her parents by her side throughout her life. In a neonatal setting, observations and concerns expressed by parents regarding a change in their child's condition or presentation should be captured in medical notes to allow other medical personnel dealing with the child to be aware of the parental concerns.

Observation 2

In a neonatal setting, there should be implementation of regular and thorough cleaning of mobile phones using appropriate disinfectants. Hospitals should develop and enforce clear local policies regarding mobile phone use in NICU areas and educate visitors to NICU on the risks and importance of phone hygiene. The use of mobile phones in close proximity to high-risk patients should be avoided to ensure that the risk of any bacterial spread is reduced.

Observation 3

In a neonatal setting, visitors should be aware and reminded of the risk of infection that wearing outdoor clothing brings and there should be strict monitoring of any breaches of this requirement by staff, ensuring that lockers/ cloakrooms are used.

Observation 4

Where a clinician has been asked to comment in relation to the concerns of a family where they have lost a child, it essential that what is sent to the family properly reflects the clinician's opinion and is approved by the clinician whose views have been sought. There should be no omissions or additions made once the clinician has approved the communication that is to be sent to the family.

Observation 5

Any communications with families of deceased children should be accurate and sensitive. Where concerns are raised regarding the treatment of a child who has died, there should be a collegiate approach taken, in the first instance, to try to ascertain the truth and to address the concerns raised by the family.

Observation 6

Where a clinician has requested a post mortem report, the pathologist should be aware that the next of kin will at least wish to discuss the report and may, as happened in this case, request a copy of the report. Language that is clear, simple and understandable to lay persons should be adopted in the report or a clear, simple summary should be appended to the report to be provided to the next of kin. Additionally it may be appropriate for the paediatric pathologist to attend the meeting with the bereaved relatives to assist in their understanding.