

WITNESS STATEMENT

(CJ Act 1967, s.9: MC Act 1980, ss 5A(3) and 5B: MC Rules, r.70)

Statement of **Dr Dewi R Evans**

Age if under 18:

Occupation: Consultant Paediatrician

This statement (consisting of **11** pages) each signed by me, is true to the best of my knowledge and belief and I make it knowing that, if it is tendered in evidence, I shall be liable to prosecution if I have wilfully stated anything which I know to be false or do not believe to be true.

Signature: Date: **3 July 2019**

OPERATION HUMMINGBIRD

1. I am Dr Dewi R EVANS. I am a consultant paediatrician. I am a Fellow of both the Royal College of Physicians and the Royal College of Paediatrics and Child Health and have a Diploma in Obstetrics from the Royal College of Obstetrics and Gynaecology. I was in fulltime NHS clinical consultant paediatric practice in Swansea from 1980 until 2009. I held several part-time short - term clinical posts between 2010 and 2014 and gave up clinical practice in 2014.

I prepared a Statement of 13 pages that summarises my clinical experience dated **17 April 2019**.

Review of Published Literature regarding Air Embolus in the Newborn Infant:

Introduction:

2. At the time of preparing this Statement I have prepared over 40 reports in relation to Operation Hummingbird. A number of my statements identify very significant concerns regarding the cause of the collapse and death of several babies. It is my opinion that the death of several infants is a consequence of inadvertent introduction of air into their circulation, and that this was intentional.

3. There are a number of characteristics of individual cases in these various papers that show features that are very similar to observations made by clinical staff called to resuscitate the infants in the case study of Operation Hummingbird. I have noted these in the individual cases described.

4. None of the chest or abdominal x-rays taken of the infants who collapsed at the CoCH make any comment regarding the presence of air in inappropriate places. I claim no radiological expertise and await the opinion of a specialist paediatric radiology opinion on all of the x-rays taken. They are in the main of very good quality. Having viewed a number of x-rays from the papers published in this review [where the presence of air is indicated by means of an arrow] I suspect that the untrained eye could well overlook the significance of these abnormalities.

5. During the preparation of my reports I carried out a number of literature searches looking for published evidence citing air embolus as a causative factor in the collapse of newborn babies. This statement is based on the information I discovered as a result of carrying out a number of *on line* searches. Not unexpectedly, given the rarity of air embolus as a cause of infant morbidity and mortality this is not a condition that has attracted wide scientific interest. The literature search relating to air embolism in the newborn infant has disclosed very few cases where the air embolism is the result of air (or oxygen) from a peripheral venous cannula. There are no publications noting that an infant's collapse and demise was the result of deliberate inflicted an injury. A search of the NICE

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[National Institute of Clinical Excellence] database [carried out on **1 July 2019**] did not identify any articles relevant to air embolus in the newborn. I have relied on *Google* searches as well as benefiting from access to my membership of the Royal Society of Medicine (RSM). I include copies of all of the published papers noted in my review in electronic form, allowing the benefit of seeing several of the original articles in colour.

6. Air embolism occurs where a volume of air enters the infant's blood system via an intravenous line. This may occur as an accident, where the intravenous equipment has been inadequately supervised. It may occur intentionally, i.e, where the perpetrator deliberately inserts air into the peripheral vein.

7. One of the most tragic accidents that occurred in the paediatric department in Swansea during my clinical practice led to the death of a baby following what should have been routine surgery for pyloric stenosis (2001). At the end of the surgical procedure it was standard practice for the surgeon to ask the anaesthetist to inject air into the stomach via the nasogastric tube. A volume of air into the stomach would cause no harm and guarantee that the surgical procedure had not caused a perforation to any part of the upper GI tract during the surgery. In this particular case the anaesthetist, instead of injecting air into the nasogastric tube injected the air directly into an intravenous line. The baby collapsed quickly. Resuscitation was not successful and the baby died.

Review of published articles:

8. An air embolism is defined is an air bubble trapped in a blood vessel, obstructing blood flow. Air embolism in the newborn *"is a rare but life-threatening event that typically results in haemodynamic collapse, multi-organ failure and death"* (Beddoe) ¹.

9. An article by Newman (2017) ² defines *"What is an air embolism"*. It's defined as: *"An air embolism, or more accurately a gas embolism, occurs when one or more gas bubbles enters a vein or artery. This can block the passage of blood, and it can be life-threatening"*. In adults air embolism *"is the most common cause of death among divers"*. This occurs when the diver surfaces too quickly. This causes decompression sickness, known as *"the bends"*. Nitrogen within the air is not reabsorbed into the blood. This causes bubbles of gas. Newman described other causes of air embolism caused by medical intervention. They include intravenous drips, haemodialysis, laparoscopic insufflations, open heart surgery, lung biopsy, radiological procedures specifically when the injection of dye is necessary. Caesarean Section [in the mother] may be a cause as well as ERCP (endoscopic retrograde cholangiopancreatography).

10. A number of articles note that air embolism may be a complication of positive pressure ventilation, where an air embolism may occur as a result of the ventilation causing trauma to the lungs, leading to rupture of lung alveoli. This would lead to the entry of air into the pulmonary vasculature. This, however, must be an extremely rare complication, given the paucity of published papers describing this condition.

11. The earliest article I have found relating to air embolism in newborn babies is from Oppermann et al in 1979 ³. They described three of their own cases as well as reviewing a total of 25 cases. The two commonest mechanisms related to *"entrance of air from ruptured alveoli into the lung capillaries and introduction of air via catheters in umbilical vessels"*.

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12. They provide clinical information regarding two of their three cases. Both infants were born eight weeks early. The first was placed on ventilatory support because of severe respiratory distress syndrome [RDS]. A chest x-ray at 14 hours of age showed interstitial emphysema. Three hours later air bubbles were observed leaving the umbilicus. The x-ray showed progression of air within the chest cavity, affecting the lungs, causing a pneumomediastinum. Air embolism was detected in the heart, jugular veins, subclavian veins and portal system. Circulatory collapse occurred later and the baby did not survive. In the second case the infant required resuscitation at birth. He was found to have a right-sided pneumothorax which was treated with needle aspiration. This was followed by a right tension pneumothorax and features of RDS. The right lung expanded following drainage. Ten minutes later there was evidence of a left tension pneumothorax. This was drained with some improvement. The baby remained very ill and when attempting intracardiac injection, *"instead of blood, only gas was aspirated"*. *"Foamy blood escaped from the umbilical vessels"* when the umbilicus was cut. A chest x-ray at three hours showed *"gas within the heart and numerous vessels"*. The baby died at five hours of age. Their review identified 21 pre-term infants and four full-term ones. In most cases ventilatory assistance was necessary because of primary lung disease. In their experience air embolus was found in 3 infants of 436 mechanically ventilated newborns. In 17 patients umbilical vessel catheters were used. They therefore concluded that *"introduction of air into the systemic circulation by the umbilical vein or artery cannot be excluded"*. They concluded: *"We believe that high pressure ventilation was the most important factor in the development of gas embolism, but air passage along umbilical vein or arterial catheter could not be excluded in one patient and other authors had similar problems"*. Their paper notes that in their patients, air embolism was associated with presence of air in other parts of the body, including the lungs [pulmonary emphysema], pneumomediastinum, as well as the presence of air in the heart, jugular vein, subclavian veins and hepatic portal venous system. They also described finding gas *"in the cerebral ventricles"*. Their final comment notes: *"After death, absorption of oxygen occurs rapidly, the diagnosis of systemic air embolism could be overlooked"*.

13. I enclose a very thorough article headed "Death by 'air'ror" [error] from Daphne Broadhurst ⁴. The presentation is in the form of a PowerPoint presentation. She describes several cases. She notes a baby of eight months who was receiving intravenous fluids. The family reported the presence of air bubbles in the line after the nurse squeezed the IV bag. The baby screamed, turned blue, arrested and died. The cause of death was said to be a cerebral air embolus. Another example noted a 4 week old infant receiving intravenous fluids via an infusion pump. A minute later the IV set was seen to be 2/3rds empty. The baby became cyanotic with grunting, had a mottled skin and unmeasurable blood pressure. He recovered fully. The cause was deemed to be; *"inadequate priming of the administration set"*. The presentation also notes examples of adults who suffered complications from intravascular air embolus.

14. Broadhurst's presentation notes that it is difficult to be certain of the exact volume of air required to cause symptoms of air embolism. She notes that studies with dogs show that as little as 20 ml per second of air may be symptomatic and that 70 to 150 ml per second (3 to 5 ml/kg) of air can be fatal. Her presentation notes that dogs have been known to withstand up to 1400 ml of air if given over a period of several hours. Her presentation makes a point that; *"The closer the entry into the venous system to the right heart is and the faster the air entry the smaller the amount of air is needed to cause a fatal outcome"*.

15. The presentation notes that the presence of a persistent foramen ovale (FO) increases the risk of air embolism. She quotes a paper where 40% of 26 cases of cerebral air embolism had a

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patent FO and that 15 of 31 patients with neurological symptoms following air embolism had right to left shunting. This is particularly relevant in air embolism in newborn babies as one can accept that virtually all of them will have a patent FO. Broadhurst quotes a paper by Heckman noting that 14 of 26 published cases of cerebral air embolism were due to accidental disconnection.

16. Sowell's publication (2006) ⁵ appears to show a definite link between air embolism and a peripheral cannula. The paper describes an infant death due to air embolism from a peripheral venous infusion. Their case relates to an 11-week-old baby who returned to hospital five days following a hernia repair. His mother was concerned about the presence of some reddening at the operation site and his having a slight fever. This could indicate an infection, thus the need to observe carefully.

17. Prior to the baby's admission the nurse set up an infusion pump that contained a standard fluid mix. An intravenous catheter was inserted in the vein on the back of the right-hand. The infusion pump was connected to the intravenous line. The nurse flushed the intravenous line with normal saline. The report continues; *"Immediately thereafter the nurse started the infusion pump and returned to the head of the crib to record the time. Meanwhile the baby's cries had turned into screams; he then coughed or gasped loudly; his back arched and his arms stiffened. He lost consciousness"*. Resuscitation was not successful and after five minutes of effort he was declared dead. The chest x-ray carried out during the resuscitation was described as being a poor quality. No air was seen in the vascular structures or the heart. A post mortem x-ray taken 12 hours after death was reported to show; *"air in the pulmonary and systemic circulation as well as air in the portal venous system beneath the diaphragm"*.

18. They note that; *"The peripheral venous infusion system was the avenue for air entry causing venous air embolism, and then paradoxical arterial air embolism. Clinical signs of significant venous air embolism include tachypnoea and tachycardia. Right ventricular activity churns the mixture of air and blood into a bloody froth well known to forensic pathologist"*. They add that; *"In young infants with a persistent patent ductus arteriosus [PDA] or, as in this case a patent foramen ovale [FO] right to left shunting is enhanced by increased central venous pressure. Venous air becomes the more sinister systemic arterial emboli"*. They add that; *"all organs may be affected including the brain, kidney intestinal tract and coronary arteries"*.

19. They conclude that their case is one of *"tragic error: infant death by air embolism introduced through peripheral venous access with paradoxical systemic crossover"*. They continue; *"In this previously healthy infant clinical deterioration began immediately following an intravenous tubing change, and no other precipitating event explains the constellation of findings. Widely disseminated venous and arterial air collections in the thorax, abdomen, heart and brain are the only radiographic or post mortem abnormalities apart from agonal pulmonary oedema"*.

20. A short report from Fenton and colleagues (1988) ⁶ describes five cases of air embolism in ventilated very low birth weight infants. All the babies in their report were very pre-term. They weighed respectively 960 grams, 1175 grams, 1170 grams, 880 grams and 630 grams. All had severe respiratory problems and required ventilatory support. All the babies died.

21. I note the description of the infants at or around the time that they collapsed. Case 3 was a baby who suddenly deteriorated at 14 hours of age. *"The legs and abdomen became white and air was seen in the blood sample drawn from the umbilical artery catheter"*. The baby In Case 4 *"became visibly white with no cardiac output"* at 15 hours of age. The cardiac monitor also registered

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supraventricular tachycardia (SVT). Chest x-ray showed bilateral pneumothoraces, pneumomediastinum and air in the ventricles. Case five was described as: *"suddenly deteriorated becoming mottled and blue despite the indwelling oxygen level reading 18 kPa". A chest x-ray showed air in the chambers of the heart and great vessels*".

22. Their conclusion was that all babies suffered massive air embolism with no evidence of accidental injection of air via syringes or infusion sets. Their paper notes that the clinical features which alerted them to the diagnosis in the last three patients were: *"the pallor of the infant, the discrepancy between the state of the baby and the high readings of the continuous oxygen monitor and finally the presence of air in the sample of blood drawn from the umbilical artery catheter"*.

23. The paper from Lee and Tanswell (1989) ⁷ noted that 50 cases have been described in the world literature up until that time. They note: *"The presenting signs of pulmonary vascular air embolism were usually sudden and dramatic"*. The most common signs included *"sudden collapse with either pallor or cyanosis, hypotension, bizarre ECG irregularities varying from tachycardia to bradycardia"*. They also note *"blanching and migrating areas of cutaneous pallor were noted in several cases and, in one of our own cases we noted bright pink vessels against a generally cyanosed cutaneous background"*. They attributed this to the presence of direct oxygenation of erythrocytes [red blood cells] adjacent to free air in the vascular system, while the tissues continue to be poorly perfused and oxygenated. They also noted that the most distinctive sign of vascular air embolism; *"is the finding of free air when blood is withdrawn from the umbilical arterial catheter"* and; *"a frothy mixture of blood and air were often obtained"*. They add that post mortem radiographs need to be interpreted with caution as; *"intravascular air may appear as early as 25 minutes after death"*. In their review of 53 infants, only 4 survived. Two of the four infants died 13 and 16 days later. Another died at ten months of age from the complications of viral pneumonia. There was therefore only one long-term survivor. This is a case described by Kogutt ⁸. In this particular case the air embolism was detected on routine radiography alone. He was not symptomatic. [I have not included the article by Kogutt with the bundle of references].

24. Smith and Els (2001) ⁹ describe the presence of venous air embolism in 4 infants. The first was a baby of 1,770 grams born at 31 weeks' gestation and who was receiving ventilatory support. En route to the neonatal intensive care unit *"the infant's skin turned blue-black with blotchy redness. The feet were extremely pale"*. Subsequent chest x-ray noted; *"an area of hyperlucency behind/within the left cardiac border"*. An antero-lateral chest x-ray revealed *"the presence of air in the retrosternal area, anterior to the heart as well as a hyperlucent area within the heart border"*. A cranial ultrasound scan showed *"striking evidence of cerebral air embolism"*. The infant did not survive. Their 2nd case related to a pre-term baby of 34 weeks' gestation who weighed 1760 grams. She developed moderate RDS and recovered from her treatment over the next four days. On day 6 she developed abdominal distension. Abdominal x-ray showed free peritoneal air. Resuscitation was unsuccessful. A pathological examination *"confirmed the presence of air in the right ventricle"*. The 3rd case was a baby of 27 weeks' gestation who weighed 990 grams. At the age of 80 days; *"the electronic infusion pump alarm and the attending nurse noted that the infusion fluid chamber and infusion set were empty. She re-filled the chamber and then saw that the infant was quiet and cyanotic"*. Resuscitation was not successful. Autopsy confirmed; *"the presence of air within the right atrium and right ventricle"*. Their 4th case was a baby of 1,020 grams who developed significant anaemia on Day 47. Because of anaemia a blood transfusion was arranged. This was controlled via a volume infusion pump. 90 minutes later the attending physician found that the baby was lying motionless. Resuscitation was not

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successful. Post mortem chest x-ray performed within 30 minutes of the incident revealed intracardiac air. Autopsy revealed the presence of air in the right ventricle.

25. In their discussion Smith and Els described the mechanisms proposed to explain the presence of air in the heart, brain and/or systemic vessels. They note that it may be the consequence of ventilator-induced barotrauma or the development of a broncho-venous fistula in the face of high intra-bronchial pressures. They quote an article of an experiment in dogs where; *“over-expansion of the lung results in lung rupture at a level distal to the terminal bronchioles”*. They add that; *“a second and less well-recognised mechanism of systemic air embolism is the introduction of air into the venous circulation via a peripheral site”*. The paper of Smith and Els comments on the effect of injecting air into newborn piglets [Juvik et al (2001)] [see below].

26. The paper from Watkins ¹⁰ described a three-month infant with congenital heart disease. At three months of age cardiac surgery was carried out. Immediately following the surgical procedure the infant collapsed. A chest x-ray showed; *“an abundant collection of air bubbles visible through the wall of the superior vena cava”*. A needle was placed in the SVC and a large amount of air escaped through the needle hole. In their opinion the collapse was due to a; *“sudden bolus or entrainment of air from one intravascular line rather than an accumulation of residual air”*. They were unaware of such a bolus of air occurring. The infant made a successful recovery.

27. All the published articles note that this is incredibly rare, which is my experience of working in a neonatal intensive care unit for over 25 years, and where mechanical ventilation of babies was carried out routinely in babies as small as 24 weeks' gestation, I cannot recall any occasion where air leaks (such as a pneumothorax) was complicated by an air embolus. Complications such as pneumothorax from mechanical ventilation of infants became far less common during my time in clinical practice. This was due to better monitoring equipment and of course better understanding of optimal mechanical regimes. It is worth noting that the 3 papers that describe air embolism in the newborn as a complication of mechanical ventilation were published in 1979, 1987 and 1988.

28. The article from Timpa et al (2011) ¹¹ describes massive systemic air embolism during extracorporeal membrane oxygenation [ECMO] support of a baby with acute respiratory distress syndrome following cardiac surgery.

29. A paper from Kalane et al (2018) ¹² describes two cases. Air embolism was diagnosed in one infant of 900 grams at 26 weeks' gestation after a retrospective view of chest radiographs. The baby was on ventilatory support at the time. This infant survived and is making normal developmental progress at four years of age. In their opinion; *“it was concluded that air was not accidentally introduced via umbilical arterial or venous catheter”*. The second case was a pre-term infant of 30 weeks' gestation who weighed 1360 grams. Serial chest x-rays showed pneumothorax, pulmonary interstitial emphysema and pulmonary oedema at different times. On the 5th day, despite being stable, he developed severe bradycardia requiring extensive cardiopulmonary resuscitation (CPR). Chest x-ray showed air in the right and left side of the heart, inferior vena cava and hepatic vein. Despite CPR the baby died. They decided that the cause of death was not due to the accidental introduction of air via a catheter.

30. Qazi et al (2015) ¹³ report a case of fatal systemic air embolism in a neonate after cardiopulmonary resuscitation. Their case was a baby of 2.5 kg who presented at five hours of age with a history of respiratory distress from birth. The diagnosis was a left congenital diaphragmatic

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hernia. Surgical repair was successful. He was extubated 24 hours following surgery (Day 3). On day six he was breathing on his own and receiving intravenous fluids via a 24g size peripheral cannula via an infusion pump. That evening he; *"suddenly collapsed with cyanosis, bradycardia and severe hypoxaemia."* CPR was carried out but was unsuccessful after 30 minutes. A chest x-ray carried out after 30 minutes of resuscitation; *"revealed significant volume of air in the right atrium, systemic and pulmonary vasculature"*. This publication was from Pakistan, and post mortems are usually not carried out. Their paper is equivocal regarding the cause of the air embolus. They did not think that it was due to air passing through the infusion pump. They also wondered whether it was due to vigorous chest compressions and assisted ventilation during resuscitation.

31. Ponté (1974) ¹⁴ describes two cases of systemic air embolism occurring as a complication of interstitial pulmonary emphysema. The first was a baby of 30 weeks' gestation who weighed 1,400 grams. He had clinical evidence of septicaemia. An umbilical venous catheter was inserted into the left atrium. At 24 hours of age he was started on ventilatory support because of apnoea. The baby died suddenly at 36 hours after birth. X-ray carried out immediately after death showed; *"air embolism in the left atrium, the aorta and its branches, the inferior vena cava and hepatic veins. Air was also found in the cerebral ventricles and the basal cisterna"*. The report notes the *"possibility of air being introduced through the catheter may be definitely excluded"*. The 2nd case was a baby of 40 weeks' gestation weighing 2,350 grams. The birth was complicated by the presence of a distended left lung with heart shift to the right. This returned to normal within 24 hours. The diagnosis was that of a *"bronchial plug of meconium"*. All the catheters were withdrawn at 46 hours. The infant died suddenly at the 75th hour. Chest x-ray post mortem showed air in the left ventricle and in the aortic arch.

32. A paper from Yikilmaz and Lee (2007) ¹⁵ described massive air embolism in a newborn infant. He was a pre-term baby who required intubation because of respiratory distress. X-ray showed *"pneumocardium and air filling the heart as well as the great vessels including the main pulmonary artery (ascendant aorta and right axillary vessels)"*. The baby suffered a cardiovascular arrest and died soon after.

33. The paper from Beluffi and Perotti (2009) ¹⁶ described three cases where infants were compromised by air embolism. The first was a baby of 720 grams born at 25 weeks of age. She received ventilatory support. A 2nd chest and abdomen x-ray showed; *"bilateral interstitial emphysema and air with the right heart chambers, superior and inferior vena cava, hepatic and splenic veins, iliac and femoral veins, both axillary and upper limb veins, as well as in the supraclavicular soft tissue small vessels."* Resuscitation was not successful. The second case was in an 830 gram premature baby of 25 weeks gestational age. He was intubated and given ventilatory support promptly. X-ray showed diffuse bilateral lung opacities. The tip of the umbilical vein catheter was slightly bent to the right above the diaphragm and signs of free air within the liver were detectable. Seven hours later the baby's condition abruptly worsened; *"with desaturation, pallor and an increase in oxygen demand"*. X-ray showed a left pneumothorax and signs of diffuse interstitial emphysema in association with free air within the hepatic, iliac, femoral and popliteal veins as well as in the upper limb veins and within the jugular vein. The stomach was distended by air. The baby died soon after. The 3rd case was a baby weighing 3,660 grams born normally at 39 weeks' gestation. At 20 days of age she developed evidence of sepsis. The baby died 20 hours later despite intensive care with no signs of pneumothorax or air leaks. The x-ray taken two hours after demise showed; *"massive air embolism with air occupying heart chambers, lung parenchyma, superior and inferior vena cava, right and left branches of the hepatic veins, bilateral jugular veins and upper and lower limb veins, without evidence of pneumothorax."*

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34. In their discussion the authors note that; "*Rupture of alveolar into pulmonary capillaries due to barotrauma through alveolar-capillary or broncho-venous fistula is thought to be the main cause of massive air embolism in infants with an air leak*". In their opinion the two pre-term infants sustained their air embolus as a result of an air leak. The third may have sustained an air leak as a complication of his sepsis.

35. There is doubt regarding the volume of air required to cause a potentially lethal effect. The lethal volume of air in an adult human is unknown but is estimated to range from 200 to 300 ml. Toung et al ¹⁷ describe a case report of an adult male who weighed 68 kg who had serious life-threatening heart condition complicated by a pericardial effusion [the presence of fluid within the pericardial membrane but outside of the heart]. (A pericardial effusion interferes with cardiac output and untreated may lead to death.) The pericardial fluid was drained on the first occasion. On the second occasion 200 ml of air was injected into the pericardial space but the patient almost immediately became restless, apnoeic and opisthotonic. Resuscitation was unsuccessful. Their report notes that the patient died because 200 ml of air was injected directly into the right ventricle (by accident). This paper is the first to describe an exact volume of air required to cause death, be it in an adult patient.

36. In their discussion Sowell et al quote a paper from Swartz (1993) that notes that; "*symptomatic venous air embolism has been reported in infants with only 0.4 ml/kg introduced into the circulation.*" The paper from Toung et al (2001) quotes a volume of 7.5 ml/kg in dogs [from a paper by Oppenheimer et al published in 1953, which I have not seen]. Toung also quotes a paper from 1963 demonstrating a lethal volume of only 0.55 ml/kg in rabbits. The overall view is that the volume of air necessary to compromise the stability of a small baby is very small, less than 1 ml / kg.

37. Juvik ¹⁸ describe an experiment involving 12 piglets, where 0.05 ml/kg per minute is infused via a modified syringe pump into newborn piglets (over 25 minutes). This works out at volume of 1.25 ml/kg. In 6 of the piglets arterial air embolism was seen within five seconds. All piglets were shown to have evidence of air embolism within 45 seconds. The significance of this study is this. In newborn piglets (and newborn infants) the foramen ovale (FO) remains open. This is the "hole in the heart" that connects the right side of the heart to the left side of the heart at the level of the atrium. Usually the FO closes soon after birth but is more likely to remain open for longer in pre-term infants. Also, pressure on the right side of the heart [right atrium] may be higher than in the left side of the heart [left atrium]. Therefore any air, or any other substance, injected into the peripheral venous system would move to the right atrium and cross through the foramen ovale into the left side of the system. This would lead to the more serious **arterial** air embolus, where the air could circulate to the cardiac arteries and cerebral arteries. The paper describes that the piglets were killed at the end of the experiment, which suggests that they did not die from the effects of the air injected.

Overview:

38. During my review of numerous cases as part of Operation Hummingbird several of the deaths occurred in infants who were previously stable, were not on positive pressure ventilation at the time, and whose collapse was both sudden and unexpected. Most concerning was that the infants failed to respond to resuscitation procedures that were prompt and consistent with standard practice.

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39. Preterm infants are at increased risk of numerous complications. These include infections such as pneumonia, septicaemia and urinary tract infection. Haemorrhage, including intracranial haemorrhage is well recognised. Feeding difficulties are common, requiring naso-gastric [NG] support. Ill infants may need intravenous nutrition; a procedure known as Total Parenteral Nutrition [TPN]. Neonatal nursing and medical staff are familiar with the signs of an unwell infant, and are aided by sophisticated monitoring equipment, allowing immediate resuscitation as and when a baby deteriorates. Irregular breathing, cessation of breathing (apnoea), alterations in temperature, or variations in heart rate; reduced heart rate [bradycardia] or increased heart rate [tachycardia] are common features that signal deterioration, irrespective of the cause. Resuscitation is usually effective. If the infant fails to respond one usually can find a cause in the form of overwhelming infection, severe haemorrhage, or total systems failure. The latter is often found as a terminal event in an infant who has already suffered numerous life-threatening problems in their short life and has sadly reached an end point of resistance.

40. It is therefore concerning, and unusual, to discover an infant failing to respond to standard resuscitation procedures, and where post death investigations fail to identify an obvious cause of death, e.g, massive brain haemorrhage, overwhelming infection, or intestinal perforation and peritonitis.

41. Several of the scientific papers described above identify a link between air embolus and other conditions that cause 'leakage' of air [or oxygen] beyond its normal place in the lungs. These include pneumothorax [air outside the lung but within the rib cage], pneumo-mediastinum [air within the chest cavity but outside the lungs] and pneumo-pericardium [air within the lining (pericardium) of the heart]. These conditions are all life-threatening. The diagnosis is usually confirmed by chest x-ray.

42. The infants whose deaths I have reviewed in Operation Hummingbird do not fit into this category, with the exception of one of the [REDACTED] triplets. The other infants who collapsed, and where resuscitation was unsuccessful exhibit manifestations that have characteristics of air embolus. The paper of Lee and Tanswell describes very graphically the *"blanching and migrating areas of cutaneous pallor were noted in several cases and, in one of our own cases we noted bright pink vessels against a generally cyanosed cutaneous background"*. Smith and Els (2001) provide a similar description; *"the infant's skin turned blue-black with blotchy redness."*

43. I note the observations of Dr Jayaram's regarding [REDACTED] collapse [Case 05]. He describes the baby's unusual discoloration noting that: *"he had an odd sort of discoloration where there were flitting patches of pink areas on the background of bluey grey skin; these patches seemed to appear and disappear. It wasn't like the rash seen with a meningococcal sepsis which is caused by blood vessels bursting. It would flit and then reappear and disappear. It didn't fit with anything I'd ever seen before."*

I would describe the marks as blotches which were fairly ill-defined, about 1 cm to 2 cm, not discreetly round but blotchy patches of brighter pinkness on a background of bluey grey. After about 30 minutes of resuscitation [REDACTED] had no spontaneous activity and after discussion with his parents resuscitation was stopped."

44. Sudden collapse and failure of response to resuscitation is characteristic of several of the babies from Operation Hummingbird. It is characteristic of the description of the babies in the studies

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described above whose death was attributed to an air embolus. The volume of air necessary to compromise the stability of a small baby is very small, less than 1 ml / kg.

45. At the time of preparing this Statement I do not have access to an independent radiology opinion regarding the findings of the chest x-rays. Scientific publications cannot provide all the answers to this very intriguing constellation of cases, given the rarity of the condition and the understandable failure of potential perpetrators to admit to their actions to anyone, least of all have them described in a scientific paper.

46. The descriptions of the clinical features of infants proven to have died from the effects of air embolus and described in many of the enclosed publications show marked similarities to the pattern of collapse and death of many of the babies of Operation Hummingbird.

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Signature:

Signature witnessed by:

Continuation of statement of **Dr D R Evans**

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Declaration:

I confirm that insofar as the facts stated in my report are within my own knowledge, I have made clear which they are and I believe them to be true, and that the opinions I have expressed represent my true and complete professional opinion.

Dr Dewi R Evans
Consultant paediatrician

3 July 2019

Signature:

Signature witnessed by: