SHERIFFDOM OF GLASGOW AND STRATHKELVIN

2010 FAI 15

UNDER THE FATAL ACCIDENTS AND SUDDEN DEATHS (SCOTLAND) ACT 1976

DETERMINATION

of

SHERIFF LINDA MARGARET RUXTON

in

FATAL ACCIDENT INQUIRY

into the death of

GORDON EWING

GLASGOW, 7 April 2010

The Sheriff, having resumed consideration of all the evidence adduced, **FINDS AND DETERMINES** in terms of 6(1) of the Fatal Accidents and Sudden Deaths Inquiry (Scotland) Act 1976 that:

(a) time and place of death

Gordon Ewing, born 29 September 1961, formerly of 22 Cherrytree Avenue, Cambuslang, died on 4 May 2006 at 17:13 hours in the anaesthetic room of Theatre 1 at the Victoria Infirmary, Glasgow.

(b) the cause of death and any accident resulting in the death

The cause of death was barotrauma as a result of perforation of the right lung as a complication of anaesthetic administration. The relevant underlying condition was a fracture of the distal phalanx of the right little finger.

During anaesthesia for a surgical procedure to repair a fracture of a finger, an unsecured airway exchange catheter inserted into Mr Ewing's trachea migrated downwards, puncturing the right lung and exiting through the intercostal muscles before becoming lodged in the chest wall. The subsequent introduction of oxygen through the catheter at high volume allowed air to flow directly into the tissues causing widespread surgical emphysema, barotrauma, hypoxia and cardiac arrest.

(c) reasonable precautions that might have prevented the death and any accident resulting in the death

(1) The termination of the anaesthetic procedure thereby allowing Mr Ewing to waken up was a reasonable precaution which might have prevented his death. There were several opportunities when that decision could and should have been taken.

(2) Taking steps to ensure that the catheter was secured and maintained in position in the trachea was a reasonable precaution which might have prevented the death. There were several ways in which that could easily have been achieved.

(3) The issuing of a clear instruction as to the appropriate flow of oxygen to be introduced through the catheter was a reasonable precaution which might have prevented the death. Had the instruction been given to deliver the oxygen at a rate of 2 litres per minute, the risks and consequences of perforation and barotrauma would have been avoided or significantly reduced.

(e) other facts which are relevant to the circumstances of the death

(i) There was a failure to observe and follow clear operating instructions for the safe use of the airway exchange catheter. As a result the catheter was inserted too far into the trachea and simple precautions to avoid the known risks of perforation and barotrauma were not observed. These would have been known to anyone familiar with and trained in the safe use of the Cook airway exchange device. Had they been observed, migration of the catheter, which resulted in both perforation and barotrauma, would have been prevented.

(ii) There was a breakdown of communication among the anaesthetic team as to the experience of those present in the use of the Cook airway exchange device. What communication there was failed to elicit the true factual position and a number of false assumptions were made. Had the true position been known that no-one was adequately familiar with the device or properly trained in its use, greater care would have been taken and closer attention paid to it. Alternatively, the device would not have been used in such circumstances.

(iii) While the lead clinician has the over all responsibility to ensure safe use of equipment, individual clinicians have a professional responsibility to use only equipment with which they are familiar and competent to use. This is particularly so where the piece of equipment is rarely used. The Medical Director's letter addressed to all medical staff served as a reminder of their individual professional responsibility in this connection.

(iv) It was a matter of concern that a device rarely used and designed for airway exchange in specialised elective procedures was readily available on a general emergency airway trolley. No control had been exercised over the content and organisation of the trolley in circumstances where it had become overloaded with a miscellany of equipment. The shortcomings associated with the emergency trolley were recognised and acted upon by the Greater Glasgow Health Board and steps since taken to rationalise and regulate the content of these trolleys and to provide relevant training in the equipment available should have resolved these concerns.

(v) Equipment failure during the removal of a laryngeal mask played a part in Mr Ewing's death. The failures associated with the disconnection of an end-connector, a loose stabilising rod and the damage to a pilot cuff resulted in the loss of a secure airway thereby creating a situation of critical emergency. It is likely that these failures were as a result of repeated use of the equipment. Disposable tubes are now used routinely. This change in practice should have addressed any problems associated with repeated sterilisation of such equipment.

(vi) An attempt to insert a tracheal tube by means of a fibre-optic laryngoscope was unsuccessful due to a combination of poor positioning on the part of the operator and incomplete relaxation of the patient. However, it is unlikely that this affected the final outcome as high flow oxygen would already have been introduced into the tissues had the operator waited to obtain the optimum position.

(vii) The diagnosis of barotrauma should have been made at an earlier stage in circumstances where additional oxygen was being delivered through a small bore catheter. However, the implementation of a treatment protocol for the incorrect diagnosis of anaphylaxis did not adversely affect Mr Ewing's condition and the delay in diagnosing barotrauma would not have affected the final outcome.

(viii) The most striking feature of this Inquiry was that none of the three experienced anaesthetists in attendance gave any consideration to the fundamental option of waking the patient, particularly having regard to the minor nature of the surgery involved. Anaesthetists need to be *actively* aware of that option, particularly, in anaesthesia for elective procedures for minor or non-essential surgery.

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NOTE

Introduction

[1] This is an Inquiry under section 1(1)(b) of the Fatal Accidents and Sudden Deaths Inquiry (Scotland) Act 1976 into the circumstances of a death which it appears to the Lord Advocate has occurred in circumstances such as to give rise to serious public concern. Mr Gordon Ewing died in the Victoria Infirmary, Glasgow as a result of complications during the administration of an anaesthetic for an elective orthopaedic procedure to straighten his right little finger.

[2] The Inquiry heard evidence over a period of 10 days in November 2009. Legal submissions were heard on 25 January 2010 and the Inquiry concluded. Miss Kate O'Sullivan, Procurator Fiscal Depute appeared in the public interest; Mr Douglas Jessimen, Solicitor, appeared for Dr Deepa Singh; Miss Catriona Watt, Solicitor, represented Sister Ann Forshaw; Mr David Holmes, Solicitor, represented Dr Colin Goutcher and Mr Vinit Khurana, Advocate, appeared on behalf of Greater Glasgow Health Board.

[3] The following witnesses gave evidence to the Inquiry:

Mr Duncan Taylor, on behalf of Mrs Ann Ewing and the Ewing family;

Dr Robert Ainsworth, Consultant Forensic Pathologist, University of Glasgow;

Dr Deepa Singh, Consultant Anaesthetist, Victoria Infirmary, Glasgow;

Dr Colin Goutcher, Consultant Anaesthetist, Department of Neurological Sciences Southern General Hospital, Glasgow;

Sister Anne Forshaw, Anaesthetic Recovery Sister, Victoria Infirmary;

Mr Alan Hamilton, Operating Department Assistant, Victoria Infirmary;

Dr Fiona McCardie, Consultant Anaesthetist, Victoria Infirmary;

Dr Ronald Glavin, Consultant Anaesthetist, Victoria Infirmary;

Dr John Howie, Consultant Anaesthetist, Victoria Infirmary, Associate Director of Anaesthetics and Surgery for Glasgow and Clyde;

Dr William McRae, Consultant Anaesthetist, Stobhill Hospital, Glasgow. Lead Consultant for Anaesthetics North Glasgow;

Mrs Karen Cormack, Clinical Risk Manager for Surgery and Anaesthetics, Victoria Infirmary; and

Dr Graham Johnston, Consultant Anaesthetist, Aberdeen Royal Infirmary.

Greater Glasgow Health Board Inquiry

[4] An inquiry panel was set up by the Health Board to review the circumstances of Mr Ewing's death. This panel ("the hospital inquiry") was convened under the chairmanship of the late Professor Timothy Cooke, Professor of Surgery and Associate Medical Director of Surgery and Anaesthesia, NHS Glasgow and Clyde and Consultant Surgeon, Glasgow Royal Infirmary. Dr Bill McRae and Mrs Karen Cormack were also members of the panel and gave evidence to this Inquiry. The hospital inquiry team met in the week following Mr Ewing's death and on 9 May 2006 the panel interviewed broadly the same witnesses as those who gave evidence in court. The court had the benefit of the findings of that inquiry.

Mr Gordon Ewing

[5] Gordon Ewing was 44 years old when he died, having been born on 29 September 1961. He lived at 34 Cherrytree Avenue, Cambuslang with his wife and his young son who was 2 years old at the time of his father's death. Mr Ewing also had an 18-year old son. He operated a garage petroleum franchise and managed two garages. He was described as an outgoing family man who took great delight in his extended family. His cousin, Mr Duncan Taylor described the devastating effects of Mr Ewing's death upon his family.

Background

[6] Some 6 weeks before his death, Mr Ewing had sustained a complex fracture to the terminal phalanx of his right little finger of his right hand. As a result, he had received treatment in Hairmyers Hospital in March 2006. This included the insertion of wires into the fracture which was a surgical procedure under general anaesthetic. The anaesthetic was uneventful but the orthopaedic treatment was unsuccessful as the fixation gave way. He was left with a crooked pinkie finger and associated loss of function. He was referred to the Victoria Infirmary for specialist treatment involving reconstruction and secondary fixation of the fracture.

[7] Although there was no direct evidence from the orthopaedic surgeon to whom Mr Ewing was referred (Mr Timothy Hems), from the notes and from the information which was before the court from the hospital internal inquiry, it seems that Mr Ewing was offered two options: a second attempt at surgical correction; or no further treatment with the acceptance of some deformity of his finger and loss of function to his dominant hand. Mr Ewing opted to have further surgery. The surgical procedure

was an open reduction and internal fixation of the fracture which was designed to straighten the finger and restore function.

[8] There was no evidence before the court as to what discussion had taken place between Mr Ewing and the surgeon as to the risks involved in the procedure or whether any options for anaesthesia had been explored other than a general anaesthetic.

[9] The following paragraphs set out the events which occurred in he anaesthetic room during the procedure to anaesthetise and intubate Mr Ewing. These facts were not in dispute. However, there were three areas where there was noticeable divergence of testimony. I have considered these separately.

PRE-ANAESTHETIC ASSESSMENT

[10] Mr Ewing was admitted for surgery on the morning of 4 May 2006. Dr Deepa Singh, consultant anaesthetist, first met Mr Ewing that morning to conduct a pre-anaesthetic assessment. The main purpose of such an assessment is to identify any risks associated with anaesthesia and any potential problems that might be encountered. The assessment allows the anaesthetist to plan the most appropriate procedure. That involves eliciting from the patient any relevant medical history with particular emphasis on previous experience of anaesthesia, allergies or any family history of problems associated with anaesthetics. Against the background of certain baseline values – e.g. blood pressure, pulse – further tests relevant specifically to anaesthesia are carried out. Importantly, tests are carried out to assess the patient's

airway. This allows the anaesthetist to work out the anaesthetic plan and to discuss that with the patient.

[11] On the morning of the Mr Ewing's surgery, Dr Singh had a new anaesthetic trainee with her. Accordingly, she took the additional time during the pre-operative assessment to demonstrate certain tests and procedures to her trainee. Dr Singh was aware of the nature of the scheduled procedure and the previous surgical history, having been given this information from the surgeon who was also on the ward at the time. She proceeded to take a history from Mr Ewing which identified that he had not, to his knowledge, experienced any problems with the previous general anaesthetic at Hairmyers Hospital. Accordingly, Dr Singh proceeded on the basis that he had recently undergone uneventful general anaesthesia, some six weeks previously.

[12] Dr Singh carried out a number of tests designed to evaluate the patient's airway and, in particular, to give an indication whether difficulties with intubation can be anticipated. First, Dr Singh established that there were no problems associated with the movement of Mr Ewing's neck. She noted full movement with no restriction on extending the neck upwards and backwards (a position required during intubation). Likewise, there was no indication to suggest that there would be any problems with manoeuvres to Mr Ewing's mouth. He had good neck movement and mouth opening. Another test (the Mallampatti score) which involved having Mr Ewing stick his tongue out as far as he could to enable the anaesthetist to grade what could be seen, disclosed no difficulty and Mr Ewing was assessed as Grade 1 (the highest score). A further test involved a check of the thyro-mental distance which, with the patient's neck extended, is the distance between the thyroid to the bottom of the chin. If the

distance is greater than 6.5 cm the likelihood of problems is very small. Mr Ewing's measurement was well in excess of 7cm. Accordingly, Dr Singh concluded that Mr Ewing should not pose any difficulty in terms of his airway or intubation. Although these tests do not guarantee that intubation will proceed without difficulty, they do provide the anaesthetist with a broad expectation of the likely procedure.

[13] In the course of her assessment, Dr Singh identified two specific risk factors associated with general anaesthesia, both of which influenced her anaesthetic plan. First, Mr Ewing had a suspected hiatus hernia and suffered from oesophageal acid reflux. Secondly, he was overweight. He was a very large man who weighed about 19 stone (124 kg). He had a high body mass index of 40+.

Oesophageal reflux

[14] The significance of acid reflux in the context of anaesthesia is that it increases the risk of aspiration of stomach contents, particularly during the stages of intubation and extubation. Aspiration of acidic stomach contents has potentially serious consequences which include burning and scarring of lung tissue and which in turn can compromise lung function due to difficulties in oxygenation. The consequences can be fatal.

[15] Because of this increased risk of aspiration, Dr Singh decided that Mr Ewing should undergo rapid sequence induction ("RSI") at the outset of anaesthesia. Such a procedure would reduce the risk of re-gurgitation of stomach contents into the trachea during anaesthetic induction. The procedure involves the application of 3 kilos of pressure to the cricoid cartilage, slightly below the Adam's apple. The effect of

applying direct backward pressure is to press the oesophagus against the backbone thus physically preventing the stomach contents from coming up.

[16] The procedure for RSI involves pre-oxygenating the patient for 3 minutes to fill the lungs with oxygen and remove the nitrogen. This allows a longer period to ensure that the airway is secured. The technique requires to presence of an additional assistant whose role is dedicated to applying the manual cricoid pressure whilst supporting the back of the neck. The pressure is maintained after the patient is asleep, only to be released on the instructions of the anaesthetist after the airway has been secured.

[17] As an additional precaution prior to surgery, Dr Singh prescribed Ranitidine, an antacid, to neutralise the stomach acid and Metoclopramine to promote emptying of the stomach contents downwards into the colon. Dr Singh also noted a contra-indication to Voltarol, a non-steroidal analgesic routinely used for post-operative pain relief, as it is known to promote the production of acid in the stomach.

High body mass

[18] Mr Ewing's size and weight meant that he would require to be intubated during surgery as he would not have been able to maintain his own airway satisfactorily during the operation without being paralysed and ventilated artificially. When lying flat on the operating table, patients with a high body mass index are unable to ventilate effectively because they do not have sufficient muscle strength to maintain their oxygenation.

Discussion of anaesthetic plan

[19] Dr Singh discussed the anaesthetic plan with Mr Ewing. She asked him if he had any strong preference to being asleep or awake during the procedure. Mr Ewing said that he definitely wanted to be asleep. Given that Dr Singh had identified no counter-indication to general anaesthesia, she was happy to comply with his wish to be asleep.

SEQUENCE OF ANAESTHETIC EVENTS

[20] The following paragraphs describe the factual sequence of events during the attempts to anaesthetise Mr Ewing. I did not understand that any of these facts were disputed.

Preparation

[21] Shortly after 3pm, Mr Ewing was brought into the anaesthetic room. Dr Singh was assisted by Theatre Sister Ann Forshaw and Operating Department Practitioner ("ODP") Alan Hamilton who was to apply the cricoid pressure. The room was fully prepared and equipped for the procedure and the necessary checks had been carried out. Dr Singh herself checked the airway equipment required for endotracheal intubation, drew up drugs that would be required to be administered and checked the supply of emergency drugs which are kept for ready availability in all procedures. Sister Forshaw and other theatre staff also carried out checks of the equipment and documentation and ensured that the patient was in the correct position, connected to the various monitors and prepared for the induction of anaesthesia. In particular, Sister Forshaw checked that a wide range of airway equipment of varying sizes was readily to hand.

[22] Venous access was established by the insertion of an 18g cannula into the back of Mr Ewing's left hand and a 500 ml bag of Hartman's fluid was attached. Full monitoring equipment was then connected to Mr Ewing. This included equipment to monitor his blood pressure; a pulse oximeter to measure the saturation of oxygen in the blood (this device was attached to Mr Ewing's ear); ECG leads to monitor his heart and a capnograph to measure the amount of expired carbon dioxide. These devices were attached to the breathing circuit. One end of the breathing circuit would be attached to the patient. The other end of the breathing circuit was attached to the large rectangular metal container known as the "King's Head" which houses the anaesthetic gases and vapours and the various mechanisms to control the flow of these substances. Suction was switched on and placed under Mr Ewing's pillow in case he vomited.

Rapid Sequence Induction

[23] Having obtained a steady blood pressure reading, Dr Singh pre-oxygenated Mr Ewing for three minutes with a face mask. She then induced anaesthesia with three drugs in sequence: 100 microgrammes of Fentanyl (a very strong painkiller); 500 milligrammes of Thiopental (to put him to sleep) and 100 milligrammes of Suxamethonium (a short-acting muscle relaxant and paralysing agent). The last drug was given only after there was no eyelash reflex and Dr Singh was satisfied that Mr Ewing was asleep. After the administration of the paralysing agent, Mr Ewing was no longer breathing for himself. At that point there was a window of one to three minutes in which to achieve intubation and ventilation. Mr Ewing's weight meant that his oxygen reserve was less so the time frame would be at the lower end of the range.

[24] After Mr Ewing was asleep, Dr Singh instructed ODP Hamilton to apply cricoid pressure. After having noticed vesiculation (a fine twitching of the muscles from head to toe) Dr Singh was satisfied that the Suxamethonium had worked. She then took a laryngoscope – a standard size 3 Macintosh curved blade – to view the larynx. Although Mr Ewing was a large man, his neck was not longer than average, only wider.

First attempt at intubation

[25] The procedure involves introducing the blade on the right side of the tongue to push it over to the left so that the epiglottis (the flap over the entrance to the larynx) can be viewed. The epiglottis – which is anchored – then requires to be lifted out of the way to visualise the larynx. It requires a moderate degree of force to lift the epiglottis. The larynx is the inlet that leads to the trachea or windpipe. Under direct vision of the larynx, the ET tube is passed through the vocal cords of the larynx. The laryngoscope is then removed, a pilot cuff on the ET tube inflated to keep it in place and form an airtight seal and, finally, the tube is connected to the breathing circuit thus establishing ventilation.

[26] Dr Singh was unable to lift the tongue and epiglottis out of the way and was therefore unable to visualise the larynx. Accordingly, she was not able to intubate Mr Ewing.

Second attempt at intubation

[27] Dr Singh considered that her difficulty might have arisen from the fact that ODP Hamilton's hand applying the cricoid pressure was in her way. Although she could

have asked him to move his hand, she was concerned that if he removed the cricoid pressure, the protection against reflux and aspiration would be lost. Instead, she asked for an alternative blade – a Polio blade – which, compared to the 90 degree angle of the standard blade, has a blade angled more obtusely from the handle at 135 degrees. The Polio blade was kept on the difficult airways trolley ("the emergency trolley"). This trolley was kept in readiness in the corridor adjacent to the four operating suites in case of emergency. The trolley was brought into the anaesthetic room.

[28] The Polio blade did not resolve the difficulty. Dr Singh was still unable to manoeuvre the blade around her assistant's hand into the correct position and remained unable to visualise the larynx. By this time, almost 3 minutes had passed. At this stage, the procedure had become a difficult airway and, in accordance with the protocol for difficult airways, Dr Singh called for assistance from senior colleagues.

[29] Dr Singh had noticed after this second attempt at larygoscopy that there was bleeding inside Mr Ewing's mouth. She attributed this to inadvertent trauma as a result of the laryngoscopy. At this stage she did not look to identify the source of the bleeding. Having called for assistance, her priority at this point was to maintain oxygenation.

Maintenance of ventilation via LMA

[30] In this connection, the option she chose was to set up laryngeal mask airway (LMA). The LMA is inserted into the mouth and is directed backwards until it comes to rest in the position above the larynx and the vocal cords. Once it is in place the pilot cuff around it is inflated to give it a better seal.

[31] A No.4 LMA was inserted and connected to the breathing circuit. Ventilation was thus achieved affording a period of stability. However, in order to maintain effective ventilation, additional jaw thrust was required - a technique whereby the lower jaw is pulled forward and backwards to keep the tongue, epiglottis and soft palate from collapsing against the back of the throat thereby obstructing the airway. This manoeuvre was carried out by ODP Hamilton. Mr Ewing's oxygen saturation was recorded as 97% which was satisfactory.

[32] The ventilation achieved via the LMA was temporary. Because of the need to maintain additional jaw thrust, Dr Singh was aware that anaesthesia could not continue on this basis. She therefore switched to her back-up anaesthetic plan.

Back-up plan for anaesthesia

[33] Dr Singh's back-up plan for Mr Ewing involved the use of an intubating laryngeal mask airway ("ILMA") which has an endotracheal (ET) tube attached. The advantage of using the ILMA is that it allows the anaesthetist to insert the tube without the need to visualise the larynx. Like the LMA, it allows the anaesthetist to work with both hands free.

[34] During the short time it took to remove the LMA, insert the ILMA and connect it to the breathing circuit, Mr Ewing's oxygen saturation fell to 80%, somewhat below the optimum 96-99%. At this point, prior to inserting the ET tube, Dr Singh increased the flow of oxygen to the breathing circuit. As the Thiopental given at induction would be wearing off, Sevoflurane, an anaesthetic vapour, was administered to ensure

that Mr Ewing did not wake up. Improved oxygenation was noted and effective ventilation was achieved (the capnograph confirmed that Mr Ewing was expiring carbon dioxide into the breathing apparatus). However, Dr Singh was hand ventilating by squeezing the bag and vigorous jaw thrust continued to be required.

[35] At the point at which Dr Singh was about to introduce the ET tube through the IMLA, Dr Colin Goutcher and Dr Fiona McCardie arrived in swift response to the call for help with a difficult intubation. Dr Goutcher arrived in the anaesthetic room first with Dr McCardie close behind. At that time, Dr Goutcher was an experienced sixth year trainee in anaesthetics, a matter of months away from a being appointed a consultant. Dr McCardie was a consultant anaesthetist. At this stage, the patient was stable and ventilated. Dr McCardie immediately took over bagging and ventilating the patient so that Dr Singh could have both hands free. Dr Goutcher assisted with the intubation procedure.

Difficulty passing the endotracheal tube

[36] Dr Singh attempted to pass a size 8 (8mm, referring to the internal diameter of the tube) ET tube through the ILMA. When she did so it went some way in and then became stuck. She was unable to advance it further. During this attempt, she noted a rise in Mr Ewing's heart rate (pulse 136) together with a massive rise in blood pressure (214/136) and a drop in oxygen saturation to 51% from 98. At this point Mr Ewing appeared to cough - a sign, not that he was waking up, but that the Suxamethonium was wearing off and consequently that paralysis was insufficient. This might have accounted for the difficulty experienced in passing the ET tube if the vocal cords had closed.

[37] In response to these physiological changes, Dr Singh instructed that 1 milligramme of Alphentanyl be administered and this was done by Dr McCardie. Dr Singh chose to administer this drug in preference to a muscle relaxant which would induce further paralysis. Alphentanyl is a powerful hypnotic and painkiller that also relaxes the tone of the upper airway. It is a drug often used in difficult airway situations. Dr Singh did not wish to paralyse Mr Ewing as he did not have a secure airway. A smaller tube, a size 7, was then selected and passed it without further difficulty. The capnograph reading confirmed that it was correctly positioned in the trachea. The pilot cuff was inflated to form an airtight seal and the airway was attached to the breathing circuit. Successful intubation was thus achieved and secure ventilation was established. Oxygen saturation returned to 91% and Mr Ewing's heart rate and blood pressure came back down. Mr Ewing's condition was stable and there was a feeling of relief within the anaesthetic room.

Removal of the IMLA and loss of secure airway

[38] Dr Singh became concerned that the bleeding that she had noticed earlier was continuing. Earlier when the LMA has been removed some blood had been noticed on the back of the mask. Despite having applied suction, the bleeding persisted. Doctor Singh explained that problems could arise when the ET tube was removed. The presence of blood or secretions can irritate the vocal cords which can cause laryngeal spasm. Dr Singh was concerned that the cause of the bleeding was likely to have been traumatic injury from the airway manipulation. She considered that she needed to investigate the source of the bleeding. Accordingly, she made a decision to remove the mask part of the ILMA device while leaving the ET tube in place.

[39] Removal of the mask is a two-person manoeuvre. First, the mask must be deflated. The next stage is to remove the connector from the tube so that the mask and tube can separate. The main concern in this procedure is that as the mask is removed over the tube, the tube will come out with it. To guard against losing the airway in such circumstances, a stabilising connector rod is inserted and attached to the ET tube to give it additional length. Once the mask is removed beyond the ET tube, the stabilising rod can be removed. The 50mm end-connector is then reconnected at the top of the tube which, in turn, is re-connected to the breathing circuit.

[40] Dr Singh was assisted in this procedure by Dr Goutcher and Sister Forshaw. Dr Singh removed the connection from the ET tube. This proved difficult as the 50mm end-connector attached to the tube was stiff. Normally these connectors slip off effortlessly. However, on this occasion the connector was rigid and stuck. It required effort to wiggle it free and at one point forceps were applied in an attempt to release it. Sister Forshaw deflated the cuff. Dr Singh put in the stabilising rod but at that stage she encountered a difficulty because the rod was not secure. The interface between the stabilising rod and the ET tube was loose.

[41] At this stage, Dr Goutcher suggested the use of a Cook airway exchange catheter in order to gain stability and to have a pathway for the airway should the ET tube come out with the mask. This is a process known as “railroading”. It is a technique used to ensure that the airway pathway is maintained during certain procedures when airways are exchanged e.g. where a small tube is exchanged for a large one after an airway has been secured. There are several devices used in railroading procedure. One

such is a gum elastic bougie – a solid, flexible tube. The Cook catheter is airway exchange device used for railroading purposes. It has the advantage over solid devices such as the bougie in having a hollow lumen with side ports at the end with a connector which can be attached to the breathing circuit. Thus additional oxygen can be delivered via the Cook catheter during the process. The device was available on the emergency trolley on that day.

[42] Dr Singh had no experience in using a Cook catheter but considered that it would be an advantage to use it over the gum elastic bougie given that Mr Ewing's saturation levels had fallen on two occasions. She agreed that Dr Goutcher should proceed to use it. The Cook catheter was inserted by Dr Goutcher when the ILMA was still in place when the loose connection with the stabilising rod was discovered. He introduced it into the trachea to a point at where he met slight resistance. He judged this to be the carina, the point at which the trachea divides into the right and left main bronchi to the lungs.

[43] With the Cook catheter in place, Dr Singh attempted to remove the IMLA. During that process, a further problem occurred when the pilot cuff (the balloon part) sheared off at the point where it connected to the ET tube. The result was to create a leak so that there was no longer an airtight seal. The secure airway had been compromised and Mr Ewing was at risk of aspirating. The whole process had in any event taken longer than usual because of the difficulty with the stiff connector. The loss of the airtight seal, together with of the fact that the size 7 tube was a small tube for an adult male, caused a fall in oxygenation from 99 to 69%.

[44] Dr Singh removed the whole set, including the now dysfunctional ET tube. She attempted to replace it with a standard size 9 ET tube by railroading it along the Cook catheter. Dr Goutcher then attempted to insert the tube. Both encountered resistance at the vocal cords. Their efforts were unsuccessful, possibly because there was by now no active muscle relaxant (the Suxamethonium would have worn off) and the effect of the Fentanyl would have been minimal. As Mr Ewing's saturations had started to fall, Dr Singh put the ILMA back in place and re-connected it to the breathing circuit as a temporary but stable airway. Oxygen saturation returned to 92%. The Cook catheter remained in place in the trachea.

Further attempt to re-intubate by means of fibre-optic scope

[45] Dr Singh decided to attempt to pass another size 7 ET tube to secure Mr Ewing's airway. She instructed that Rocuronium, a muscle relaxant of intermediate length be administered. Dr Goutcher administered a 25mg dose. In view of previous difficulties it was agreed that any further attempt to intubate should be done under direct visualisation of the larynx. This was to be achieved by means of a fibre-optic laryngoscope.

[46] The scope is plugged in to a light source to give clear and direct vision. The telescopic end of the scope which is looked through negotiates the pathway that the ET tube will take. The operator is able to view the larynx, the vocal cords and the trachea. This is a similar railroading technique: the ET tube is loaded on to the scope so that once visualisation has been achieved the tube can slide off directly into place whereupon the scope is withdrawn. During the procedure, the patient is detached from the breathing circuit and so is not being ventilated. Mr Ewing had effectively been

pre-oxygenated prior to this as he had been receiving 100% oxygen via the laryngeal mask. Normally that would allow a window of about three minutes in which to achieve intubation but, again, that would be nearer two minutes in Mr Ewing's case because of his high BMI.

[47] At around this point Dr Singh asked for additional oxygen to be delivered via the Cook catheter. There was an extra cylinder of oxygen on the trolley directly beneath the patient. The decision was taken to attach the additional oxygen supply from the cylinder to the Cook catheter. Sister Forshaw attended to that. She obtained oxygen tubing from another theatre and connected that to a free-standing oxygen source in a cylinder on the trolley. While she was doing that, Dr Goutcher attempted to use the fibre-optic scope.

[48] Dr Goutcher took the scope and passed it through the ILMA until he had a clear view of Mr Ewing's vocal cords. Because Sister Forshaw was underneath the trolley attaching tubing and the additional oxygen to the Cook catheter, Dr Goutcher could not get into the correct position as she was in his way. He had positioned himself at Mr Ewing's right hip. This was far from an optimal position to attempt intubation as he had to stretch over. It was too far for him to reach and he was unable to manoeuvre the scope. He therefore withdrew the fibre-optic device and waited until Sister Forshaw had finished and there was space for him to take up the correct position.

[49] In the meantime, Sister Forshaw had successfully connected the addition supply of oxygen. No instructions were issued as to the correct level of flow of the oxygen. Sister Forshaw set it at its highest level, namely 15 litres of oxygen per minute. The

normal rate would be 2 litres up to a maximum of 4 litres for delivery via a Cook catheter. It appears that this rate of flow continued for some time although the exact period was not clear.

[50] As soon as Sister Forshaw had moved out of the way, Dr Goutcher attempted to re-insert the fibre-optic scope. However, on this occasion he saw a completely different picture: everything was swollen and he was unable to see any recognisable structure or anatomical landmarks. There had been a dramatic change in a matter of minutes.

Rapid swelling reaction

[51] At the same time as Dr Goutcher's second attempt to insert the fibre-optic scope and very shortly after oxygen had been introduced, Mr Ewing began to swell up extremely rapidly. There was a sudden swelling of his right arm, right eyelid and the right side of his face. The rate was described as very, very rapid. In association with that swelling was a redness which was a very bright cherry-red colour. Within seconds this swelling spread equally rapidly to the entire face, neck, both arms, upper chest extending down the trunk to the abdomen.

[52] Dr Singh considered that there might have been a leakage of air and felt the loose tissue at the top of Mr Ewing's neck for crepitus, the tell-tale sign of subcutaneous emphysema which is associated with a leakage of air into the tissues under the skin. Crepitus is a crackling feeling which is caused when air or gas moves in the tissues under palpation. Dr Singh felt no crepitus. Instead she noted that the neck, top of the chest and the top of Mr Ewing's arm felt very solid. There was no give whatsoever.

What she felt was a solid, brawny oedema. Dr Singh described the swelling as so rapid and extensive that it could not have increased any further.

[53] Given this and the florid red colour, it was thought that Mr Ewing might have been suffering an anaphylactic reaction – a severe allergic reaction – to the Rocuronium. Rocuronium and muscle relaxants like it are implicated in anaphylaxis. The situation was now one of extreme emergency. An alternative diagnosis of malignant hyperpyrexia, a very rare complication of anaesthesia, was also considered but quickly ruled out following a check of Mr Ewing's temperature (37.2 degrees). Accordingly, the protocol for the treatment of anaphylaxis was instituted.

Treatment for anaphylaxis

[54] In terms of the protocol, 10mls 1/10,000 Adrenaline and 10mg x 2 of Chlorophenoramine (an antihistamine) were administered and Dr Singh instructed that Midazolam (a sedative with amnesic effect) was also given to ensure that Mr Ewing had no awareness of what was happening to him. There was no response to the drugs. The swelling did not reduce, nor was there any improvement in oxygenation.

[55] At this point adequate ventilation was not being maintained by hand ventilation via the ILMA and Mr Ewing's saturations were falling. The oxygen saturation had fallen to 40% and the heart rate to 42. Rescue procedures were instituted. Surgical assistance was called for to achieve a surgical airway (tracheostomy). Dr Goutcher attempted to perform a cricoidthyroidotomy by pushing a needle through the cricothyroid membrane and inserting a tube into the airway. This was unsuccessful due to the degree of swelling. At this point there was no effective airway and Mr

Ewing had no pulse showing that there was no cardiac output. Cardio-pulmonary resuscitation (CPR) was commenced in response to cardiac arrest.

Resuscitation Efforts

[56] External cardiac compressions – which were maintained almost continuously over a fifty minute period - were carried out in turn by Dr Goutcher, ODP Hamilton and others. As they were commenced, Dr Ronnie Glavin, another consultant anaesthetist, arrived in response a further call for assistance. Dr John Howie, consultant anaesthetist and then Clinical Director of Anaesthetics and Intensive Care for Glasgow arrived moments after. On entering the room, Dr Glavin observed that external cardiac compressions were being performed. He noted that Mr Ewing was very swollen and that the subcutaneous tissue was very tense. He then heard a loud crack from the region of Mr Ewing's lower abdomen which made him suspect immediately that barotrauma had occured and that the swelling had been caused by surgical emphysema. The loud crack was in fact the release of air through the scrotum.

[57] Surgical emphysema and subcutaneous emphysema are synonymous terms for the same condition, namely air underneath the tissues. Such a condition is usually the result of barotrauma of some sort whereby air or some other gas is inadvertently introduced into the subcutaneous tissue.

[58] Barotrauma describes the damage to the lungs and other parts of the body as a result of changes in pressure within the body in relation to atmospheric pressure. It occurs when air entry exceeds air exit.

[59[Given the diagnosis of barotrauma, Dr Glavin considered it highly likely that Mr Ewing had sustained pneumothoraces – collapsed lungs due to the presence of air in the pleural cavity. Mr Ewing did, indeed, have a double phneumothorax – that is both of his lungs had collapsed. Dr Glavin noted that oxygen saturation displayed on the pulse oximeter was in the 90s and there was no indication of cyanosis – the blue tinge of the lips and skin due to lack of oxygen. Dr Singh confirmed that she was in control of the patient's airway. Dr Glavin immediately carried out emergency treatment for pneumothoraces and inserted an intravenous cannula (basically a large bore needle) into the mid-curricular line just above the second intercostal space on the upper chest on both sides. He was able to aspirate air. The rigidity and tension in Mr Ewing's right upper arm and chest on the right side lessened slightly as a result. However, there was concern that the tension in the chest wall would compromise the effectiveness of the cardiac compressions.

[60] Treatment continued for anaphylaxis during this time. As barotrauma could have resulted from anaphylaxis, the latter could not be excluded at that stage. The needle aspiration was a temporary measure of relief. The insertion of chest drains into the pleural cavity was required in an attempt to re-inflate the lungs. Due to the distortion to Mr Ewing's anatomy as a result of the swelling and because of doubt about the underlying pathology, it was considered prudent to order a portable chest x-ray before proceeding further. At this point 500mg of hydrocortisone was administered in accordance with the anaphylaxis protocol.

[61] Likewise, hampered by the amount of swelling, the on-call general surgeon was unable to perform a surgical airway. Specialist surgical help was required to establish an airway. Accordingly, Dr Glavin left the room to make a telephone call to the Southern General Hospital for urgent assistance from Ear, Nose and Throat surgeons there. (There is no longer an ENT Department in the Victoria Infirmary. The department is housed in the Neurological Sciences Building at the Southern General.)

[62] A chest x-ray was taken at 16:39 hours. During the resuscitation procedure, it was noticed that the rate at which oxygen was being delivered was 15 litres per minute. As that was too high, it was immediately reduced to 2 litres.

[63] The x-ray was viewed by Dr Glavin and Dr Howie and discussed by telephone with Dr Peter Calder, Consultant Radiologist. The x-ray confirmed the presence of bilateral pueumothorax and surgical emphysema. Chest drains were inserted by Mr Timothy Hems, the consultant orthopaedic surgeon who had been due to carry out Mr Ewing's surgery and by Miss Blauthen Paige, general surgical registrar. Dr Howie detected a dorsal pulse and an arterial line was successfully inserted into Mr Ewing's left foot. Cardiac compressions were stopped as there was a cardiac output although that was slow, at 30 beats per minute. Dr Glavin therefore administered 3 mg of Atropine in an attempt to stop it slowing down any further and to counteract any vagal nerve activity which would further slow the heart rate.

[64] A sample of arterial blood was taken so that blood gases could be analysed. Contrary to all other indications (the readings from the pulse oximeter and lack of cyanosis) and most unexpectedly, the blood results showed that Mr Ewing was

hypoxic (suffering from a lack of oxygen) reflecting a saturation level in the 50s, perhaps even as low as the 40s. The results showed that saturation levels were well below what was being indicated on the pulse oximeter which had continued to show falsely high oxygen saturation levels at 96-98% throughout this time. The true situation was that ventilation had been ineffective. The blood results also showed that Mr Ewing was acidotic due to a build-up of carbon dioxide as a result of the cardiac arrest.

[65] Cardiac resuscitative measures continued. Dr John Marshall, consultant ENT surgeon arrived from the Southern General Hospital together with his senior registrar. They carried out a tracheostomy – the creation of a surgical airway – and the saturation readings on the oximeter appeared to improve slightly. However, analysis of a further blood gases also showed that to be false: there had been no improvement in the arterial oxygen saturation and there was a worsening of the metabolic acidosis reflecting the on-going cardiac arrest.

[66] A second chest x-ray was performed. That showed some resolution of the pneumothoraces in that there were signs of a partial re-expansion of the lungs but it also showed a large bubble-shaped lesion in the stomach. It was thought that this might have been due to the distended stomach. As that had the potential to interfere with the venous return to the heart and further compromise the chest compressions, a naso-gastric tube was passed to deflate the stomach.

[67] By the time Dr Glavin had returned to the anaesthetic room having viewed the x-ray in an adjoining theatre, Mr Ewing was in asystole (no electrical response from the

heart). In accordance with the asystole protocol, Dr Glavin administered two further doses of Epinephrine. There was no response. A consultant cardiologist, Dr J Adams, was summoned to see if there was a tamponade (a collection of blood in the cardiac sac which mechanically obstructs and prevents the beating of the heart). Cardiac tamponade was the only other condition which might have accounted for the lack of output. An ultrasound scan excluded any significant tamponade.

[68] In view of the lack of response to all resuscitative measures, it was felt that further attempts at resuscitation were not appropriate. Resuscitation was stopped and Mr Ewing was pronounced dead at 17:13 hours.

[69] Examination of the second x-ray disclosed the presence of the Cook catheter outside the right lung. It had penetrated through the intercostal muscles and was lodged in the chest wall.

POST-MORTEM EXAMINATION AND CAUSE OF DEATH

[70] Dr Robert Ainsworth, Consultant Forensic Pathologist, University of Glasgow carried out an autopsy examination on 11 May 2006. He had the benefit of the assistance of Dr McRae, acting as an independent anaesthetist having also been involved in the hospital inquiry team following Mr Ewing's death. Dr McRae was able to provide valuable background details and explanations of the anaesthetic procedures involved.

[71] The examination confirmed that Mr Ewing died as a result of barotrauma (increased pressure within the chest) in relation to perforation of the middle lobe of

his right lung which had occurred as a complication of anaesthetic administration where something had been pushed from within through the outer wall of the lung. This had created a hole in the chest wall. Examination of the chest and neck revealed the presence of subcutaneous emphysema which was associated with a small perforation in his chest wall in relation to the perforating wound in the middle lobe of his right lung. In addition, there was evidence of a residual right-sided pneumothorax (the right lung was collapsed) while the left lung appeared partially collapsed. There was bilateral apical emphysema (at the top of the chest) and evidence of air in the lining of the chest wall, areas of which had been torn away with associated bleeding. There was evidence of bubbling of fat in the chest wall on both sides where air had tracked down.

[72] These findings accounted for Mr Ewing's death and would also have accounted for the rapid swelling that occurred whilst he was undergoing intubation. The delivery of high pressure oxygen in these circumstances would have caused Mr Ewing to inflate.

[73] Thus the cause of Mr Ewing's death was intrinsically linked to the perforation of the right lung as a complication of anaesthetic procedure. The pressure effects of barotrauma including the collapse of the lungs and subcutaneous emphysema as a result of the puncture of the lung and chest wall all formed part of the pathology of which Mr Ewing died and all were complications of anaesthetic administration. The fact that Mr Ewing was unable to breathe together with the pressure of general swelling led to the terminal event of cardiac arrest. The perforation of the lung and

chest wall was consistent with having been caused by the blunt end of the Cook catheter during attempts to aid endotracheal intubation.

[74] The only other findings of note were a split in the skin of the scrotum consistent with the escape of gas heard by Dr Glavin and two areas of bruising on the tongue and the frenulum (the membrane connecting the lip to the inside to the gum) consistent with intubation attempts and possible bleeding in the mouth as noted by Dr Singh.

[75] Dr Ainsworth certified the primary cause of death as barotrauma, due to perforation of the right lung as a result of complication of anaesthetic administration. The fracture of the distal phalanx Mr Ewing's right little finger was noted as a potential contributing factor, being the condition that had given rise to the surgical procedure.

DISCREPANCIES IN THE EVIDENCE

[76] The fatal accident inquiry into Mr Ewing's death was convened over three years after his death. Inevitably the ability of individuals to recall particular details of events and their exact chronology has decayed with the passage of time. On matters of detail, memories have faded although it was clear that the traumatic nature of what happened had left a deep impression on all who were in attendance in the anaesthetic room on that day.

[77] However, for the most part, the sequence of events was clear and there was little, if any, divergence of evidence. Essentially, there was no dispute about what happened. Of course, there were discrepancies among the witnesses on matters of

detail. Such minor variations are to be expected. Most were inconsequential and few can now be resolved. However, there were discrepancies among the witnesses on certain matters of significance. These included (i) the number of times the Cook catheter was inserted; (ii) the length of time that the oxygen was delivered at a flow of 15 litres per minute; and (iii) whether, by reference to the x-rays, it was appreaciated at the time that the Cook catheter had penetrated the chest wall. I consider each of these issues in turn.

(i) The number of times the Cook catheter was inserted

[78] Dr Goutcher gave evidence that the Cook catheter was inserted on two occasions. He was clear in his evidence that the catheter had been removed and re-inserted. This happened after the pilot bulb had sheared off. At that point it had been decided to check whether there was adequate ventilation via the ILMA. In order to do that, the Cook catheter was taken out so that the ET tube could be attached to the anaesthetic circuit. Adequate ventilation could not be achieved. At that point the Cook catheter was re-inserted by Dr Goutcher using the same technique as before.

[79] None of the other persons present could recall that procedure. Dr Singh's evidence was that the defective ET tube was simply removed after the pilot cuff sheared off. Similarly, Sister Forshaw recalled a single insertion only. OPD Hamilton's evidence was vague on the point and Dr McCardie's confused.

[80] I was unable to resolve this issue. However, the important matter was *how* the Cook catheter had been inserted, not whether it was inserted once or twice. In considering the evidence on this point, it became very obvious from the inability of

the witnesses to recall anything specific at all about the position of the Cook catheter that no-one was paying any attention to it at the time.

(ii) The rate of flow of oxygen via the Cook catheter

[81] It was a matter of agreement that the rate of flow of the oxygen from the cylinder on the trolley was initially set at 15 litres per minute. According to Dr Singh, she had first become aware of this when chest x-rays were being taken. As Mr Ewing was returned to a supine position on the trolley, she noticed that the tubing had become detached from the cylinder and that the oxygen supply had become disconnected. At that point she asked Dr Goutcher whether he wanted it connected at a rate 2 or 4 litres per minute. Dr Goutcher confirmed a rate of 2 litres whereupon Dr Singh recalled Sister Forshaw saying that she had better turn it down as it had been set at 15.

[82] Dr Singh was asked if she could calculate how long the oxygen flow had been running at 15. With reference to the anaesthetic record sheet on which significant timings were recorded, Dr Singh was able to estimate a period of about 10 minutes. The fibre-optic laryngoscopy had commenced at 16:07; cardiac arrest occurred at 16:22 and Dr Howie inserted the arterial line at 16:27 when tracings began; the chest x-ray was taken either just before or just after that so the period was roughly between just after 16:07 to just before 16:27.

[83] Dr Goutcher's evidence was that it was he who had noticed that the oxygen level was set too high at 15 litres per minute. He recalled that as he had stepped back to take a rest from administering cardiac compressions, he noticed that the level of flow at 15. He brought that to Dr Singh's attention and he himself turned it down to 2. He

was not able to estimate how long after CPR had commenced that he noticed it as he had been fully focussed on resuscitation. The oxygen was still connected to the catheter. Dr Goutcher did not recall that the tubing had become detached at any time.

[84] Sister Forshaw gave a third and very different account of events. She was sure that she had originally connected the oxygen at the highest rate of 15. Shortly after Dr Goutcher's second attempt to pass the fibre-optic scope, she remembered that she had not checked the level of oxygen in the cylinder. She was concerned that it might run out and so she checked it. At that time she noted that the level was set at 2 litres per minute. She had not altered the flow, nor had Dr Goutcher and they were the only two persons standing in the space above the cylinder. No one else was seen to go near it. She asked what the flow should be. According to her, Dr Singh did not know and asked Dr Goutcher who instructed that the rate should be set at 2 litres. It remained at 2. Sister Forshaw estimated that about 2 to 3 minutes had passed since she had set it at 15 and subsequently noticed the change to level 2.

[85] Sister Forshaw described how on another two occasions she had checked the oxygen cylinder and had discovered that the tubing had become disconnected from the nipple of the oxygen regulator on the cylinder. She had first noticed this at a stage after the swelling of the patient had been observed and she brought it to Dr Singh's attention. The tubing was re-connected but after a further five minutes or so, when she checked again, it had once more become disconnected. According to Sister Forshaw, she offered to get a smaller cylinder to place on top of the trolley where it could be monitored but Dr Singh told her simply to disconnect it. She could not account for the alteration in the flow rate and was at a loss to explain how it might have come about.

(Neither Dr Singh nor Dr Goutcher was asked to comment on this account as they had already given their evidence.)

[86] The report of the hospital inquiry did not assist in reconciling these accounts. It was silent on the issues of when or how the high rate of oxygen had come to the notice of the anaesthetists.

[87] I found Sister Forshaw's evidence on this point both confused and confusing, as she herself acknowledged . I did not find it convincing evidence and have concluded that she must be mistaken in what she now remembers. What was clear enough from the evidence was that the initial rate was set at 15 litres and was later discovered and reduced to 2. I was persuaded by Dr Singh's careful evidence about the timings that the delivery of oxygen at 15 litres per minute continued for approximately 10 minutes. Dr Goutcher's evidence that he had noticed this after CPR had been continuing for some time tends to confirm that timescale, if not the circumstances in which the problem was first appreciated. It is, of course, possible that Dr Singh and Dr Goutcher each noticed the problem independently at the same time.

[88] It is evident from the extraordinarily rapid and extensive swelling of Mr Ewing's body that occurred as soon as the high flow oxygen was introduced, that the catheter must already have migrated into the pleural structures. Given the immediate and dramatic effects, the exact duration of the high flow delivery is of relatively minor importance. However, it was a matter of significance at the time about which I would have expected careful note to have been taken.

Interpretation of x-rays

[89] Dr Howie was primarily in charge of this aspect of Mr Ewing's care. He, together with others, went into an empty theatre to view the X-rays on the PAC system – a digital computer screen. The second chest x-ray had been taken to confirm the position of the chest drains and to determine the extent to which the lungs had re-inflated following the drainage of air. However, on viewing the x-ray, Dr Howie was able, amongst all the clinical artefacts visible on the x-ray, to spot a tube running down through the trachea towards the right lung and into the pleural cavity. The difference between this and the first x-ray was that the distal end (the end inside Mr Ewing's body) could now be visualised. From that it was clear that the tube came to a discreet end and was therefore not something that should normally be seen in a critical care chest x-ray. Dr Howie could see that whatever this was on the x-ray had passed through the intercostal muscles and had become lodged in the subcutaneous tissues.

[90] During his evidence, Dr Howie described how he immediately went back into the anaesthetic room and asked what there was that was travelling down the airway. He was told it must be the Cook catheter. That was the first Dr Howie had been aware of the catheter. He instructed its immediate removal. He could not remember who removed it. He did not think he had done so himself.

[91] Dr McCardie had been present when the x-rays were looked at and she remembered that the tube was noticed and that its position too far down was discussed. She thought it looked as if it had gone down the right main bronchus and into the lung tissue. She did not know what had happened after that as she became

immediately involved with emergency procedures on her return to the anaesthetic room and her focus was at the level of Mr Ewing's feet.

[92] Dr Glavin had also been present when both x-rays were looked at. He recalled having looked at the second x-ray with Dr Howie and noting that the chest drains were doing their job and that the lungs were beginning to re-expand. He then returned to the anaesthetic room where, by then, Mr Ewing was in asystole. He could not recall any discussion of an errant tube nor did he see that on the x-ray. On looking at the x-ray in court he was able to confirm the presence of a device that looked like a Cook catheter in the pleural cavity. Dr Glavin's recollection was that it was not until the following day that it became clear what had happened.

[93] Neither Dr Singh nor Dr Goutcher could remember anything having been said about the misplacement of a tube on Dr Howie's return from viewing the second x-ray. Nor could they recall any questioning about airways or instructions for the immediate removal of the catheter. They were, of course, dealing with a critical emergency situation as Mr Ewing had no cardiac output. It appeared from their evidence that the first they were aware of any problem with the Cook catheter was the following day when it was noticed that there was something outside the chest. She recalled that Dr Howie had spotted the problem. However he had been unsure of what it indicated and had gone to radiology to have an x-ray taken of a Cook catheter for comparison purposes. (An x-ray of a Cook catheter was a production in court.)

[94] Sister Forshaw's recollection was that Dr Howie came back into the room and that he himself removed the Cook catheter from the patient's chest. This was just after

the oxygen had been disconnected. She did not recall any discussion or comment about the catheter.

[95] The hospital inquiry Report refers to *retrospective* analysis of the chest x-rays establishing the misplaced catheter. That infers that the information before them, a matter of days later, was that the problem with the Cook catheter was discovered later.

[96] It is quite extraordinary, even with the passage of time, that neither Dr Singh nor Dr Goutcher could recall Dr Howie coming back into the anaesthetic room having seen the wayward Cook catheter in the chest wall and ordering its immediate withdrawal - if that is what happened. Its discovery would have been a matter of huge significance and it seems inconceivable that the anaesthetist in charge would not have been made aware of this finding. The anaesthetic room was busy and those present were engaged in a full-scale emergency situation but surely something of that significance would be bound to impact upon the memories the two persons most closely involved in the whole procedure.

[97] In the course of submissions it was suggested that I could not now, over three years on, readily resolve these matters and that, in any event, these were not crucial matters that would affect my conclusions. While that may be so, I consider it worthy of comment that such conflicting accounts could be given about issues of fundamental importance, particularly from experienced professionals. Although it was clear to me that all these witnesses were entirely honest and endeavoured to answer questions to the best of their ability, nevertheless, such divergence of testimony on important matters was an unsatisfactory feature of this Inquiry.

EXPERIENCE OF THE ANAESTHETIC TEAM

[98] It is important to describe the experience of the anaesthetic team who were involved in Mr Ewing's procedure in 2006. The initial team consisted of Dr Singh, Dr Ladd (not a witness) Sister Forshaw and ODP Hamilton. They were quickly joined by Dr Goutcher and Dr McCardie who became involved in the further attempts to intubate Mr Ewing after difficulties had been encountered. Dr Glavin and Dr Howie arrived later by which time the anaesthetic procedure had become an emergency rescue procedure. Their involvement was therefore confined to resuscitation efforts.

The main team

[99] Dr Deepa Singh was the lead anaesthetist in charge of Mr Ewing's procedure. She began her anaesthetic training in 1980, some 29 years ago. She had been a consultant anaesthetist for about 10 years at the time of Mr Ewing's death. She has carried out many thousands of anaesthetic procedures in her career. She has particular exposure to patients whose airways are potentially difficult in her weekly list of ENT patients in whom difficult airways are regularly encountered. It was clear from the evidence that Dr Singh is regarded as a careful and technically skilled anaesthetist and is held in high esteem by her colleagues, both junior and senior.

[100] Sister Ann Forshaw is an anaesthetic recovery sister in the Victoria Infirmary, a post she has held for 8 years. As such she is a very experienced theatre sister with clinical duties as an anaesthetic assistant and management responsibilities. She has

worked in anaesthetic nursing since 1988. She is one of the most experienced theatre sisters in the hospital.

[101] Mr Alan Hamilton has been an operating department practitioner in the Victoria Infirmary since training as an ODP in 2001. He has worked there for 28 years having previously been a theatre auxiliary from 1982 until 1999 when he commenced his training. His duties are as an anaesthetic assistant.

The extended team

[102] Dr Colin Goutcher is a consultant neuro-anaesthetist in the Department of Neurological Sciences in the Southern General Hospital, Glasgow. He was an experienced sixth year anaesthetic trainee and specialist registrar at the time of Mr Ewing's death, having specialised in anaesthetics since 1998. Such was his experience that he was a matter of months away from his first consultant appointment in January 2007. At the time he was working in intensive care department.

[103] Dr Fiona McCardie has been a consultant anaesthetist for 10 years. In addition to her general anaesthetic duties, she undertakes regular urology and gynaecology lists and day surgery patients.

The rescue / resuscitation team

[104] Dr Ronnie Glavin is one of the most senior consultant anaesthetists at the Victoria Infirmary having been a consultant for over 20 years. He has worked at the Victoria Infirmary since 1989. He is Associate Dean for NHS Education Scotland, is a

post-graduate tutor and is involved with the Scottish Clinical Simulator Centre. He undertakes certain training responsibilities with the Royal College of Anaesthetists.

[105] Dr John Howie is a consultant anaesthetist at the Victoria Infirmary with special interest in intensive care. His clinical practice is now exclusively in intensive care. He is currently the Associate Medical Director for Anaesthetics and Surgery for Glasgow and Clyde. At the time of Mr Ewing's death, he had recently been appointed Clinical Director for Anaesthetics and Intensive Care for Glasgow.

THE EXPERT WITNESSES

[106] The Crown led Dr Graham Johnston as an expert and produced a report by him. Dr Johnson is a consultant anaesthetist at the Aberdeen Royal Infirmary with a specialist interest in anaesthesia in maxillo-facial, head-and-neck and paediatric surgery. He was appointed to his current post in 1991 and has 16 years experience at consultant level of anaesthesia for difficult airway cases. For the first eight years of his consultant career, he covered weekly maxillo-facial lists requiring a wide range of special skills for difficult airway patients. He has extensive experience in anaesthetics in cases involving tumours of the mouth, pharynx and larynx associated with airway impairment. He has dealt with somewhere in excess of 600 difficult airway cases. Dr Johnston was a most impressive and compelling expert witness and was clearly well qualified to act in that capacity.

[107] I considered, too, that I had the benefit of the opinions of a second expert witness in Dr McRae. Dr McRae is a consultant anaesthetist of 12 years standing having worked exclusively in anaesthetics for over 20 years. As lead clinician for

Stobhill Hospital and Glasgow Royal Infirmary with management responsibilities at both sites, he was the independent senior anaesthetist on the hospital inquiry team and as such had reviewed the actions of the anaesthetic team and his consultant colleagues. I considered that he, too, was qualified to provide opinion evidence as a skilled witness and, as with Dr Johnston, I placed considerable reliance on his views.

[108] As can be seen, I had the benefit of evidence from a number of highly qualified and experience professionals. Their combined experience and knowledge was considerable arising from many thousands of anaesthetic procedures. Had he not been a witness to fact, Dr Howie, too, would otherwise have been well qualified to give opinion evidence. Although he was not before the Inquiry in a expert capacity, Dr Howie spoke with authority and gravitas. Accordingly, I paid particular regard to his testimony.

[109] Dr Singh, Dr Goutcher and Sister Forshaw gave evidence in difficult and anxious circumstances in the knowledge that their actions and decisions were under close scrutiny. Much to their credit, they gave their evidence in an open and straightforward manner and it was my impression that they were being unreservedly frank. In this connection it is appropriate that I acknowledge Dr Singh in particular who gave her evidence over an extended period of three days. At all times she conducted herself with great dignity, composure and professionalism.

THE LEGAL FRAMEWORK

The scope and purpose of a fatal accident inquiry

[110] A number of issues of public concern arose and were explored in detail in the course of this Inquiry. These require to be examined in turn. It is considered convenient to examine these issues under separate headings relating both to the subject matter and their relevance in terms of section 6 of the 1976 Act. However, before doing so, it is appropriate to examine the scope and purpose of a fatal accident inquiry and the submissions that were made in that connection.

[111] The duty of the Sheriff in any inquiry is to issue a determination in terms of the statutory framework set out in section 6(1):

At the conclusion of the evidence and any submissions thereon or as soon as possible thereafter the Sheriff shall make the determination setting out the following circumstances of the death so far as they have been established to the satisfaction:

> *(a) where and when the death and any accident resulting in death took place;*
>
> *(b) the cause or causes of such death and any accident resulting in death;*
>
> *(c) the reasonable precautions, if any, whereby the death and any accident resulting in death might have been avoided;*
>
> *(d) the defects, if any, in any system of working which contributed to the death or any accident resulting in death; and*
>
> *(e) any other facts which are relevant to the circumstances of the death.*

[112] It is appropriate to set out the purpose of a fatal accident inquiry in positive terms. First and foremost it is to enlighten and inform those persons who have an interest in the circumstances of the death. Most importantly, it is to ensure that members of the deceased person's family are in possession of the full facts surrounding the death. However, in an inquiry such as this where the Lord Advocate considers that the death occurred in circumstances which give rise to serious public concern, the broader function of such an inquiry is to ensure that the circumstances are fully examined and disclosed in the public domain. It is the function of the FAI, where appropriate, to establish whether there were any reasonable precautions which might have prevented the death and to examine whether any defects in the system working were identified which contributed to the death. Thus the objective of such a public enquiry must be to ensure where lessons can be learned and steps taken to avoid any future recurrence, that these are identified and brought to the attention of those who are in a position to implement them. In this connection, it is a legitimate aim of an FAI brought under section 1(b) where there may be serious public concern, that wherever possible, that concern is assuaged and public confidence restored. This is particularly so where, as here, a public institution such as hospital is involved.

[113] It follows that it is vital that those called to give evidence before the inquiry should feel able to speak freely and openly about the circumstances of any death. To encourage and facilitate this, section 6(3) of the 1976 Act provides that the determination of the sheriff shall not be admissible in evidence or be founded upon in any judicial proceedings, of whatever nature, arising out of the death.

[114] It is well-settled that it is not the purpose of a fatal accident inquiry to determine any questions of criminal or civil liability or to apportion blame between any persons who might have contributed to the accident [or death] (Black v Scott Lithgow Limited 1990 SLT 612 *per* the Lord President (Hope) at p 615G-H). For a number of reasons, all of which have been fully rehearsed elsewhere, it is not a forum in which it is appropriate to make finding of fault. It is a fact-finding procedure, not a fault-finding procedure. However, that does not exclude the leading of evidence which may tend to demonstrate fault. Nor does it mean that the sheriff is precluded from reaching findings which may infer fault where it is proper to do so. In the words of the learned author I H B Carmichael: *If the evidence led before in the inquiry is sufficiently strong, then findings made under section 6 (1) (c and (d) may well point fairly strongly to the existence of… fault…..[W]here evidence is sufficiently compelling, the responsibility of exposing and finding fault should be accepted. The whole object of impartial public inquiry is to get at the truth, to expose any fault where fault is proven to exist, and in all cases to see to it so far as humanly possible that the same mistake, when it arises through fault or any other reason, is not made in the future. The public interest, in whose name inquiries are held, requires and deserves no less. (Sudden Deaths and Fatal Accident Inquiries 3rd Edition, paragraphs 5-63 and 5-76.)*

[115] This has been recognised, too, by Lord Cullen in his recent review of fatal accident inquiries: *It is true that the investigation into the circumstances of a death in an FAI may disclose grounds for criticism from which a basis for alleging fault may be inferred. That may be unavoidable if the FAI is to fulfil its function of investigating the circumstances of the death* (Report of the Review of Fatal Accident Inquiry Legislation (2009) at paragraph 3.23) That view corresponds with the observations of

Sheriff Principal Bowen following an Inquiry into the death of Gordon Scott Niven, Glasgow, 5 March, 1999, a case involving consideration of medical decision: [T]*he court is entitled to examine much wider issues, including areas of practice generally, and is entitled to direct criticism in such terms as seem appropriate if satisfied upon examination of the facts that it is right to do so. The making of such criticism has no necessary implication for any other proceedings in which issues of professional standards may be properly focused.*

[116] In the course of this Inquiry, it was accepted that Mr Ewing's death was preventable. In other words, it should not have happened. Moreover, the court had the benefit of the findings of a hospital internal inquiry convened shortly after Mr Ewing's death. The inquiry recognised that sub-optimal clinical decisions had been taken and that mistakes had been made. Professional responsibility for a number of these decisions was squarely shouldered by those involved and by the Health Board. To shy away from concluding that mistakes were made and that "fault" - in the generally accepted sense of the word, as opposed to the notion of legal liability - did feature in Mr Ewing's death would not only compromise this Inquiry but would fail to recognise the courage of the professional witnesses who openly and frankly gave evidence knowing that their candour would expose them, together with the hospital and the Health Board, to public criticism. To their immense credit, these individuals gave their evidence in the true spirit of the inquiry and did not shirk from their mistakes and responsibilities.

[117] In terms of section 6(1)(c) (the reasonable precautions, if any, whereby the death and any accident resulting in the death might have been avoided), there are two

parts to any finding under this heading. First, the court must be satisfied that the precaution was such that it might (not would) have prevented the death. Secondly, in addition the court must be satisfied that the precaution was a reasonable one. What is reasonable has been the subject of much discussion. I was referred to a number of observations by learned sheriffs in various inquiries.

[118] It seems to me clear that, having regard to the purpose of a fatal accident inquiry, the court is afforded a wide discretion to consider these issues with the benefit of hindsight. The statutory provisions are not concerned with whether such reasonable precautions could or should have been recognised, only whether they existed. The sheriff is encouraged to look at the broad circumstances in which the death occurred to determine whether any such precautions existed whereby the death might have been avoided. Therefore I concur with the view of my learned colleague Sheriff Fiona Reith QC that there can be no question of the reasonableness of the precaution depending on foreseeability of risk. (Inquiry into the death of Sharmain Weir, Glasgow 23 January 2003) Notions of reasonable foreseeability, standards and duties of care are properly matters for another forum. The purpose of identifying reasonable precautions which might have prevented the death is to inform those looking to the future so that steps may be taken to prevent future accidents and death.

[119] Equally, it seems to me that it cannot be said, as was suggested, that consideration of what is or is not reasonable in a "medical FAI" is any different from any other type of inquiry. It is certainly no different from any other inquiry in which the subject matter under consideration, as here, is of a complex technical nature. In these types of inquiry, what is important is that the sheriff understands what is

involved and has the assistance of professional and expert witness to explain and interpret these complexities - in this case, procedures involved in the induction of anaesthesia. Individual actions are not to be judged in strict terms of the civil standard of the reasonably competent medical practitioner. But, fairness and principles of natural justice require that the court looks at the whole facts and circumstances as they existed at the time and in considering whether a precaution was reasonable will often be informed and guided by the observations and opinions of skilled witnesses who inevitably will consider the issue in that light of accepted professional practices and procedures. The court can take these matters into consideration whilst still applying the wisdom of hindsight in determining whether a particular precaution was reasonable: the two concepts are not necessarily incompatible.

[120] Different considerations apply to a finding under section 6(1)(d) (the defects, if any, in any system of working which contributed to the death). Here the court must be satisfied, on the balance of probabilities, that there is a causal link between the defect and the death.

[121] Although the wording of the subsection has its origins in the Factories Acts of the late 19th century, the phrase "system of working" in modern times is widely interpreted. In the words of the learned author, *[t]he phrase "system of working" must be understood as including... any system -- or lack of system -- of working such as supervision where necessary, or routine in any custodial institution, where such has contributed positively to the death or accident resulting in death. It must also include systems (or lack of systems) and routines of laboratory, diagnostic, medical, surgical and therapeutic procedures (Carmichael, ibid at 5-76).*

[122] In this case, several features of Mr Ewing's care and the circumstances of his death require to be scrutinised. In such a situation, it is almost inevitable that there will be a degree of overlap whereby some of these features could properly be included under more than one heading in terms of section 6. Some of the issues that I have included under sub-heading (e) might equally have been included under (c). However, I have determined that three features in particular were decisive in Mr Ewing's death: first, the failure to abandon the procedure; secondly, the failure to secure the Cook catheter in position; and, thirdly, the failure to issue specific instructions as to the rate of flow of oxygen through the catheter. I have, therefore, restricted my findings under the principal heading (c) to these issues. Other relevant issues which were of concern I have considered under sub-paragraph (e).

[123] On some of the other matters, there was disagreement among the experts and the professional witnesses as to what was deemed reasonable in the circumstances. Where there was such a divergence of opinion in the evidence concerning matters often referred to as "judgment calls", I have decided that while these merit full consideration, they are not matters about which I need make formal findings in terms of section 6.

[124] It is easy in the calm of the courtroom and with the benefit of hindsight, to dissect and analyse in minute detail the decisions and actions that were taken on that afternoon in May 2006. It is, however, important to bear in mind the context in which these occurred. Although there was evidence confirming that throughout the procedure the atmosphere in the anaesthetic room remained tense but at all times

controlled, without any suggestion of panic, this was a rapidly developing and fluid situation of extreme emergency and complexity. Speed was of the essence and difficult clinical decisions had to be made quickly and under pressure. The extraordinary nature of Mr Ewing's presentation cannot be over-stated. Indeed, the circumstances which confronted Dr Singh and her colleagues were as unique as they were awful.

ANALYSIS OF THE ISSUES

[125] Two issues dominated the Inquiry: whether Mr Ewing's surgical procedure should have been abandoned thus allowing him to waken up; and the circumstances in which the Cook catheter device was used. These will be considered in some detail.

(i) THE DECISION TO CONTINUE

[126] An examination of any clinical decision involves consideration of relevant clinical protocols, guidance and accepted practices which exist within the profession. Such information is necessary in determining the various factors that require to be taken into account in analysing the risks involved in a situation where unexpected problems are encountered (the "unanticipated difficult airway").

[127] As a matter of background, Dr Johnston informed the court that the incidence of an unanticipated difficult airway is somewhere between 3 and 18 per cent of all intubations. About 1 in 10 procedures are classified as difficult. The bedside airway tests are said to identify about 7% of these in advance. Leaving aside the predicted cases, about 1 in every 30 intubations will be unexpectedly difficult. Therefore, it is

by no means rare for an anaesthetist to experience this: the average busy consultant anaesthetist will come across about one case per fortnight.

[128] In such cases where, as in Mr Ewing's case, there are unexpected difficulties in obtaining a view of the larynx, Dr Johnston stressed that it is important that the anaesthetist follows a clear, logical sequence of actions. All anaesthetists must be skilled in following a series of actions which will afford the best chance either of obtaining an artificial airway or allowing the patient to awaken and maintain his own airway.

Difficult Airway Society Guidelines

[129] To this end there are various algorithms and protocols in place. Important among these are the guidelines produced by the Difficult Airway Society ("DAS"). The Court heard that these are guidelines accepted by the profession which guide the anaesthetist on each step that they would recommend should be taken in order to achieve the best outcome. The Society is a British organisation and their guidelines are highly regarded within the professional community. The guidelines, developed by consensus and based on evidence and experience, are regarded by many as the best methodical strategies for optimal care of difficult airway patients.

[130] The essence of the DAS guidelines for management of unanticipated difficult intubation is a series of flow-charts. These were produced to the court together with the accompanying DAS publication. Essentially, three clinical scenarios are covered: (i) unanticipated difficult tracheal intubation during routine induction of anaesthesia; (ii) unanticipated difficult tracheal intubation during rapid sequence induction; and

(iii) the situation of failed intubation with increasing hypoxaemia and difficult ventilation in a paralysed anaesthetised patient. The flow charts are designed to be simple, clear and definitive. However, they are guidelines only and are not to be regarded as a substitute for good clinical judgment.

[131] The flow-charts set out four plans: A, B, C and D. Plan A refers to the initial tracheal intubation plan. Plan B covers the secondary intubation plan where Plan A has failed. Plan C deals with the maintenance of oxygenation and ventilation, postponement of surgery and wakening the patient when earlier plans fail. Plan D covers rescue techniques in a 'can't intubate, can't ventilate' situation.

[132] The second scenario described in the guidelines applies where,as here, rapid sequence induction is used. Where any problems are experienced in direct laryngoscopy, the anaesthetist should call for help. If, after a maximum of three attempts, intubation fails the guidelines state that a failed intubation plan should be initiated immediately with the aim of maintaining oxygenation and awakening the patient – Plan C.

[133] Proceeding to a secondary intubation plan (Plan B) in *not* advised in such patients. This is because of increased risk to the patient. In such circumstances, the safest plan in most patients is not to continue but to postpone surgery and awaken the patient. Without doubt this is so where the surgery is not urgent or essential.

[134] Dr Johnston explained that all anaesthetists are trained to make rapid evaluations of risk versus benefit intervention. In a case of an airway obstruction, any

delay due to deviation from a logical algorithm of treatment can have devastating consequences.

[135] In examining the quality of the clinical decisions which were made in connection with Mr Ewing's anaesthetic and their outcome, it is convenient to consider these in separate stages. These correspond with the discreet points at which there were options to consider continuing or terminating the procedure.

Initial difficulties with intubation – Stage 1

[136] From the outset, there were difficulties in intubating Mr Ewing. In accordance with hospital protocol and the DAS Guidelines, Dr Singh immediately called for assistance from other anaesthetists. This call for help was answered promptly with the arrival, within minutes, of two senior and experienced anaesthetists, Dr McCardie and Dr Goutcher. Having failed to achieve intubation at this stage where there is rapid sequence induction, the recommendation in the DAS guidelines is to proceed immediately to Plan C and waken the patient.

[137] In Dr Johnston's opinion that is what should have happened, not only in terms of the DAS guidelines but on a simple risk/benefit analysis. At this stage, several factors required to be considered: how difficult the procedure had been up to this point, the experience of the anaesthetist and the urgency in terms of the surgery. Considering the difficulties experienced so far, including the dropping of oxygen levels, some trauma to the airway evidenced by the bleeding and taking account of the relatively minor nature of the surgery, Dr Johnston's opinion that was that it was appropriate move to plan C to allow Mr Ewing to wake up and that to continue with

anaesthesia was a misjudgement. Proceeding to Plan B would only be justified if the surgery were urgent or life-saving.

[138] Waking Mr Ewing up at this stage would have been a straightforward matter. The short-acting drugs that he had been given would have worn off quickly. His ventilation and oxygenation would have been assisted by means of the LMA and additional jaw thrust until he began to breathe on his own.

[139] Dr Singh acknowledged that she had not been working specifically to the DAS guidelines. These she regarded as generally useful but she relied on her own observations and experience in making clinical decisions about individual patients. Broadly, her overall plan for all anaesthetics followed the general plan described in the guidelines: a Plan A, a Plan B as back-up, a Plan C and a Plan D. In other words, have a plan and a back-up plan and if these do not succeed, then oxygenation and ventilation required to be maintained. Her back-up plan (DAS Plan B) in Mr Ewing's case was to switch to the intubating laryngeal mask. In fact, from the outset her anaesthetic plan was not in accordance with the DAS guidelines in connection with rapid sequence induction anaesthesia. In having a back-up plan, she had introduced a stage which is by-passed in the DAS guidelines. Dr Singh acknowledged that she could have stopped the procedure at that early stage but she considered that most of her colleagues with a similar experience would have continued at that point.

[140] The hospital inquiry team supported her decision to proceed at that stage. Their focus was not on Dr Singh's plan but on the clinical circumstances at the time. They considered that her decision to proceed with a further attempt to intubate could not be

criticised. They concluded: *There was adequate oxygenation at the time and there were three experienced anaesthetists with assistance to carry out this procedure. The insertion of the intubating laryngeal mask and a successful placement of a size 7 endotracheal tube was evidence of this.* This accorded with Dr McRae's own view that a situation where there were two consultants and a very experienced trainee together with other experienced assistance would be one in which it would be perfectly reasonable for a consultant anaesthetist to attempt to intubate in some other fashion.

Stage 2

[141] Having successfully achieved tracheal intubation by means of the ILMA, the next stage at which the anaesthetic options should actively have been considered arose when Dr Singh decided that the blood in Mr Ewing's mouth was such that it would not be safe to allow surgery to proceed. Thus a further difficulty had arisen which required the removal of the laryngeal mask. This additional problem did not cause Dr Singh to pause to consider the available option other than proceeding at that stage. In particular, no consideration was given to abandoning the procedure and allowing Mr Ewing to waken.

[142] Dr Singh herself acknowledged that this would have been an appropriate time to have woken Mr Ewing. She accepted that she had an opportunity to discontinue the proceedings when she noticed the bleeding in the mouth. During her evidence she said that in retrospect she should have wakened Mr Ewing then at the point when she had secured his airway with the insertion of the ILMA.

Stage 3

[143] The next stage where there was an option to discontinue arose during the difficulties experienced with the removal of the laryngeal mask. It had been a struggle to remove the end connector and stabilise the tube. No consideration was given to terminating the procedure then. However, the point at which the pilot cuff sheared off and the secure airway was lost effectively was the final stage at which the waking option was available. After that, the situation rapidly deteriorated and became one of attempted rescue and resuscitation. Again, the option was not considered. Until then, Dr Singh explained that she had been in control. Once the pilot cuff burst and the airway became compromised she started reacting to the situation rather than being proactive. She accepted, again, that she should have stopped then. The stage at which she had been unable to railroad a 9 mm tube and had put the ILMA back in was the point at which, instead of proceeding to the fibre optic attempt, she considered that she had failed. She should have taken steps to try and waken Mr Ewing. She appreciated also that what she described as "the completely minor nature of the surgery" was something that should have influenced her.

[144] The hospital inquiry team was critical of the decision to proceed from this point. They concluded that *as there had by then been three separate significant difficulties in establishing a permanent airway in the patient and in view of the... relatively minor nature and importance of the surgery, the anaesthetic should have been terminated at that point.*

[145] In Dr Johnston's view, the benefits of waking the patient hugely outweighed the risks of proceeding. The induction agent would have worn off by then so Mr Ewing

would no longer have been paralysed. His lungs would have been ventilated with 100 per cent oxygen until he awoke. The ILMA would then have been removed and, as he was awake, he would have breathed on his own and maintained his own airway.

Conclusion

[146] Although the DAS guidelines have advisory status only, they are highly regarded within the anaesthetic community as the best available guidance. As such, any departure from the recommendations contained therein should be for good reason. However, it is equally clear that their status is as guidance only and that clinical judgment must remain the paramount consideration.

[147] During stage 1, Dr Singh had ensured that Mr Ewing was in a stable condition having inserted the LMA and achieved temporary ventilation. By that time she had assistance from two experienced colleagues. In these circumstances it is understandable that she felt confident to proceed to her back-up plan. In the course of the Inquiry, different opinions were expressed as to whether Dr Singh was justified in proceeding to a secondary plan to intubate. In the circumstances, she may well have been able to justify departing from the accepted guidelines, *had she made a conscious decision to do so.* However, having a routine practice that by-passed the DAS guidelines from the outset meant that she did not give these any active consideration. Thus the relevant guidelines in association with rapid sequence induction were clearly not in her mind; unfortunately, neither was the recommended option to abandon the procedure and waken the patient. Had Dr Singh not immediately proceeded to Plan B, but had she consciously departed from the guidelines, she might actively have thought about the option of waking Mr Ewing, even if she had then discounted it. In that case,

she might have had the option of terminating the procedure more to the front of her mind during the subsequent stages when proceeding became progressively less justifiable.

[148] The same considerations applied at Stage 2, when the bleeding became a problem. The issue was not so much Dr Singh's decision to remove the ILMA (this was a clinical decision for her – a judgment call); rather, once more it was the decision to proceed without apparently undertaking a simple risk/benefit analysis. Had she done so, the difficulties so far encountered and the minor nature of the surgery would surely have entered her conscious thinking and thus triggered consideration of the waking option.

[149] By stage 3, the risks of continuing clearly outweighed the benefits of continuing. Without doubt, on any risk / benefit analysis, the balance of the equation hugely favoured bringing matters to an end and allowing Mr Ewing to waken up. Accordingly the decision to proceed further was unjustifiable.

[150] It seemed to Dr Johnston that there had been a determination to achieve intubation which drew attention away from the option of waking patient. That is, indeed, what appears to have happened. The goal was to achieve intubation and ventilation in terms of the anaesthetic plan. It can easily be understood that the efforts of the team were focussed on overcoming the various difficulties as they arose. Dr Singh took a series of careful and logical steps, ensuring at each stage that Mr Ewing's condition was stable before proceeding to the next step. However, in so

doing, she was deflected from considering the over all circumstances in terms of risks against benefits.

FAILURE ACTIVIELY TO CONSIDER WAKING MR EWING

[151] Dr Singh very frankly acknowledged that she ought to have stopped the procedure and allowed Mr Ewing to waken and that at no time had she considered that option. Dr Goutcher was equally frank. He, too, recognised that they should have wakened Mr Ewing at the stage before fibre-optic laryngoscopy was attempted. He regretted not having considered the option. His evidence on that point was in the following terms: "I'm sorry to say that it didn't even cross my mind at that point. I think if I'd been by myself in the middle of the night it would have but, because it was during the day and there were lots of experienced people around, it didn't even enter my head." Later on in the course of his evidence he stated that “the biggest mistake that happened on that day was not to waken Mr Ewing up when we had the opportunity”.

[152] Dr McCardie likewise realised in retrospect that the procedure should have been aborted but like the others, gave the waking option no conscious thought. She believed that perhaps subconsciously she thought at the time that they had done enough but she did not actively think to waken the patient at any point. Neither she, nor Dr Goutcher considered the DAS guidelines.

[153] The court was told that waking the patient is *always* a fundamental option and that it is not an uncommon for this to happen. Dr Johnston explained that it is most likely to occur in an unanticipated difficult airway situation which is where the DAS

guidelines quite clearly say there is one option: to waken the patient. In such circumstances, he explained that the anaesthetist has, in a sense, to be slightly humble having failed to achieve the plan to anaesthetise the patient so that the planned surgery may proceed. However, the anaesthetist has to accept that he will not endanger the patient's well-being in order to achieve an anaesthetic for a non-urgent, non-essential operation.

[154] Dr Howie agreed that it is *always* an option under consideration: whenever there is someone who cannot be intubated, one of the strategies in the anaesthetist's mind will always be *should I wake the patient up*? How hard an anaesthetist will try to intubate will depend on a number of factors including the individual anaesthetist's experience and the nature of the surgery involved. He explained that different anaesthetists will have different strategies and, in particular, will have a different threshold for going no further and waking up a patient. At any one time, the anaesthetist knows that he has a number of the strategies and choices available. However, Dr Howie described the waking option as a passive thought - something that would be at the back of the anaesthetist's mind. Most experienced anaesthetists would recognise the point at which the best option is to wake up the patient. Although he described the option of waking the patient to be "an absolutely fundamental option that is always available" Dr Howie considered the waking option to be so much a part of the range of options available to anaesthetist that the did not require to have to think about it actively.

[154] It was the most striking feature of this Inquiry that not one of the highly experienced anaesthetists in the room actively thought about the waking option. There

were three clear opportunities to have done so and at none of these stages was this course considered at all. As time went on, the risks of continuing with the anaesthetic increased. None of the obvious difficulties and risks caused consideration of the option to be triggered. The focus on overcoming the individual problems as they arose seemed to prevent proper consideration of the whole clinical picture, including a reminder of the reason why Mr Ewing was undergoing anaesthetic in the first place – a minor, non-essential orthopaedic procedure involving a repair to the tip of his pinkie.

[155] This, then, was by far the most significant omission in the whole proceedings. Had the decision been taken to abandon the procedure and let Mr Ewing waken up, rather than proceed, his death would have been avoided.

(2) ISSUES CONCERNING THE USE OF THE COOK CATHETER

The device

[156] According to the manufacturer's instructions, the Cook catheter is a device intended for use in uncomplicated, atraumatic endotracheal tube exchange. The device used in Mr Ewing's case was the CAE-14.0/-DLT(-EF) product for double lumen endotracheal tubes or endotracheal tubes whose internal diameter is 5mm or larger. (These tubes are longer than the standard ET tube.) The catheter itself is 3mm in diameter and has positional markings placed 5cm to 50 cm markings from the catheter tip and is for use with a 15mm connector. In addition, the catheter is hollow which

allows oxygen to be delivered through it and has side ports to ensure adequate air flow.

[157] The Cook catheter used in this case was coloured green and had a length of 100cm. (The average length of an adult male trachea is 24 cm.) This was a very long, stiff plastic catheter with a firm blunt tip.

[158] Dr McRae explained that a Cook catheter is a useful device in an elective situation in intensive care where the patient is paralysed and ventilated. Such catheters are used routinely, for example, in airway exchange in major burns patients.

[159] Dr Johnston confirmed that the device's indication is for use as an airway exchange – for the exchange of one tube for another, provided the first tube is in the trachea. The catheter is inserted through the defective tube which is then removed. The new tube is then railroaded over the exchange catheter which is itself removed. Thus its use is as a railroading device during airway exchange. Dr Johnston explained that there had to be a combination of factors leading to the requirement to use the Cook catheter, namely, laryngoscopy has been difficult; the patient is asleep; and intubation has been achieved by an alternative means but the tube has subsequently failed. These factors were present in Mr Ewing's case (albeit in an emergency setting).

Anaesthetic team's experience of Cook catheter

[160] The Cook catheter is not a routine piece of equipment. It was Dr Johnston's opinion that the average experience of any consultant surgeon would be that they had

either never used a Cook catheter or that they had done so, like him, on a handful of times in their entire careers. The circumstances in which the use of such a device is indicated occur only rarely.

[161] Dr Singh had never used one before. She would normally use a gum elastic bougie in situations which required the exchange of an airway tube. She had seen a Cook catheter in a demonstration at a meeting of the Difficult Airway Society. She had held one and had observed one being inserted into a mannequin. She had not read the instructions which come with the device.

[162] When Dr Goutcher suggested its use, he himself had only seen a Cook catheter being used in a clinical situation on one occasion some four years earlier. This was in a completely different situation – not in an emergency setting but in a semi-elective airway exchange procedure in a burns patient in intensive care. He could not recall whether he had been shown how to use it by the consultant carrying out the procedure or whether he, himself, had inserted it under direction and supervision. Other than on that single occasion, Dr Goutcher had never seen a Cook catheter in a clinical or training situation. He was not aware that the Cook catheter came with manufacturer's instructions.

[163] Dr McCardie estimated that she had seen a Cook catheter used once, some 9 years prior to 2006. She was unaware of any specific safety precautions that should be observed when using such a device. She herself had never used one.

[164] Dr Glavin likewise had no experience of a Cook catheter although he knew what it was. He had seen similar devices (though possibly not Cook's) used for the administration of oxygen during the changeover of tracheal tubes. However, he had never seen one used in a clinical setting nor used one himself.

[165] Dr Howie had never had cause to use a Cook catheter either. He did not notice it *in situ* inside Mr Ewing and, even if he had, he doubted whether he would have recognised it. In over 30 years of practice he had never seen one used either in a clinical or a training environment. Like others, he had never seen one out of its packet. It is interesting to note that a consultant specialising in intensive care had never seen or used the device.

[166] Sister Forshaw had no experience in the use of such a device. She had not seen one in a training session either and although it was a device which she was aware was on the difficult airway trolley, she, too, had never seen one out of its packaging. As it was her job to be aware of all equipment available in theatre, she vaguely recalled that she had, on some occasion in the past, read the instructions. It was her evidence that when she handed the item to Dr Goutcher she told him that she had no experience of using a Cook catheter nor had she ever seen one used before.

[167] ODP Hamilton had seen a Cook catheter used once about a year before during an ENT procedure. In his experience it was a piece of equipment that was rarely used.

[168] Even the expert witnesses had limited experience of the device. Dr McRae had seen one used once in an elective exchange of an endotracheal tube but, again, had never used one himself. Dr Johnston had used it but only on "a handful of occasions".

Decision to use the Cook catheter

[169] It was Dr Goutcher's suggestion to use the Cook catheter at the stage when Mr Ewing's airway was compromised following the loss of the airtight seal when the pilot cuff burst. Initially it seems that it was suggested as a means of providing stability after the connector rod failed to work properly. However, Dr Goutcher suggested it principally as a railroading device. It was clearly of benefit to have a device in place for railroading purposes given the previous problems with the attempts at direct laryngoscopy. Other devices that might have been utilised included the gum elastic bougie, a piece of equipment regularly used by Dr Singh and Sister Forshaw.

[170] According to Dr Johnston, the decision to insert the Cook catheter as a stabilising rod constituted a use outwith its correct indication and, as such, was inappropriate. The catheter is not designed to stabilise the tube when an ILMA is being removed. However, he considered its use for railroading purposes to be perfectly reasonable and regarded the Cook catheter a far superior piece of equipment to the gum elastic bougie. The former is purpose-made for the process whereas a latter is not. Critically, the Cook catheter has a hollow lumen so that oxygen can be administered directly into the trachea in the process. The gum elastic bougie has no such facility. However, what made the gum elastic bougie impossible to use in this situation was its length. It would have been impossible to maintain the position of the gum elastic bougie by keeping hold of the proximal end of the inner catheter at all

times during the exchange of tubes. Something longer than a bougie was required. The Cook catheter is longer and thus provides a length of tubing outside the patient's mouth which can be easily gripped in the process: it is important to have enough of the catheter outside of the patient to afford grip. According to Dr Johnston, using a long catheter does not usually present problems whereas using one which is too short does.

[171] The decision to use the Cook catheter was considered to have been perfectly reasonable in the view of the hospital inquiry team. According to Dr McRae, they considered the logic of Dr Goutcher's thinking to have been "quite good" as a means of having some sort of guide into the airway while allowing the patient to be oxygenated.

[172] It was also considered to have been a sensible option by Dr Johnston. This was a situation where the ILMA had been removed; there was a small tracheal tube in the airway of a large patient; pulmonary ventilation was inadequate leading to a drop in oxygen levels as a result of the deflation of the catheter; and earlier laryngoscopy had been difficult. Had the Cook catheter been passed in to the trachea and a replacement tube safely railroaded into position and the airway exchange catheter removed, Dr Johnston considered that the use of the Cook catheter would have been ideal.

Conclusion

[173] From the evidence before the court, the decision to use the Cook catheter in the clinical circumstances which presented when Mr Ewing's airway became compromised was a sound and logical one. The need to maintain an airway track was critical if further attempts at intubation were to be carried out given the previous failed laryngoscopy. The Cook catheter would have allowed blind intubation without the need for visualisation of the larynx or the vocal cords and would have had the added advantage of enabling additional oxygen directly into the trachea during the process. This was a clear advantage over other types of railroading devices.

Manufacturer's Instructions

[174] A set of manufacturer's instructions for use is sealed into every Cook catheter packet. Potential adverse events are clearly highlighted before the instructions for use. There are two such events: barotrauma and perforation of the bronchi or lung parenchyma. These are associated by clear warnings and precautions which include that:

- *Catheter should not be advanced beyond the carina. Attention should be paid to the depth of insertion of the catheter into the patient's airway, and to the correct tracheal position of the endotracheal tube. Markers on the catheter refer to distance from the tip of the catheter.*
- *High pressure jet oxygenation may result in barotrauma.*

CAUTION: To avoid barotrauma, ensure that the tip of the catheter is always above the carina, preferably 2 - 3 cm.

[175] The instructions for use contain advice on measuring the correct position of the endotracheal tube against the markings on the catheter and placing a piece of tape or other marker on the catheter at the corresponding distance from the tip to aid in correct placement of the catheter within the endotracheal tube.

The correct procedure using the Cook catheter as a railroading device

[176] Dr Johnston outlined the correct procedure for airway exchange using the Cook catheter as a railroading device and demonstrated that to the court. The first step is to insert the catheter down the (defective) tracheal tube advancing it, critically, to a point above the carina. In accordance with the information sheet that accompanies the Cook airway exchange catheter, it is imperative that stringent efforts are made to maintain the tip of the Cook catheter above the carina. Dr Johnston explained that previous case reports have demonstrated that perforation of the airway had always occurred below the carina. Thus it is considered much safer if the tip of the catheter is maintained some distance above the carina.

[177] The next step is to withdraw the tube leaving the Cook catheter in place. This requires the position of the catheter to be maintained very carefully so that it is neither pulled back or advanced. The tip of the Cook catheter should stay in the same position in the trachea.

[178] The new tube is then threaded over the catheter, through the mouth, through the vocal cords and into position within the trachea. The final step is to remove the Cook's airway exchange catheter leaving the new tube in position.

[179] Accordingly, in order to avoid the two main risks of perforation and barotrauma, there are two fundamental principles which must strictly be observed when using this piece of equipment: first, insertion to a safe distance above the carina; and, secondly, maintenance of the device in position so that it neither advances further into the respiratory structures nor withdraws out of the trachea.

Insertion the Cook catheter

[180] The catheter was removed from its packaging by Sister Forshaw and lubricated so that it would slip easily into the trachea. Dr Goutcher inserted the catheter dowm through the tube and passed it to a point at which he met a gentle resistance. He interpreted this as the carina. He inserted the catheter gently and with care. This was the technique that he had previously been shown some time previouly. He was aware that the catheter should not be inserted beyond the carina.

[181] There are measurement markings on the catheter. Dr Goutcher recalled that the catheter marking at the end of the ET tube was about 40 cm. There was a distance of some 10cm between the end of the tube and Mr Ewing's mouth. Accordingly that meant that there was about 30 cm of catheter inside Mr Ewing's body. However, at another stage in his evidence Dr Goutcher seemed to confirm that there was some 50cm of catheter inside the patient. The evidence about the exact measurements was unclear, confusing and, at times contradictory and it was evidence that was difficult to understand and readily misunderstood. In the circumstances, I was not confident that I could rely on it. In any event, it was clear that, at the time, Dr Goutcher had not been guided by the measurements or the markings on the catheter but by the resistance he met at the carina. Equally, it was clear that whatever measurements may have been

noted by him, no information about them was made known to anyone else present. Dr Goutcher did not recall having confirmed these measurements to the others.

[182] Although the hospital inquiry team acknowledged that the catheter had not been inserted in accordance with manufacturer's instructions, they were satisfied that the device had been correctly placed within the trachea. There was some evidence from Dr Johnston that had the catheter been inserted to a depth of 30cms then it would have been positioned correctly above the carina. He explained that the ideal position for the tip of the Cook catheter should be somewhere between mid-trachea and carina. The adult trachea is approximately 20cms long, the distance from teeth to the mid-tracheal point is about 24cms. The estimated distance from teeth to carina is 34cms. However, Dr Johnston referred to the authoritative view expressed by Professor Jonatan Benumof who recommends that these catheters should never be inserted further than 26 cms and should never be inserted when resistance is encountered. Dr Goutcher accepted that he had failed to observe both of these principles.

[183] Notwithstanding that, had the catheter remained in its original position within the trachea, it is unlikely that any significant damage would have been caused by subsequent events. Therefore it was the failure to secure and maintain a catheter in that position which brought about the catastrophic events.

Maintenance of catheter in position

[184] It was clear from the evidence that no instructions were issued or steps taken to ensure the security of the catheter. It is crucial that the device is neither advanced nor pulled back during railroading manoeuvres. If the catheter is pulled back its tip may

no longer lie in trachea making railroading impossible. If the catheter is advanced, the risk of perforation of the tracheo-bronchial structures increases.

[185] There are several ways of securing the device. The anaesthetist can call out the length to which the catheter is inserted so that other operators know the correct position. Alternatively, a piece of tape can be placed at the lip to act as a marker flag so that if it disappeared or moved, it would be easily spotted. In this connection it should be noted that with so much catheter remaining outside the patient, it would not necessarily have been obvious that the catheter had moved simply by looking at it. However, perhaps the safest method to secure the catheter is to have an assistant delegated the sole task of physically holding it in place.

[186] None of these steps was taken. Indeed, what is clear from the evidence is that scant attention was paid to the position of the Cook catheter after it was inserted. The situation was an emergency one where events were moving rapidly. During the subsequent procedures and manoeuvrings in and around the patient's mouth and airway (including the difficult removal of the ILMA, the defective ET tube, the difficulties in railroading another tube and then the aborted attempts with the fibre optic scope) the Cook catheter was allowed to move and was pushed downwards beyond the carina and through vital structures without anyone noticing.

[187] The failure to secure the Cook catheter was an omission of critical importance to the final outcome. There was evidence from several witnesses, including Drs Howie, McRae and Johnston, that had the Cook catheter remained in position in the trachea, it was unlikely that the administration of inappropriately high flow oxygen at

15 litres per minute would have had any adverse affect. It was the combination of the downwards migration of the catheter and the introduction of high flow oxygen that led to the appalling consequences to Mr Ewing. One without the other would probably not have resulted in his death.

[188] Post-mortem findings confirmed that the Cook catheter had shifted downwards into the right bronchus and from there had perforated the right lung. That perforation in itself was likely to have caused a right-sided pneumothorax following the loss of pressure and collapse of the lung. The court heard how the lung tissue is air filled and delicate and thus easily damaged. It would not have required much pressure for the blunt end of a firm Cook catheter to have perforated the structure. However, the same was not true for the intercostal muscle which was also perforated, allowing the catheter to become lodged outside in the chest wall. That was an issue raised by Dr Howie and considered, for the first time, at this Inquiry.

Mechanism of perforation through the chest wall

[189] Dr Howie simply could not understand how this could have happened and he was at pains to stress just how extraordinary a situation this was: the idea that enough pressure could be applied along a flexible tube to make it go through the intercostal muscle was what was extraordinary to anyone who has ever put an intercostal drain into a big, muscular man like Mr Ewing. Dr Howie considered that the blunt tip of the catheter simply could not be put through the muscle by pressure applied from the other end. This was clearly something which had greatly troubled Dr Howie and prompted him to carry out an experiment of his own whereby he applied high flow oxygen at 15 litres per minute to a piece of butcher meat. He was astonished by the

result. He described how the oxygen acted like a pneumatic drill, destroying and disrupting tissue in its path. He concluded that the high flow of the oxygen had assisted the catheter's path in breaking through the intercostal muscle.

[190] Dr Johnston agreed that significant pressure would have been required for the catheter to go through the intercostal muscles. Trying to pass the blunt end of the catheter through muscle and skin would require "a huge amount of force" (albeit that the catheter had not punctured Mr Ewing's skin). To get through lung and the lining of the lung would give noticeable resistance as it was pushed forward. In his opinion, that resistance could have been interpreted as resistance to the passage of the tube through the vocal cords rather than the tip of the catheter going into the chest wall. He thought that in the attempt at railroading the size 9 tube, the tube and the catheter must have been advanced together instead of the tube having been slipped forward over the catheter.

[191] Initially, Dr Johnston's view was that the addition of high flow oxygen would not have had any effect on the passage of the catheter through the lung and into the muscle tissue. On hearing Dr Howie's hypothesis for the first time, he could not say whether such a scenario was possible or impossible. However, on Dr Howie's experiment being described to him in greater detail, Dr Johnston concluded that, when he thought about it in that way, it was entirely understandable. He could definitely see how that might have happened, although he was not able to say which of the two scenarios was more likely to have caused the perforation.

[192] There was no evidence that suggested any significant force was applied in the course of the attempt to railroad the size 9 tube although clearly some resistance had been felt. Dr Goutcher could not explain how the catheter had gone down as far as it did but was certain that there was never any force applied during the railroading attempts. Thus while it is possible that the pressure applied during these manoeuvres was sufficient to perforate the intercostal muscles, such an explanation did not convincingly resolve Dr Howie's point that, in his opinion, it would be impossible to exert sufficient pressure through a long, flexible length of catheter. I considered this to be an important point. Thus his explanation with reference to an experiment which he had carried out was entirely feasible, as confirmed by Dr Johnston.

[193] Although it was submitted that Dr Howie's evidence on this point was no more than a theoretical hypothesis, I found his analysis logical, coherent and entirely persuasive. It was an explanation supported by a practical experiment which provided a convincing solution to an otherwise unresolved problem. Accordingly, I have concluded that it is probable that the appliance of high flow oxygen created sufficient pressure to allow the already displaced catheter to penetrate the intercostal muscle and enter the chest cavity. Without the pressure effect of the oxygen, it is likely that the displaced catheter would have caused no more damage than a one-sided pneumothorax as a result of the lung perforation. Moreover, such a condition would have been more readily diagnosed without the confusion which resulted from the surgical emphysema and redness which occurred once the airflow penetrated the tissues. Accordingly, the oxygen flow rate hugely exaggerated the impact of the catheter being in the wrong place.

Rate of oxygen flow

[194] The high flow of oxygen was only important because the catheter was in the wrong place. Dr Johnston explained that in the absence of flow through the catheter there is minimal risk of barotrauma. However, once oxygen flow is introduced, attention must be paid to the potential complications of perforation and barotrauma. Here the principle to be borne in mind is that air exit must exceed air entry. He explained that the basal metabolic rate for oxygen is 0.3 litres per minute for a man of Mr Ewing's size. Accordingly, a flow set at 15 litres per minute into the trachea is giving 45 to 50 times the minimum requirement for oxygen. So the anaesthetist must ensure that the flow that is being put in can get out. Since one of the potential complications is barotrauma due to too high flow being used, priority should be given to ensure that the flow is minimised.

[195] That being the case, it is considered vital that clear instructions are given as to the correct flow to be applied. No such instruction was given or sought in Mr Ewing's case.

[196] Sister Forshaw, of her own accord, decided to set the level at 15 litres per minute. She did so because she was aware that Mr Ewing was a big man, he was de-saturating and the oxygen supply through the catheter was his only means of ventilation at that stage. Moreover, she was aware that 15 litres per minute was the flow rate given to patients in the recovery room, although she accepted that she had not taken account of the different size and length of tubing used (the tubing in the recovery room being large bore tubing compared to the Cook catheter, and longer). Sister Forshaw conceded that she did not know what the correct rate of flow was but

when she tried to ask for instructions Dr Singh and Dr Goutcher were busy doing something around the patient's airway. Sister Forshaw could and should have waited to ask for specific direction. In retrospect, she told the court that she was "devastated" that she did not do so.

[197] Notwithstanding Sister Forshaw's position, and that of Dr Goutcher who considered that it was his responsibility to issue these instructions, it is clear that the responsibility to instruct the appropriate rate of flow lay ultimately with Dr Singh as the anaesthetist in overall charge. It was she who had instructed that the oxygen be switched on. Dr Singh, herself, acknowledged that she should have issued clear instructions to Sister Forshaw and this she failed to do.

[198] Although it was not entirely clear from the evidence how long the oxygen flow continued to be delivered at the rate of 15 litres, it was evident that it had remained at this high level for several minutes at least, probably as long as 10 to 15 minutes.. Clearly in Mr Ewing's case it was long enough to cause irreparable damage. He had begun to swell dramatically within 2 or 3 minutes of the oxygen having been switched on. Once the catheter was through the intercostal muscle, oxygen was being delivered directly into the tissues at this rate thus accounting for the dramatic swelling and extensive surgical emphysema. Moreover, according to Dr Johnston, once there was a situation where the tension pneumothorax had caused a massive reduction in cardiac function, reducing the flow would have had no effect whatsoever.

Assumptions

[199] In the course of the proceedings it became clear that a number of assumptions had been made about the ability of others to use the Cook catheter. Dr Singh's position was that when Dr Goutcher had suggested using the catheter, she had asked him if he had used it before and if he felt comfortable about using it. She could not remember if she had asked two separate questions, or one. However she was satisfied from his reply that he felt able to use it and she mentally delegated that task to him. Dr Singh accepted that she should have explored the matter in greater detail.

[200] Dr Goutcher did not remember having been asked about this but accepted that Dr Singh may well have done so. No-one else in theatre at the time remembered any conversation of that nature.

[201] Dr Singh was also aware that Dr Goutcher was a very experienced trainee and that he had worked for a year in neurosurgery and maxillo-facial surgery where difficult airways were common. She knew from her intensive care colleagues that airway exchange was a regular procedure there. Accordingly, she *assumed* that Dr Goutcher was experienced in using the Cook catheter.

[202] Dr Goutcher, for his part, was aware of Dr Singh's considerable experience and, in particular, her work in ENT, a speciality involving difficult airway cases. Dr McCardie, another consultant, was also present and so were two of the most experienced anaesthetic assistants in the hospital, Sister Forshaw and ODP Hamilton. He therefore *assumed* that, compared to him, others there would have had more experience of using a Cook catheter.

[203] Like Dr Singh, Dr McCardie *assumed* that because Dr Goutcher had trained in the neuro-institute that he would have been familiar with the use of and risks associated with the Cook catheter She knew that he had worked in the neuro-institute.

[204] In reality, although those present understood broadly the theoretical purpose and function of the Cook catheter, no-one was experienced in its use and none of the anaesthetists had either read or taken account of the manufacturer's instructions. Dr Goutcher appreciated that it was, not a routine, but a specialised piece of equipment. In his view: "The Cook catheter looks like a very simple piece of equipment to use but I don't think it is." Dr Johnston agreed. Airway exchange is a very simple concept but the potential consequences, if one or two fairly simple principles are ignored, are life-threatening. He considered that there was a low realisation of the extent of these complications within the anaesthetic community. He described the Cook catheter as a useful airway adjunct *in properly-trained and experienced hands*.

The difficult airway trolley

[205] The very presence and availability of Cook catheter on the emergency difficult airway trolley ("the emergency trolley") caused concern to the hospital inquiry team and prompted a review of practice, not only in the Victoria Infirmary, but across anaesthetic sites in the Glasgow and Clyde NHS area. Two of their four recommendations concerned this issue.

[206] Dr Howie explained that the idea behind the emergency trolley was to have ready access to equipment that might be required in an emergency situation,

particularly where difficulties were not anticipated. He explained that, hitherto, there had been no real control over the content of the emergency trolley. It seemed that individual anaesthetists who found a particular device useful would simply add it to the trolley. Consequently, the trolleys tended to be over-populated and contained different equipment at different locations. Thus the emergency trolley had evolved in a somewhat haphazard manner. The hospital inquiry team recognised that this was far from an ideal situation. The panel made the following recommendation:

*It appeared to the inquiry team that the typical (*sic*) intubation trolley was over-complicated and given that anaesthetic teams will now be working on many sites in Glasgow, these trolleys need to be rationalised and be consistent from site to site.*

[207] As a result of this recommendation, a single consultant was identified to take this forward. He obtained the views of anaesthetists and their teams from each department in Glasgow and invited suggestions as to what the minimum content of such an emergency trolley should be. He then produced a design for a standard layout, so that the same equipment would be found in the same position on each trolley in hospitals throughout Glasgow and Clyde. Thus the equipment would be readily available and clearly identified centre. Specifically, decisions were made as to the appropriate basic equipment for the emergency trolley, that is, equipment used only rarely in our "can’t intubate, can't ventilate" situation. The new trolley was designed, assembled and equipment ordered. Additional trolleys were made available so that each anaesthetic area had its own trolley. The programme rolled out over Glasgow and was completed by summer 2008.

[208] In relation to the Cook catheter, no one was able to explain how it had come to be on the emergency trolley at the time of Mr Ewing's death. In light of what happened with that device the hospital inquiry team made a further recommendation: *The anaesthetic section at each site needs to decide whether continue to use of the Cook airway exchange catheter is justified and, if it is, clear protocol is used and training required.*

[209] Following the review, it was decided that, as a default position, the Cook catheter would be removed from the emergency trolley. That was as a direct consequence of Mr Ewing's death. Although Dr McRae explained that the hospital inquiry team recognised that had the catheter not been available on the trolley it would not have been used, there was no evidence before the court on that matter. Dr McRae explained that the team considered that the Cook airway catheter was not the best airway adjunct to be using in such a difficult airway situation. They acknowledged that the guidelines indicated its use in elective rather than semi-urgent or urgent situations. Moreover, it had been a surprise to many anaesthetists in Glasgow that it had been found on the emergency trolley. It was not equipment that many would use. Dr Howie explained that the device has a safety margin which implies that there requires to be a good reason for its use and a good understanding of its use.

[210] Accordingly, it was removed from the emergency trolley. It was recognised that the Cook catheter has a place in intensive care and it has been retained in that department. The device has been used routinely, for example, in burns patients and

has been part of the department's difficult airway management elective airway exchange for many years.

[211] As a result of their findings, the hospital inquiry team made a further recommendation that *All medical staff in Glasgow require to be informed of the dangers of using unfamiliar equipment, particularly when carrying out emergency and urgent procedures.* A letter dated 27 January 2007 was sent out to all medical staff by the then Medical Director NHS Greater Glasgow and Clyde and Medical Director Acute Services Division, Dr Brian N Cowan. The text of his letter was as follows:

Following an inquiry into the death of a patient in one of our hospitals, the inquiry team has asked me to write to all medical staff to remind you that you should ensure that you are trained in the use of all equipment you may be required to use.

While this may seem self-evident, there is an occasional requirement to use equipment, especially in the emergency setting, which you may use at no other time. It is essential that you are familiar with such equipment and its proper use.

[212] A group of anaesthetists at the Institute of Neurological Sciences at the Southern General Hospital in Glasgow having an interest in providing teaching on difficult airway management have since organised courses in Association with the new emergency trolley. Locally based courses for anaesthetists and nursing staff have been introduced to ensure familiarity with the equipment. Trainees who travel among the various hospitals can now expect to be familiar with the equipment available in an

unanticipated difficult airway and to be trained in its use. It remains the individual choice of any anaesthetist as to which equipment he or she will use from the emergency trolley in any given situation.

Conclusion

[213] Taking into account the combined circumstances in which the Cook catheter was used, the action taken by the Health Board in connection with the emergency trolley (including the introduction of training sessions) and the terms of the letter issued by the Medical Director, I gave careful consideration as to whether a finding was merited in terms of section 6(1)(d) - that there was a defect in the system of working which contributed to Mr Ewing's death. Although I was invited to make such a finding by the Procurator Fiscal Depute, after lengthy consideration, I have concluded that such a finding would not be justified. The features were indicative of failures and mis-judgments on the part of individuals in the particular circumstances – circumstances that were complex and highly unusual. Thus it could not be said that they reflected any systemic failure or shortcomings in any method of working in place in the anaesthetic department.

[214] Although the hospital inquiry team considered that the Cook catheter would not have been used had it not been readily available on the emergency trolley, there was no evidence to that effect before me. Dr Goutcher was not specifically asked what it was that had prompted him to suggest using the catheter. In the absence of specific evidence on point, I did not consider that it would be appropriate to draw an inference that he had simply seen it on the trolley and suggested its use. He suggested it because the catheter was hollow and had side ports through which oxygen could be delivered.

It was an unusual suggestion to meet unusual circumstances. There was nothing to say that his choice was influenced by its mere presence on the trolley.

[215] The Greater Glasgow and Clyde Health Board should be commended for its decision to rationalise the content and layout of the emergency trolley, and for the introduction of the relevant training. Undoubtedly that has been a positive outcome in the aftermath of Mr Ewing's death. The greater availability of uniformly stocked emergency trolleys throughout the health board area will both enhance patient safety and promote good clinical practice.

OTHER ISSUES EXPLORED DURING THE INQUIRY

(i) THE DECISION TO PROCEED UNDER GENERAL ANAESTHETIC

[216] No evidence was lead as to what, if any, discussions had taken place between Mr Ewing and the surgeon as to the risks associated with the proposed surgical procedure. Specifically it was not known whether information had been given to him as to alternative forms of anaesthesia and the relative risks of local, regional or general anaesthesia or the option of awake fibre-optic intubation.

[217] In her pre-operative assessment, Dr Singh did not discuss any alternatives to general anaesthesia with Mr Ewing. She had asked him if he preferred to be asleep or awake during the procedure and he had indicated a strong preference to be asleep. It was Dr Singh's evidence that if a patient wishes a general anaesthetic, the anaesthetist is obliged to respect his wishes unless there are definite contra-indications which

would make a general anaesthetic unacceptably risky. Dr Johnston agreed with that: "In the real world, if the patient says I want to be asleep, to try to persuade him to stay awake is going to be time-consuming and probably futile, unless there is a serious concern that local anaesthesia would be significantly safer".

[218] Dr Singh explained that a general anaesthetic is by far the most common type of anaesthesia in Britain whereby the patient is unconscious and unaware throughout the procedure. Regional anaesthesia involves numbing the part of the body to be operated on so that, while the patient may feel sensation, he does not feel pain. More peripheral forms of regional anaesthesia can range from a major nerve block which blocks, for example, all of the nerves to the arm or a leg, or it can be a more minor block of a specific area such as a wrist or an ankle. Regional anaesthesia can be stand-alone when the patient is awake, or the patient can be sedated to varying degrees.

[219] As Mr Ewing had recently undergone an uneventful general anaesthetic at Hairmyers Hospital and there being an appropriate plan in place to counteract the known risks of high BMI and reflux, Dr Singh was satisfied that there were no contra-indications to proceeding under general anaesthesia and, accordingly, she was happy to go along with the Mr Ewing's strong preference to be asleep.

[220] The hospital inquiry report recorded that the decision to carry out the operation under general anaesthesia was because it was a complex operation that might have required up to an hour with a tourniquet on the arm. This would have been difficult to achieve with a ring block of the finger although it would have been possible with more complex regional anaesthesia. Dr Johnson confirmed that the procedure itself

was a tricky one - the fracture had been a complicated injury in the first place and, following the breakdown of the surgical fixture, the repair procedure required would have taken 1 to 1 ½ hours. Regional anaesthesia would have been possible but potentially difficult. It would have involved a brachial plexus block whereby local anaesthetic is injected in the auxilla, underneath the arms or at the clavicle to block the nerves that supply the arm. This was technically possible but likely to have been difficult in someone of Mr Ewing's size. In any event, the procedure was not likely to have been a pleasant one for a conscious patient and in the circumstances it was understandable why Mr Ewing opted for a general anaesthetic.

Conclusion

[221] In the absence of strong reasons to the contrary, the decision to proceed under general anaesthetic was appropriate. Regional anaesthesia was likely to have been challenging for both doctor and patient.

(ii) CHOICE OF BLADES AND MAINTENANCE OF CRICOID PRESSURE

[222] Two attempts to visualise Mr Ewing's larynx had failed because of initial difficulties in moving his tongue and lifting the epiglottis. These difficulties were associated with obstruction caused by the hand of the assistant applying cricoid pressure and the difficulty in swinging the laryngoscope around the obstructing hand. Dr Singh opted at this stage to use an alternative laryngoscope in an effort to overcome the obstruction. The use of an alternative blade is another option envisaged in the DAS guidelines. However, the use of a standard Macintosh blade and the Polio blade during attempted laryngoscopy were the subject of adverse comment by Dr Johnston.

[223] Dr Johnston was critical of the decision to use the standard Macintosh size 3 in the first instance. He considered that a long-blade Macintosh would have been the optimal choice in a man of Mr Ewing's size. It would not be long enough to afford the best chance of laryngoscopy. He considered that it was likely that the length of the blade was one of the factors which made the initial attempt at laryngoscopy difficult and considered that the second attempt should have been with a longer blade.

[224] Dr Johnston felt that the Polio blade was not a good choice for the second attempt to visualise the larynx. Likewise, according to the DAS guidelines, a Polio blade was not what would be considered to be an optimal blade in this situation. There were certain disadvantages associated with the use of such a blade. One of these was poor mechanical advantage. The Polio's obtuse 135 degree angle between handle and blade rather than the normal 90 degree angle, reduced the ability to exert full lifting force on the tongue and hence would have made laryngoscopy more difficult.

[225] Dr Singh had carried out bedside airway tests and from her examination of Mr Ewing she considered that the Macintosh size 3 standard blade which she used for adult male patients would be adequate. Although Mr Ewing had a wider than average neck, it was not longer than average and she did not anticipate any difficulty. Dr Singh chose the Polio blade because she had experience in using it previously when she had successfully overcome obstructions under the chin. That the Polio blade was equally ineffective caused her to think that the difficulty lay in the hand applying the cricoid pressure. She was aware that Mr Ewing had undergone successful intubation

previously and therefore it was likely that the difficulties were due to the different anaesthetic procedure, a view shared by the hospital inquiry team.

[226] It is well known that the application of cricoid pressure during rapid sequence induction can impair insertion of the laryngoscope. In such situations there are options open to the anaesthetist. One is to ask the assistant to move his hand position while still maintaining the required cricoid pressure. Alternatively, he could be asked to reduce or release the pressure. Where there is a poor view, the DAS guidelines recommend that cricoid pressure is reduced and further intubation attempted, if necessary using an alternative laryngoscope. If the cricoid pressure impedes laryngoscopy, it is suggested that the cricoid force should be reduced with suction at hand in the event of aspiration.

[227] Dr Johnston considered that ODP Hamilton could have been asked to flatten his hand against Mr Ewing's chest while still maintaining pressure until Dr Singh was able to manoeuvre the blade into place. Another possibility would have been to attempt to introduce the blade with the handle on one side - rotated round 90 degrees- then twist it round into position, a commonly used technique where there is an obstruction. Dr Johnston readily accepted that the option of releasing the cricoid pressure altogether was a contentious issue, partly because it is not known whether the application of cricoid pressure actually works. Against that is clear and definite evidence that cricoid pressure can make laryngoscopy more difficult. In those circumstances, he would defend anyone who thought it reasonable briefly to remove the cricoid pressure in order to achieve successful intubation. The DAS guidelines recommend that pressure is continued in such circumstances.

[228] Dr Singh was worried about the risk of aspiration and did not want to compromise the protection afforded by the cricoid pressure. For that reason she did not order the reduction or removal of pressure but opted instead to try again using an alternative blade, a blade she was familiar with and had successfully used in the past.

[229] On a risk/benefit analysis of the option to release the pressure, the benefit would be to achieve rapid laryngoscopy and intubation at the risk of compromising the protection against potential reflux and aspiration. In his report, Dr Johnston believed that it would have been more logical to ask the assistant to adjust his hand position than to attempt laryngoscopy, which has failed once already, with a blade which was more difficult to use. In other words, in such a situation priority should be given to optimising the chances of successful intubation even if that means compromising protection against regurgitation of stomach content.

[230] No criticism was made of the decision to maintain cricoid pressure by the hospital inquiry team. Nor did they take issue with Dr Singh's choice of blades.

Conclusion

[231] Dr Singh made a clinical decision not to reduce or release cricoid pressure. That was a matter for her judgment. Although Dr Johnston criticised this decision, he acknowledged that the issue is a contentious one among the profession. There was no criticism of this decision by the hospital inquiry team. The decision was a clinical one for Dr Singh and given the risks of aspiration, the decision was a reasonable one in the circumstances. Likewise, notwithstanding Dr Johnston's criticism of Dr Singh's

choice of Polio blade, this was a matter of individual choice. It was very evident from the evidence that the equipment used is very much a matter of person choice of the individual clinician. Dr Singh had successfully used the Polio blade in the past to overcome obstructions and was experienced in its use.

(iii) DECISION TO REMOVE LARYNGEAL MASK

[232] One of the decisions which led to the critical emergency situation was the decision by Dr Singh to remove the mask part of the ILMA set so that she could establish the source of the bleeding in Mr Ewing's mouth. Although the ILMA is designed so that once the tube is in place the mask part which occupies most of the mouth can be removed, practice varies among anaesthetist as to whether the mask should be removed routinely or left it in place. Dr Singh explained that opinion among the profession is divided on this. The original instructions recommended that the mask part be removed because its continued presence could cause pressure. This was Dr Singh's routine practice. As if to illustrate that conflicting opinion, Dr Johnston's evidence was that standard practice is to leave the mask in place until surgery is completed because the removal of the mask while leaving the tracheal tube in place is recognised to be a difficult thing to do.

[233] Dr Singh's evidence was that there was a significant amount of blood in Mr Ewing's mouth and that the bleeding was persistent, having continued after suction had failed to clear it. As already noted, the accumulation of blood in a patient's mouth can lead to serious complications during the reversal of anaesthesia and subsequent extubation. Thus she considered that the blood presented an unacceptable risk in Mr Ewing's case where an increased risk of aspiration had already been identified. In

addition, she believed that the bleeding had resulted from injury caused by the intubation attempts and so she had a duty to find out where it was coming from. Accordingly, she made the decision to remove the laryngeal mask leaving the tube in place so that she could identify the source and assess the extent of the bleeding. She was experienced in the technique and had removed laryngeal masks on many occasions in the past without difficulty.

[234] This decision was the subject of criticism. At the time, Dr McCardie and Dr Goutcher had doubts about the wisdom of removing it, as did Sister Forshaw. This was, first, because of the amount of bleeding involved. Dr Goutcher thought that the bleeding was slight as did Dr McCardie. Sister Forshaw confirmed that she had only seen a small amount of blood and saliva on the rear of the LMA when it was taken out. ODP Hamilton saw some blood around Mr Ewing's lips but could not otherwise comment. However, none of these persons had a good view of Mr Ewing's mouth. Secondly, they were concerned about the decision to remove the mask in view of the difficulties already encountered in achieving intubation, Dr McCardie and Sister Forshaw felt that it would be best not to do anything that might jeopardise that but neither voiced her opinion. Dr Goutcher had not thought that the decision was unreasonable at the time but felt that most people would have said to leave it in place. All, however, bowed to Dr Singh's experience and judgment and none expressed out loud any contrary view.

[235] The hospital inquiry team concluded that the decision was a matter of clinical judgment and was not one that could be criticised in the circumstances. The increased risk of aspiration had already been identified and Dr Singh considered the bleeding to

have been significant. They supported Dr Singh's decision to remove the mask so that the source of the intra-oral bleeding could be established given that the patient suffered from oesophageal reflux. That, together with blood or fluid in the mouth could have caused some difficulty at the stage of extubation.

[236] Dr Johhnston was more critical of the decision to remove the mask. In his view it was not justified. Looking at it from a risk/benefit analysis, the risks clearly outweighed the benefits. He considered the benefit to be relatively minor whilst the risk was relatively major because of the difficult nature of the procedure and the associated risk of jeopardising the position of the tracheal tube in the airway. He summarised the basis of the decision thus; "the balance of the decision is whether it is worth risking the integrity of the cut tracheal tube - which has now achieved ventilation and oxygenation - in order to assess the source of what appears to have been relatively minor bleeding." He further explained that, not uncommonly, the passage of a laryngeal mask will damage the pharynx (the throat), split the mucosa and cause some bleeding but he had never seen a circumstance where that bleeding did not stop spontaneously. Accordingly, in these circumstances he would have waited to see if the bleeding was going to stop before risking the integrity of the tracheal tube. Therefore, it was his opinion that given the previous difficulty in positioning the tracheal tube, any action which jeopardised the tube was unwise and could only be justified if the bleeding was thought to be life-threatening.

Conclusion

[237] As to the risk caused by the blood in the mouth, I was satisfied that Dr Singh was best placed to identify and assess that. She was able to see inside Mr Ewing's

mouth and had already aspirated blood and had observed persistent bleeding. None of the others could see that properly. Moreover, Dr Singh had already assessed Mr Ewing to be at increased risk of aspiration and the extent to which the presence of blood added to that risk was a matter of clinical judgment for her. As a consultant anaesthetist with extensive experience in ENT cases where blood in the mouth was not an uncommon feature of such procedures, this was not a feature which was likely to worry Dr Singh unnecessarily. Accordingly, I concluded that there must have been a significant amount of blood for Dr Singh to have been concerned about it.

[238] Assessing the soundness of the decision to remove the mask from a risk/benefit point of view is more difficult. In normal circumstances, the presence of blood might in itself have justified the removal of the mask but Mr Ewing's circumstances were not normal. There had already been repeated abortive attempts to intubate and additional jaw thrust had been required throughout these initial efforts. An unanticipated difficult airway situation had arisen and additional assistance had been called for. Thus the situation was far from routine.

[239] Although it was Dr Singh's practice to remove the mask after achieving intubation, she confirmed that it was specifically because of her concern about the bleeding that she decided to remove the mask in Mr Ewing's case. It was not clear whether she would have done so in the absence of the blood.

[240] In assessing the quality of her decision, I had regard to the fact that out of those who gave evidence, Dr Singh was the only person who had extensive experience of using the mask and of its removal. Unlike the others present, Dr Singh used laryngeal

masks routinely. Sister Forshaw had previously assisted where such a mask was used on only two occasions. Dr McCardie thought that the procedure to remove them was "fiddly" and difficult and for that reason she did not use the masks. Dr Goutcher did not routinely use these masks either. Likewise, Dr McRae did not favour the use of the ILMA although he confirmed that their use was common. Nor was the ILMA Dr Johnston's preferred technique. He also described it as "fiddly" to use and it was well known that removing it was a difficult procedure.

[241] Thus, while there was much evidence about how difficult these masks were to remove, Dr Singh was the person best qualified to comment on the technique involved and how difficult or easy it was. Her evidence was that she had never before encountered any difficulty in removing them - she described how every time she had removed the masks previously the procedure had worked "flawlessly". Certainly she could not have anticipated that there would be multiple equipment failure associated with the removal of the mask on this occasion.

[242] On the face of it, Dr Singh made a clear and logical decision. Her decision that the mask should be removed rather than the bleeding allowed to go unchecked was properly a matter for her clinical judgment. However, the question that should then have arisen was whether she should continue with the procedure at all. This was yet another difficulty confronting her in an already unexpectedly difficult procedure to anaesthetise a patient for minor and non-essential surgery. Had Dr Singh also had in her mind that she had already passed a stage at which, according to the DAS guidelines, she should have abandoned her efforts and let Mr Ewing wake up, she might have paused to consider whether, at that stage, she was justified in continuing.

Thus in judging the wisdom or otherwise of her decision to remove the mask, it is difficult to separate it from the decision otherwise to continue with the procedure.

(iv) EQUIPMENT FAILURE DURING REMOVAL OF LARYNGEAL MASK

[243] The removal of the mask is a manoeuvre that requires two people: one person controls the removal of the mask while the other ensures that the ET tube remains in place. The first step of the procedure is to deflate the ILMA. The cuff of the ILMA is let down. A connector or stabilising rod is attached to the ET tube to give it additional length and stability during the process to ensure that the tube does not come away with the mask. The stabiliser is a pencil-sized plastic instrument that is placed at the end of the ET tube so that when a gentle downward pressure is exerted on it the tube remains in place as the mask is pulled up over it. In order to achieve this, the end connection from the ET tube has to be removed so that it can be attached to the connector rod. The ILMA is then withdrawn. Once it is beyond the ET tube, the stabilising rod is removed and the end connector is re-attached to the top of the tube which is then re-connected to the breathing circuit. Dr Johnston commented that it is well recognised that the stabilising rod is a difficult piece of equipment to use.

[244] In removing the mask from Mr Ewing, Dr Singh's recollection was that she was assisted by Dr Goutcher and Sister Forshaw. Dr Singh was in the lead position. She made no mention of any problem until she experienced a difficulty with the stabilising/ connection rod as she attempted to remove the mask. The connections interface between the stabilising rod and the tube felt loose and was not secure. Dr Singh was not confident that the tube would stay in place and so she held onto the junction of the connecting rod and the tube to try to keep it stable. It was at that point

that Dr Goutcher suggested using the Cook catheter as a means of stabilising the tube and to have a pathway for the airway should the tube come out with the unstable connection. The catheter was inserted. At this point, it was not intended to deliver oxygen via the catheter: there was no necessity for that as Mr Ewing's saturation was adequate.

[245] Dr Singh then tried to remove the mask. In the process the pilot cuff and balloon sheared off at the point where it was connected to the ET tube. The consequent loss of the airtight seal, together with the fact that a small ET tube had been used led to a fall in oxygen saturation (from 99 to 69). The defective ET tube was then removed, the LMA re-inserted and connected to the breathing circuit and ventilation was re-established albeit on a temporary basis.

[246] Dr Goutcher recalled that there was an immediate problem with the connector. Instead of popping out easily, it was wedged in tightly to the tube. It required to be "wiggled out" which took a lot longer than it should have. Dr Goutcher went on to describe how the stabilising rod did not fit properly. Instead of there being a neat fit, it was wobbling and not holding the tube. It was clear that Dr Singh was not happy about proceeding to remove the mask as she was not confident that the rod was going to hold. At that point he suggested using the Cook catheter as a means of additional security and he inserted it.

[247] Afterwards when the attempt was made to remove the laryngeal mask part of the ILMA set, the pilot bulb got caught on the metal part of the device, sheered off and broke. Dr Goutcher was sure that this had come about because the whole

procedure had taken “an awful lot longer than it should have”. The airway was then compromised.

[248] Sister Forshaw’s account was in similar terms. She described the initial difficulty in removing the 50mm connector. When she opened the tube prior to insertion the connector was already attached to the tube. In normal circumstances, prior to passing the tube over, she would have removed it and put it back in loosely so that it was easy to disconnect when *in situ.* However, on this occasion she had not done so. The size 7 tube had been a second option and it had not been prepared. She would normally have gone through a system of checks – testing the balloon and cuff, loosening and replacing the connector and lubricating the device before passing it to the anaesthetist. She was aware that events were moving quickly and saturation levels were dropping. In these circumstances, she took the decision to pass it over as it was with the connector still in. (Of course, at this point Sister Forshaw did not know that the mask would subsequently be removed.)

[249] She described how forceps and KY jelly were used in an attempt to remove the connector from the end of the ET tube. Eventually the connector did come away. Dr Singh then asked for a stabilising rod which Sister Forshaw opened up and passed to her. Sister Forshaw explained that the rod was simply meant to sit against the end of the ET tube to stabilise it rather than to screw in or attach in any firm way. She thought that it was Dr Goutcher who was trying to use the stabilising rod and having difficulty. Sister Forshaw told the doctors that. It was obvious that they had concerns about losing the airway and that was when the Cook catheter was suggested. When

the mask was being pulled out, Sister Forshaw described how the pilot cuff became caught on something and snapped with the consequent loss of the secure airway.

[250] ODP Hamilton's evidence on this matter was of little assistance. He was unsure of the chronology of events and his evidence generally was vague and uncertain.

Explanations for the equipment failure

[251] Different explanations for the difficulty encountered with the 50mm connector were suggested. On reflection, Dr Singh wondered if the problem had arisen because the tube had been repeatedly autoclaved. She explained that at that time, the equipment being used was all re-usable. It was sterilised after each use and a card attached to each device recorded how many times it has been used. Dr Singh suggested that a possible explanation for both of the difficulties encountered was that repeated autoclaving might have weakened the rubber silicone which might have perished in the process. Since Mr Ewing's death, the practice had changed. Although re-usable ILMA masks continue to be used, the tubes and the connection stabilising rods are for single use only.

[252] Dr Goutcher thought that the wrong connector was attached to the ILMA. He explained that all connectors are standardised. The one that comes with the ILMA (a smoky black colour) is designed to come out easily. The connector which was in the tube was not the one that comes with the ILMA but a Votex one (a blue colour) which comes with a standard Vortex ET tube. It was quite strong and fitted quite tightly. These connectors are slightly bigger and are not designed to come out easily. He considered that the use of the wrong connector had caused that part of the device

where the stabilising rod is placed to have become stretched so that it did not fit properly but was loose and wobbly.

[253] It was Sister Forshaw's opinion that the problem with the end-connector had arisen because the tube had been sterilised with the connector still attached and that it was a different connector from the one originally supplied by the company that manufactured the ILMA. She explained that it was not the *wrong* connector or the wrong size. The end connectors had been bought in because the original connectors had been getting misplaced when they went to be sterilised. If the tubes are sterilised with the connector attached, it seals them on to the end of the tube the reason for there being so much difficulty removing them. She confirmed that the correct connector is a smoky grey colour while the one used on the day was the blue one. That was why the normal practice was to loosen it, remove it from the tube and replace it less firmly prior to passing it over for use so that it is easier to disconnect once it is in place inside the patient.

[254] As far as the stabilising rod was concerned, at the time she had thought that the angle at which the doctors were trying to manoeuvre the device did not look right. As she saw it, the problem was that the ET tube was too far out of the ILMA. It needed the rigid part of the ILMA to hold it in place and that had not been achieved as the mask was not far enough out of the pharynx (the throat).

[255] The problem associated with the stabilising rod was considered by the hospital inquiry team. They concluded that it seemed likely that the difficulties encountered in removing the laryngeal mask were responsible for the subsequent damage to the tube.

From their enquiries throughout the hospital, they could find no report of any similar damage. However, in accordance with normal practice, the team recommended that an adverse event report be made regarding the ET tube attached to the ILMA.

[256] Mrs Cormack, the clinical risk manager for surgery and anaesthesia and member of the hospital inquiry team, gave evidence in this connection. Where the failure of any device is implicated in an incident, it is the practice to inform the relevant manufacturers and the Scottish Health Care Suppliers ("SHCS" as they then were) so that they can decide whether it is appropriate to issue any warnings or take the matter further. As a result of Mr Ewing's death she arranged a meeting with the SHCS in July 2006.

[257] Discussion took place with the Scottish representative who, in turn, discussed the matter with his English and Welsh counterparts. It was not considered necessary to take any further action although it appears that the reasons for that decision were not communicated to the hospital.

[258] At hospital level, no further action was taken. Mrs Cormack confirmed that at the time of Mr Ewing's death, it was the practice to re-use the tubes and the connectors. A record was kept of the number of times the equipment had been used. She had checked the card on the particular equipment used in Mr Ewing's case and found that it had been used on 6 occasions out of a maximum of 10. Independently of Mr Ewing's death, a decision had already been taken to phase out the repeated use of such equipment. Mrs Cormack again confirmed that the stabiliser rods and the ET

tubes are now disposable and are for single use only. The laryngeal masks continue to be re-used up to a maximum of 40 times.

[259] Dr McRae confirmed that the hospital inquiry team were made aware of the difficulties encountered during the removal of the ILMA although he was not aware of any specific problems with the end-connector. This aspect was not considered during the hospital inquiry.

Conclusion

[260] It does, indeed, seem likely that the problems that arose with the stiff connector and the insecure stabilising rod directly contributed to the catastrophic event when the pilot cuff sheared off and resulted in the loss of the secure airway. The removal of the mask part of the ILMA set was a procedure which at best was described as "fiddly" and required two persons to do it. It was clear that the problems encountered caused significant extra manoeuvring and handling of the mask and tube and, as Dr Goutcher emphasised, took much longer that it should have done. Initially, the evidence about the routine use of end-connectors other than the blue ones supplied with the device was concerning. However, the practice of loosening these connectors prior to their use usually overcame any difficulty. It was unfortunate that in Mr Ewing's case the connector was attached to a tube which had not been pre-prepared but was a tube of second choice which was required in a situation in which speed was of the essence. Sister Forshaw's decision not to loose it but to hand it over quickly was understandable in the circumstances.

[261] Similarly, it was unfortunate that there seemed to be no proper examination of the defective tube and connector. Such an examination might have established the root of the problem. There was some evidence that the equipment had been retained following the fatal outcome of the procedure but what thereafter happened to it and who, if anyone examined it, was not clear. The hospital inquiry team did not appear to focus on this aspect of the procedure in any depth.

[262] Equipment failure did play a direct part in Mr Ewing's death. The description of this unfortunate series of events was not one which would fill the general public with confidence. Nor would any of the explanations put forward. However, given that the practice of re-using that equipment has now ceased these problems are unlikely ever to arise in the future.

(v) DIAGNOSIS OF ANAPHYLAXIS

[263] By the evening of the day following Mr Ewing's death, results of blood tests demonstrated that he had not suffered an allergic reaction. The fact that there was no elevation of the tryptane enzyme ruled that out. Accordingly, the diagnosis of anaphylaxis was incorrect. Whether that presumptive diagnosis had been reasonable one was an issue which arose during the Inquiry. Furthermore, there was a concern as to the extent to which the mistaken diagnosis detracted from and delayed the subsequent diagnosis and treatment of barotrauma.

Symptoms and presentation

[264] Initially, when Dr Singh had noticed the rapid swelling of Mr Ewing's right side, she did wonder whether there might have been a leakage of air and so she felt the loose tissue at the top of Mr Ewing's neck for the classic sign of crepitus which

would indicate air in the tissues (surgical emphysema). Accordingly, she had been suspicious that there was a surgical emphysema at the outset. However, she felt no crepitus and on checking the top of the chest and arm felt what she described as a solid brawy oedema. There was no give whatsoever in the tissues.

[265] Taking account of the lack of crepitus, together with the redness of the skin and the fact that oxygen saturation had fallen from 92 to 81, Dr Singh concluded that Mr Ewing was suffering from a severe allergic reaction to one of the muscle relaxant drugs which had been administered short time before and that this was an anaphylactic shock. She then set in a train the anaphylaxis protocol.

[266] Dr McCardie could not believe what was happening before her eyes. It was so rapid and dramatic that she thought that she was witnessing a tracheal rupture. She had never seen anything like it. She continued to think that it was a tracheal rupture and associated subcutaneous emphysema. That was her first and continuing thought. She recalled that she said something along the lines of "Is it surgical emphysema?" to which she apparently got no response. Dr McCardie had seen patients go into anaphylactic shock before and commented that "It just didn't look like that". Thereafter, events moved rapidly. Very sensibly, after having gained venous access and inserted a cannula into one of Mr Ewing's feet, Dr McCardie focused on administering drugs through that and guarding its integrity, fearing that if lost, it would never be restored.

[267] Dr Goutcher was concerned about an allergic reaction to the Rocuronium which he had administered a very short time prior to the swelling. The first time he had

thought of barotrauma was when Dr Glavin suggested it. Notwithstanding the use of the Cook catheter, barotrauma had never occurred to him. According to him, the presentation did not feel like air under the skin - it just felt like swollen skin. However, after Dr Glavin's arrival, both he and Dr McCardie confirmed that there was then a shift in treatment to barotrauma although the anaphylaxis algorithm continued to be followed.

[268] Accordingly, it was not until Dr Glavin entered the room and heard the loud crack which he took to be air escaping through the skin that barotrauma was diagnosed. Dr Glavin deducted that Mr Ewing's appearance and the crack of the air being forced out through the skin indicated that this was more likely to be surgical emphysema than swelling due to anaphylaxis. The fact that there was no classic crepitus made diagnosis of surgical emphysema more difficult. It appeared that Dr Glavin was the only person present who heard the noise of the air being expelled.

[269] The conclusion of the hospital inquiry team was that: *The initial diagnosis of anaphylaxis was entirely understandable. The swelling and redness in the skin developing rapidly following an injection of a drug (Rocuronium) that has a significance for an allergic potential are all consistent with this. Appropriate medical treatment for this diagnosis was given".* However, in his evidence Dr McRae agreed that subcutaneous emphysema should have been considered at an earlier stage. He considered that anyone experienced with the use of a Cook Catheter should have appreciated that barotrauma is something that is associated with its misuse.

[270] From some elements of Mr Ewing's presentation, Dr Johnston could understand why anaphylaxis was considered. Signs of significant anaphylaxis include low blood pressure, difficult ventilation and cutaneous signs including an urticaria – a nettle-type rash. All muscle relaxants are implicated in severe allergic reaction, including Rocuronium. Given this, the skin changes and the significant physiological changes that occurred, a diagnosis of anaphylaxis was understandable.

[271] However, Dr Johnston was critical that no consideration was given to the idea that the swelling might be due to airflow going through airway exchange catheter. That, he thought, might underline the lack of familiarity with potential complications of an airway exchange catheter on the part of the team. If they had known that the two main potential complications were perforation and barotrauma and they were aware that oxygen flow was being introduced in the catheter shortly before the patient started to swell up, surgical emphysema and barotrauma *should* have been considered as a potential cause.

[272] The complication in Mr Ewing's case was that the swelling occurred extremely rapidly. None of the anaesthetists present had ever seen its like before. Dr Howie explained that surgical emphysema normally evolves a quite slowly, over hours. He had never seen it develop so rapidly or cause major airway comprise.

[273] In connection with the diagnosis, a further factor arose concerning the use of a stethoscope (auscultation) to check whether there was any evidence of lobar or pulmonary collapse. In his report, Dr Johnston could find no evidence that a stethoscope had been used at any point. However, Dr Singh confirmed that at the

onset of the swelling, she had instructed the trainee anaesthetist (who did not give evidence to the Inquiry) to listen to Mr Ewing's chest on both sides. This was to ascertain whether there was evidence of bronchospasm which would have been associated with anaphylaxis. Absence of breath sounds on the right side (the side which was swelling) would have alerted the anaesthetist to the diagnosis of pneumothorax and might have changed the emphasis of resuscitation from anaphylaxis to barotrauma. The trainee was asked to put a stethoscope on both sides of Mr Ewing's chest to listen for wheezing or sounds of bronchospasm. His response was "no wheezing, can't hear much". Dr Singh took that to mean that the trainee was not able to hear much in the way of breath sounds which would not be surprising in a man of Mr Ewing's girth. However, of course, that may have meant that he could not hear any breath sounds because there were none.

[274] In his report, Dr Johnston concluded that: *The diagnosis of anaphylaxis prevented appropriate treatment of the tension pneumothorax. It is difficult to understand why barotrauma was not considered as a possible diagnosis when a far rarer condition (malignant hyperpyrexia) was considered. In addition, barotrauma is listed as one of the main potential complications of the use of an airway exchange catheter.*

[275] As soon as the diagnosis had been made by Dr Glavin, emergency treatment for barotrauma was instituted. The insertion of cannulae to reduce the tension created by the air going into the plural cavity was just a temporary measure. Chest drains were required to ensure re-expansion of the lungs. Dr Glavin immediately asked one of the surgeons to insert the drains but Dr Howie considered it prudent to obtain a chest x-

ray to confirm the underlying pathology. He did, however, recognise that it would have been legitimate to proceed immediately to insert the chest drains.

[276] That inevitably delayed further treatment. Although a portable x-machine was quickly obtained, the procedure itself involved raising Mr Ewing into a more upright position, taking and processing the x-ray, moving to another room to view them and engaging in a discussion, including a telephone discussion with the consultant radiologist. As Dr Johnston pointed out, pneumothorax is potentially a life threatening and quickly developing process. Anything which delays the initiating of treatment endangers the patient although he understood why such an x-ray might have been helpful.

[277] What is clear is that this was a complex and confusing presentation. Had the risks associated with the use of the Cook catheter being fully appreciated, it is likely that barotrauma would have been confirmed as the accurate diagnosis sooner. However, there were features, notably the lack of crepitus that diverted attention from a diagnosis of surgical emphysema to one of anaphylaxis.

[278] Certain other features of Mr Ewing's presentation were consistent with such a diagnosis which was clearly influenced by the recent administration of Rocuronium and the fact that at least two of the anaesthetists present had personal experience of patients having suffered anaphylaxis as a result of the administration of that same drug, albeit that anaphylaxis is a rare response.

Conclusion

[279] In circumstances where high flow oxygen has been introduced through a small bore catheter, the potential for barotrauma should have been appreciated and the diagnosis made earlier.However, it is unlikely that earlier diagnosis of barotrauma would have avoided the fatal outcome. Such was the rapidity and the extensive nature of the swelling that it is highly unlikely that rescue procedures would have been successful. There was evidence that surgical emphysema takes days to resolve. No one had ever seen such extensive surgical emphysema. Although every effort was being made to save Mr Ewing's life, the true position was that adequate respiration was not being maintained and that he was severely hypoxic. It seems, therefore, from the evidence that Mr Ewing's fate was sealed the minute high flow oxygen was introduced via the misplaced catheter. Accordingly, the failure to diagnose barotrauma at an earlier stage, while that may be able to be criticised, was not crucial to the ultimate outcome.

[280] Furthermore, there was no evidence to suggest that the treatment given for anaphylaxis itself was detrimental to Mr Ewing. Either it had no effect or it was treatment that otherwise would have been administered in the rescue attempt.

(vi) PULSE OXIMETER

[281] A clinically bizarre feature of the events which led to Mr Ewing's death concerned the false readings on the pulse oximeter. These readings, which were consistently high, belied the true position that effective ventilation was not being maintained and that Mr Ewing was hypoxic. It was not until the results of an arterial sample of blood gases were received at 1628 hours that the true position was

appreciated. That Mr Ewing was hypoxic greatly surprised and confounded all of the anaesthetists.

[282] Dr Singh explained that from the blood gas reading, she would have expected the pulse oximeter reading to be in the 50s or even the 40s. However, the pulse oximeter was measuring saturation levels throughout the period as between 96 and 98 per cent; in other words, within normal range. She explained that normally blood measured at the periphery through the pulse oximeter is less oxygenated than blood circulating centrally. Paradoxically, in Mr Ewing's case, the pulse oximeter was showing oxygenation in the blood from the ear at a very high level when in fact the sample taken centrally was very low. (A patient is regarded as hypoxic if oxygen saturation levels fall below 90 per cent.)

[283] At the time, Dr Singh was at a loss to explain the discrepancy. However, having discussed matters further with Dr Howie during the following days, she concluded that the pulse oximeter was recording the oxygen level in the tissues, rather than in the actual blood. Given the extensive subcutaneous emphysema, oxygen was getting into the tissues rather than the blood. Dr Howie agreed with the explanation.

[284] The hospital inquiry team concluded that this was a unique clinical situation where none of the clinicians would have expected surgical emphysema to give a false reading on a pulse oximeter. Certainly, none of the anaesthetists who gave evidence to the Fatal Accident Inquiry had come across the situation before.

[285] Dr Johnston's explanation was different. He concluded that the false reading came about as a result of hypotension (low blood pressure) and low cardiac output. He believed that the fairly high reading was probably due to poor peripheral perfusion. However, like all the others, he had never come across the situation before.

Conclusion

[286] Clearly, this was an extraordinary clinical situation and one which misled everyone into thinking that adequate ventilation was being maintained while the opposite was in fact the case. It was unfortunate, to, that the vivid red colour brought about by the suffusion of oxygen in the tissues disguised any cyanosis, a tell tale sign of hypoxia. This was yet another clinical artifact which understandably mislead the clinicians into belief that Mr Ewing was being adequately ventilated.

(vii) PROBLEMS WITH FURTHER ATTEMPTS TO INTUBATE

[287] Several sub-optimal procedures and clinical decisions were identified in the subsequent attempts to re-intubate Mr Ewing following the loss of the secure airway as a result of the problems encountered in the removal of the laryngeal mask: first, the choice of ET tube for railroading purposes; secondly, the lack of muscle relaxation; thirdly, the operator position adopted for the first attempt fibre-optic laryngoscopy; and, fourthly, the administration of an insufficient dose of Rocuronium to relax the patient sufficiently.

Choice of ET tube

[288] The unsuccessful attempt to railroad a size 9 ET tube over the Cook catheter was a highly significant step in the attempts to intubate Mr Ewing. It was the

emergency situation of critical de-saturation created at that point that led to the decision to deliver additional oxygen through the catheter and to its subsequent displacement through the intercostal muscles. There was criticism of the choice of a size 9 tube rather than a smaller tube which might have had more chance of success.

[289] Dr Singh's reason for choosing the size 9 was that it was the tube she was originally going to use and it was readily available. This was the size of tube she would use in an adult male patient – a position confirmed by all other anaesthetists. She had the option of using a smaller tube but smaller tubes had not been prepared and would require to have been used uncut. Dr Singh considered that this would have taken longer and she was concerned that Mr Ewing's saturation levels were already falling. She wanted to complete the procedure in a matter of seconds. At this stage, Mr Ewing's oxygen saturation had dropped to 69 per cent. Dr Singh acknowledged that had a smaller tube been available, she might have used it as a smaller size tube was already in place and it would have been the easiest thing to do.

[290] Both Dr Singh and Dr Goutcher attempted to insert the size 9 tube. In retrospect, Dr Goutcher felt that a smaller size 7 tube would have had more chance of success because it was closer in size to the diameter of the catheter. However, like Dr Singh, when attempting to railroad the tube along the catheter he met with resistance at the vocal cords. He was convinced that part of the problem was that the bevelled edge of the tube was catching on the vocal cords.

[291] Sister Forshaw's evidence was different. When she realised that the size 9 tube would not pass, she asked, by shouting out, whether they wanted a smaller tube. She

said that she had got no response to that question. She confirmed that smaller tubes had been available – every size of tube was available on the trolley right next to her – but she would have needed to check any other tube that was asked for.

[292] Dr Singh did not consider the size of the tube to be the problem. Rather it was the fact that, in the absence of relaxation, the patient's vocal cords were probably closing or had closed. At the stage she had tried to insert the size 9 tube, Mr Ewing had no muscle relaxant on board because the Suxamethonium would have worn off and the effect of the Fentanyl would have been minimal.

[293] Dr McRae agreed that while a size 9 tube was the standard tube for routine intubation of the adult male, in a difficult airway situation as this clearly was, it was better to attempt to railroad a tube that was smaller in size and closer to the size of the conduit. Dr Johnston confirmed that one of the factors which are known to indicate the likelihood of success in any attempt to railroad a tube over a catheter was the size of the tube relative to the introducer. The size 9 tube is a fairly large tube compared to the external diameter of the exchanged catheter (4.2 millimetres). Like Dr Goutcher, he considered that the difference in diameter created a lip. The lip would be much less if a smaller tube were used and thus the risk of it catching on the vocal cords would be reduced. Dr Johnston concluded that the choice of a 9 millimetre tracheal tube for a railroading procedure reduced the chance of success. A size 7 tube would have been a more appropriate size and would have moved a path more easily into the trachea.

[294] Similarly, the hospital inquiry team had some criticism of the procedure, although less about the choice of tube than the fact that Mr Ewing's muscle relaxation would have been fairly limited. While acknowledging that the protocol for difficult airways does not recommend that further relaxants should be given in these circumstances, the inquiry team felt that if the anaesthetist chose to continue to attempt intubation, the chances of doing so successfully when the muscle relaxant had worn off must have been very low. Neither was it clear to them why a move was made to a size 9 tube when a size 7 had already successfully been inserted given the muscle relaxation and the fact that no attempt was made to give further relaxant drugs.

Fibre-optic laryngoscopy

[295] In their continuing determination to intubate Mr Ewing, Dr Singh and Dr Goutcher decided to use a fibre-optic laryngoscope in order to visualize the larynx. Apart from Dr Goutcher, the other anaesthetists were not experienced in using this equipment in technique. Dr Singh was not confident in using the fibre-optic scope and the technique was new to Dr McCardie at that time. However, Dr Goutcher had used the device on numerous occasions before.

[296] The first attempt at the procedure had to be aborted. This was unfortunate because Dr Goutcher had been able to visualize the vocal cords clearly. The problem was that he was improperly positioned – he was standing at the level of Mr Ewing's right hip, at the wrong angle and in a position which required him to over-stretch.

[297] Dr Goutcher had not been able to get into the correct position because Sister Forshaw was on her knees under the trolley attaching tubing to the oxygen cylinder. Dr Singh had, by this time, issued an instruction to attach the additional oxygen supply to the Cook catheter. Sister Forshaw was in Dr Goutcher's way. Having aborted his first attempt, he then waited until Sister Forshaw had completed her task of connecting up and switching on the additional oxygen. Within 30 seconds to a minute later, he moved into the correct position by which time Mr Ewing had begun to swell up resulting a dramatic change so that the vocal cords could no longer be visualized.

[298] As was recognised by the hospital inquiry team, fibre-optic intubation can be a difficult procedure. Therefore, it is essential to ensure that the operator attempts to get into the optimum position before starting. It was felt by the inquiry team that what had happened was probably reflective of the anaesthetic team's inexperience with the technique. Dr Goutcher himself acknowledged that, in spite of his past experience in using the device, he was inexperienced in using it in emergency circumstances.

Dosage of muscle relaxant

[299] Prior to commencing the procedure, further muscle relaxant required to be administered in order to paralyze the vocal cords. Dr Singh instructed that a dose of Rocuronium be administered for this purpose. She had already drawn up a syringe containing 50 milligrammes in preparation for its routine use. Dr McCardie passed the syringe to Dr Goutcher who in turn administered a dose of 25 milligrammes only. The court heard that a normal dose would be somewhere in the region of 30 to 50

milligrammes. His reason for delivering a reduced dose was that a few months before, he had experience of a patient who had developed anaphylactic shock from Rocuronium and so he had reduced the amount accordingly.

[300] Again, the hospital inquiry team was critical of this aspect. They concluded: *This dose was not adequate for the patient's body mass and led to a situation where they had the worse of two worlds. They had a partially relaxed patient but with the possibility of the cords not being relaxed enough to facilitate easy intubation. The drug dose chosen by the specialist registrar was deliberately kept at this low level because of his past experience with an adverse reaction to Rocuronium. The Inquiry Team can see why this decision was made".*

Conclusion

[301] It is clear from the evidence that had a size 7 tube been used, the chances of the successful intubation and the re-establishment of a secure airway would have been significantly increased. Likewise, ensuring that Mr Ewing was sufficiently relaxed so that any tube could pass easily through the vocal cords would have enhanced the changes of success. Likewise, it was clear that the attempts to pass a tracheal tube with the aid of a fibre-optic laryngoscope failed, in the words of Dr Johnston, due to a combination of poor set-up position and incomplete paralysis. The choice of a size 9 tube and the insufficient relaxation significantly reduced the chances of achieving successful intubation. It is unlikely that the failed fibre-optic procedure affected the final outcome as the high flow oxygen was being introduced through the catheter at about the same time. All three issues reflected sub-optimal decision making and procedures as identified by the hospital inquiry.

(viii) TRAINING

[302] Given the lack of familiarity with the Cook catheter, the general issue of training was explored during the Inquiry. Dr Glavin, in particular, given his training responsibilities was able to describe the training regime in relation to consultant anaesthetists.

[303] He explained that at present there is no fixed or structured training programme for consultants. That is due to change over the coming years as the General Medical Council introduce a process which will require licences to practice to be actively re-validated. In anticipation of this, the Royal College of Anaesthetists have provided the basic outline of a training programme which is currently being modified in line with the General Medical Council's requirement for a process of re-validation. At present, it is up to each individual consultant to use the training programme as he or she sees fit. It is the responsibility of every anaesthetist to ensure that his or her skills and knowledge remain up-to-date.

[304] The current mechanism requires each consultant to undergo appraisal on an annual basis. During this appraisal, evidence is collected that the consultant is fit to perform in the various clinical roles undertaken. Included in that evidence will be a review of what the consultant has done to keep up-to-date on the relevant areas. This can include attendance at external courses, shadowing a colleague, attending departmental meetings as well as self-study. The appraisal process is carried out by designated consultants who have received specific appraisal training. It is the responsibility of each individual consultant to keep an appraisal folder which will be

reviewed annually. Accordingly, this procedure is essentially a peer- based appraisal system.

[305] As part of his responsibilities, Dr Howie has responsibility for training the consultant group. He explained that consultants have 10 days per year of study leave when they can attend relevant professional courses, shadow colleagues or undertake personal study in order to consolidate their day-to-day work or study other specialities. Consultants also have 10 hours a week devoted to supporting professional activities which, for example, include observing local colleagues performing techniques that they themselves do not routinely practice. They are required to undertake a certain number of hours of continuous professional development practice (CPD) and post-graduate education.

[306] Dr Howie explained that the re-validation process will include certain core skills which an anaesthetist will require to cover, probably over a five-year period. In addition, for a number of years the Royal College of Anaesthetists has offered a programme of meetings and seminars throughout Britain covering core topics. Attendance at core training sessions will become a mandatory requirement under the re-validation process.

[307] Different considerations apply to the training of anaesthetics trainees who are trained at a number of hospital sites to gain experience of different specialities. Dr Howie explained that they are exposed to a far greater range of opportunities and techniques. Their training regime is highly systematic and is overseen by the West of Scotland Training Organisation.

[308] Dr Johnston alluded to the training which was available in connection with difficult airway situations. As one of three principal trainers in Aberdeen, he teaches trainee anaesthetists on how to manage difficult airways. In addition, there are regular courses run by the Difficult Airway Society. There are several excellent workshops on difficult airway skills which allow anaesthetists to practice their practical skills on mannequins and refresh their theoretical knowledge. In addition, there are centres where simulated emergency scenarios demonstrate what to do in a controlled environment, with de-briefing feedback at the end. He considered simulator-based training to be ideal for this purpose as these emergencies are rare but require rational decision-making. Dr Glavin explained that there is a Scottish Clinical Simulator Centre training facility in Stirling where he is an educational advisor.

[309] In his report, Dr Johnson considered that priority should be given to training all anaesthetists in the correct use of airway exchange equipment which is rarely used but can be useful in emergency situations. Similarly, all anaesthetists must ensure that they are familiar with up-to-date strategies for the management of difficult airway situations.

Conclusion

[310] The anaesthetic team who were at Mr Ewing's side were highly experienced and skilled practitioners. There was no evidence that any general lack of training contributed to Mr Ewing's death. The issues surrounding handling of the Cook catheter related more to lack of experience in the use of a particular piece of equipment than any systemic lack of training. It is for individual practitioners to

accept responsibility for using particular equipment. The procurator fiscal depute invited me to make a finding under section 6(1)(d) that the failure to have on-going training for consultants anaesthetists in the use of equipment on the emergency trolley amounted to a defect in the system of working which contributed to Mr Ewing's death. The deficiencies associated with the use of the Cook catheter have been included separately as a finding under section 6(1)(c) and (e). As to the emergency trolley, this has since been overhauled. Now that the trolley is uniform throughout the Glasgow and Clyde hospitals, specific training in the equipment to be found on the trolley, including the specific layout, is appropriate and has been implemented.

[311] In listening to the evidence of a number of anaesthetists and assistants, it was obvious was that techniques and practices vary and that the decision to use one piece of equipment in preference to another is very much a matter of personal choice on the part of the individual anaesthetist. Therefore, it would be impracticable – and unnecessary – to ensure that all anaesthetists were trained in the use of every piece of equipment. The terms of the letter which was issued by the Medical Director following Mr Ewing's death served as a stark reminder of the responsibility of each individual practitioner to ensure that before opting to use a particular piece of equipment, he or she is sufficiently familiar with it and properly trained in its use. Certainly in Glasgow and Clyde hospitals, others in the anaesthetic team may now safely assume that their colleagues do, indeed, have the requisite experience to use any piece of equipment retrieved from the emergency trolley.

[312] Accordingly, insofar as any training issues arose in connection with equipment, these have been addressed by the prompt action taken by the Health Board in response to the findings and recommendations of the hospital inquiry panel.

CHANGES TO PRACTICE

[313] Dr Singh explained that Mr Ewing's death had had a profound effect on her personally and on the team. Furthermore, she explained that lessons had been learned and that she had made changes to her own practices. Most significantly, where surgery proceeds in a patient with a high BMI, she explains to these patients that if she encounters difficulty, she will have to waken them up. She informs the theatre staff of this back-up plan. She now also explores the option of regional anaesthesia wherever possible in patients admitted for elective, non-essential surgery. Others, too, have made changes to their practices.

[314] The circumstances of Mr Ewing's death have highlighted an extraordinary situation where no thought was given by anyone to terminate the procedure and waken him, despite this being described as an absolutely fundamental option available to all anaesthetists. In circumstances where the procedure should undoubtedly have been abandoned and the patient allowed to waken, this option was not, at any point, considered by any of the three experienced anaesthetists. The question arises whether there is a need, through training, to reinforce the requirement to consider this option actively. Although the choice to waken a patient may seem so basic and so obvious that anaesthetists need no reminding, the tragic circumstances of Mr Ewing's death would tend to suggest otherwise. This may be a matter which should be considered by the relevant training bodies. Accordingly, I recommend that a copy of this

determination be sent to the Royal College of Anaesthetists for any further action which they may deem appropriate.

[315] In conclusion, I wish to record my thanks to the legal representatives for their helpful submissions and for their courtesy throughout the Inquiry. I am indebted to Miss O'Sullivan for her efficient, thorough and sensitive presentation of the evidence in the public interest.

[316] Finally, I wish to pay tribute to those members of Mr Ewing's family who listened to the evidence during the Inquiry. They conducted themselves with great courage and fortitude in what were harrowing and distressing circumstances. Mr Ewing's death occurred in highly unusual circumstances which arose from a combination of events which are unlikely ever to be repeated. While that may be of some reassurance to the public at large, it will be of little comfort to Mr Ewing's relatives. It remains for me to express my deepest sympathy to Mrs Ann Ewing and her family in relation Gordon Ewing's tragic death.