Responses to queries dated 26/10/2011 by the Inquiry into Hyponatraemia Related Deaths raised regarding previous reports on Adam Strain>

<u>Dr Simon R. Haynes</u> <u>1st November 2011.</u>

Sim A dagues

(a) In your Supplementary Report to the Inquiry, dated 7th October 2011, at page 4, you state that "anaesthesia cannot be safely provided single-handedly and suitable assistance is required [...] The impression conveyed by the documents available to me is that at RBHSC in 1995, there was no specific nurse or ODP whose job it was to provide anaesthetic assistance to Dr Taylor during Adam Strain's operation."

Dr. Taylor in a recent Witness Statement to the Inquiry (WS-008/3) has stated:

- There were two qualified nurses and a nursing auxiliary present before the anaesthetic was commenced in Adam's case. (Answer to Q70(c))
- One of these qualified nurses was his anaesthetic nurse. (Answer to Q70(d))
- The anaesthetic nurse's duties were to prepare the anaesthetic equipment, including the endotracheal tubes, laryngoscopes, suction devices and sterile trolleys for procedures prior to the arrival of the patient in theatre. He/she would provide drugs for him to draw up including controlled drugs, check the consent form, confirm the patient's identity on arrival in theatre and preoperative checks. Following this, the nurse would assist him in procedures, including venepuncture, induction, intubation, venous access, arterial line, CVP and epidural, as well as taping and securing these devices and maintaining the child's temperature. (Answers to Q70(e) and Q92(b)).
- It was normal practice to have an MTO in addition to an anaesthetic nurse in 1995 at the RBHSC. (Answer to Q70(f))
- The MTO was required to prepare the electronic monitors and anaesthetic machine prior to the child's arrival in theatre. The MTO was also responsible for the zeroing of the arterial and CVP lines and attaching these to the monitors. (Answer to Q92(b))
- (i) Assuming that the 'anaesthetic nurse' was also one of the three members of the theatre nurse team, and in the light of Dr. Taylor's comments, please provide your view of the adequacy of the assistance available to him both before and during Adam's surgery.

Response:

Both of the qualified nurses in their respective witness statements described their duties as either scrub nurse or floor nurse for the operation. Neither described herself as the anaesthetic nurse. An auxiliary nurse is not trained to provide anaesthetic assistance. The MTO fulfilled only some of the technical duties normally undertaken by an anaesthetic nurse or ODP, not all. It is therefore unclear who was the designated anaesthetic assistant. My impression therefore is that one of the scrub/floor nurses must have doubled up as the anaesthetic nurse assisting Dr Taylor, and as such would only have been able to assist him during induction of anaesthesia and preparation of the patient for surgery and would not have been available during the operation itself. If that is the case, then my opinion remains that Dr Taylor was not provided with adequate anaesthetic assistance by a suitably trained individual who had no other duties throughout the course of the operation.

- (b) In your Supplementary Report to the Inquiry at page 6, you state that "Electrolyte assays in blood gas machines will be subject to less error if the appropriate anticoagulant is used - ideally syringes containing balanced lithium heparin crystals rather than liquid sodium heparin (as is frequently the case) should be used."
 - (i) Please find attached witness statement from David Wheeler, business manager for the Critical Care and Clinical Chemistry Division at Instrumentation Laboratory UK Ltd – the manufacturers of the IL Blood Gas Analyser 1400 machine, serial number 89070125 used in Adam's case. Please indicate if the details in this witness statement cause any re-evaluation of your previous conclusions, and if so, what re-evaluations are required.

Response:

When initially asked to consider the accuracy of sodium assays carried out using a blood gas machine I did not even consider that results may be inaccurate – as previously mentioned I have relied on blood gas machine electrolyte assays for many years. By doing so I believe that I have prevented harm from coming to children in my care.

I subsequently investigated as best I could, with the assistance of the staff in the biochemistry department in the hospital where I work, including using their contacts, how accurate point of care electrolyte testing is. Inadequate care with sampling technique and machine maintainence may give misleading results, but otherwise sodium assay performed by a blood gas machine can be relied upon as being accurate.

David Wheeler in his statement is categorical that the IL 1400 machine could be relied upon to give accurate sodium results. If sodium heparin was used as an anticoagulant (sodium heparin is routinely kept for patient administration as an anticoagulant in operating theatres), then any error thus produced would be to give

too large a sodium reading by 1-3 mmol/l. Therefore the sodium concentration in Adam's blood may well have been even less than the 123 mmol/l measured during the operation.

The statement by David Wheeler supports my previous opinion that the sodium measurement carried out during the transplant operation in Adam Strain indicated that his serum sodium concentration was dangerously low and that corrective measures to treat cerebral oedema should have been instigated by Dr Taylor. David Wheeler's statement makes me even more convinced that sodium measurements using the IL 1400 blood gas analyser at an earlier stage during Adam's operation might have prompted Dr Taylor to alter Adam's fluid management at an early stage , thus preventing dangerous hyponatraemia from developing.

- (c) In your Supplementary Report to the Inquiry at page 9, you state, "it would be reasonable to anticipate that some thrombosis of the venous drainage system on the both sides of Adam's head and neck might have occurred consequent to the presence of indwelling venous catheters."
 - (i) Please explain why you consider that there might have been "some thrombosis of the venous drainage system on the both sides of Adam's head and neck".
 - (ii) The catheter Dr. Taylor inserted into the right subclavian vein passed into Adam's right internal jugular vein, which had never previously been cannulated. Please explain whether that has any impact on your statement that "it would be reasonable to anticipate that some thrombosis of the venous drainage system on the both sides of Adam's head and neck might have occurred consequent to the presence of indwelling venous catheters."

Response to i and ii:

History of central lines in Adam:

• The list provided of procedures is possibly inaccurate. I presume that there was only one laparotomy which was carried out on <u>28/11/91</u> rather than one on 27/11/91 with another on 28/11/91. I assume that Dr Gallagher incorrectly dated his anaesthetic chart as 27/11/91 (049-028-073) for the operation on 28/11/91 hence the confusion. On this occasion he inserted a central line into the left subclavian vein without difficulty. There is no x-ray made available to me, but I assume that the line tip would have been either in the superior vena cava or the right atrium. I presume that this was a temporary central line which would have remained in place for up to 10 days.

- 8/12/91: A consent form (049-034-237) for ureteric stenting, insertion of Broviac line (ie long term central venous catheter) is dated 7/12/91. An anaesthetic chart 049-026-063/4 is dated the following day (8/12/91). On this, chart Dr Crean notes that a left internal jugular line was in situ - this is presumably the line inserted by Dr Gallagher on 28/11/91. This being a temporary line, it would have had to be removed at around this time because of the risk of it introducing infection into the bloodstream. Dr Crean on the back of his anaesthetic chart requests that a chest x-ray be performed postoperatively to assess central line position. Although no operation note is available to me, I assume that a long term central line (Broviac line) was inserted at this time. I cannot find a note of where it was inserted, but I suggest that if the previous line was left sided, it is likely that the new Broviac line would have been inserted on the right side.
- <u>28/12/91</u>: there is an operation note and anaesthetic chart for insertion of a central line via a cut-down in the left ante-cubital fossa. (050-015-047 and 047-006-013). The Broviac line inserted on 8/12/91 was noted as being present on anaesthetic charts dated 24 and 25/12/91 (049-009-019 and 049-013-024)
- <u>29/5/92;</u> a Broviac line was inserted via the left facial vein (although the pathologist describes a suture around the left internal jugular vein at post-mortem examination). This line remained in place until 9/2/95 according to the letter from Brangam Bagnall and co. dated 26/4/2005.

Dr Armour in her postmortem report forming part of her deposition (011-010-037) describes 2 healed scars 2.5 cm long on the right side of the neck, and one 3 cm long on the left side of the neck. This means that there had been two cutdown procedures on the right side of Adam's neck, and a third on the left. <u>These findings contradict the list of cutdown procedures above which only account for two of the three operation scars on the neck</u>

On page 011-010-039 she states that there was a suture on the left side of the neck at the junction of the internal jugular and subclavian vein – it is not clear at this point in the report if this suture was around a vein or in the overlying skin. However, she states categorically (011-010-041 5th paragraph) that the left internal jugular vein had been ligated.

Dr Armour also states that there was no evidence of obstruction of the great veins. She does not state if this comment is made following external inspection of the veins, or if the veins were opened and either the interior examined or an attempt made to pass a probe along the length of the veins. My experience in conjunction with that of my cardiac surgical colleagues is that a normal external appearance of a vein is no indicator that the inside of the vein is patent. throughout its length if there has previously been a cannula within.

Central venous cannulation in small children frequently leads to thrombosis (clot formation) in proximity to a cannula with subsequent obstruction of veins. The thrombus formation may be at the site of insertion, but is more frequently in relation to the line tip. This tendency to thrombosis and obstruction of great veins in relation to central lines can render some children with certain kinds of heart defect inoperable. It is my experience of this problem over 17 years as a consultant paediatric cardiac anaesthetist that leads me to suspect that it may have been an issue with Adam. The availability of portable ultrasound equipment in recent years in the operating theatre which allows imaging of neck veins has provided practical evidence that this problem occurs frequently, much more often than was previously recognised. It is problematic in some cases even after brief previous episodes of central venous cannulation.

- In summary: there is no evidence that there was definite thrombosis and obstruction of Adam's great veins, equally there is not any evidence that they were patent and of normal diameter throughout their length at the time of his transplant operation. My personal experience of anaesthetising many hundreds of children over the years leads me to suspect that there might have been some narrowing of Adam's great veins caused by previous central line insertion.
- (iii) Dr. Taylor in his recent witness statement to the Inquiry (WS-008/3) stated "I had attempted to withdraw and re-wire the [CVP] line and re-insert it but I was still able to palpate it in his neck. I had considered trying his other subclavian but I was not certain that I would have been successful in locating the vein or that it would have found its way into a better position in his SVC."
 - (1) Please provide and explain your view on whether Dr. Taylor should have tried again to cannulate the right internal jugular vein once he felt the tip of the catheter in Adam's neck.

Response:

Given that Dr Taylor had already had numerous attempts at central line insertion, it is my opinion that his decision not to further pursue cannulation of the right internal jugular vein was correct. There was no guarantee of success, and he could have caused harm by doing so.

- (d) In your Supplementary Report to the Inquiry at page 12, you state, "Given the previous history and the fact that Dr Taylor had difficulty cannulating one of the great veins in the neck, surgical cutdown onto a jugular vein might have been difficult".
 - (i) If Adam's right internal jugular vein had been patent, what effect (if any) would this have on your statement that "*surgical cutdown onto a jugular vein might have been difficult*"?
 - There had been a previous cutdown onto the right side of the neck (as shown by the presence of a surgical scar). In a child of Adam's size I believe it likely that if the vein had been patent, Dr Taylor would have been able to cannulate it percutaneously. The fact that he could not suggests to me that the vein was obstructed, and even if dissected out surgically, it would have probably been difficult to advance a catheter into it

- (e) In your Supplementary Report to the Inquiry at page 12, you state that "the guidewire, when introduced into the subclavian vein through the needle ….could only be passed towards the head, rather than towards the heart."
 - (i) Please explain in detail what you mean by your statement.

Response:

(1)

Please see diagrams below and refer to illustrations in previous report

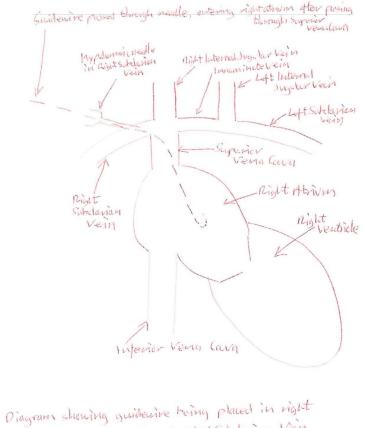
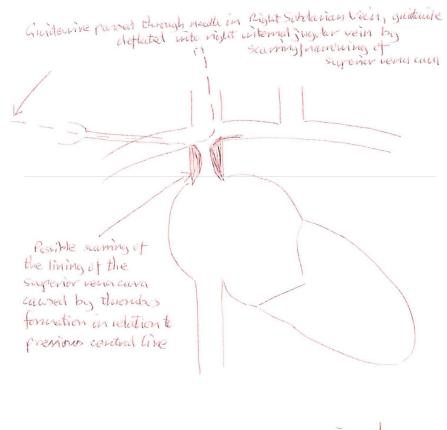


Diagram chening guidenire being placed in ngen atriven via needle puncture of night Subdarian Vien. Inter-connections of Great veins also demonstrated.

This sketch shows the anticipated path of a guidewire introduced through the right subclavian vein in the course of central line insertion



2 Diagram of guidewire advanced into the neck, rather than towards the heart.

The sketch above shows the path of the guidewire during central line insertion as introduced by Dr Taylor in Adam Strain on the day of his transplant. Partial obstruction at the level of the SVC is shown.

(f) In relation to the above queries, please see a letter on behalf of the Trust's solicitors dated 26th April 2005 (Ref: INQ-131-05), in which it is claimed that the view of the Trust was that the left internal jugular vein was never tied off. It is claimed by the Trust that a Broviac central line was inserted in an operation dated 29th May 1992 (Ref: 053-015-052 – operation notes), and that:

"[t]his procedure involved an incision in the left side of the neck and an incision in the chest where the line entered the body through the skin. The incision in the neck was created to access the common facial vein which was tied off. The central line was inserted through the common facial vein into the internal jugular vein and thence to the superior vena cava (SBC in the Operation Notes). This procedure specifically spared the internal jugular vein which was not sutured. The suture material is recorded as PDS (an absorbable suture). The Broviac line remained in place until it was removed because of infection on 9 February 1995 (Ref: 057-102-189). The neck incision was not reopened and the suture referred to (Ref: 057-078-147) was used to close the chest site."

- (i) Please comment generally on the Trust's assertion that the clinical notes indicated that Adam's left internal jugular vein was not tied off.
- <u>Response:</u> The operation note (057-115-336) is clear that the left internal jugular vein was not ligated. The post-mortem report as previously noted states that the left internal jugular vein had been tied off. I cannot comment further.
- (ii) If Adam's left internal jugular vein was not tied off, state whether this fact causes any re-evaluation of your assertions in your Supplementary Report regarding venous drainage of Adam's head and neck.
- <u>Response:</u> I think it very likely that there was a degree of obstruction to the venous drainage of Adam's head caused by previous multiple central venous line insertions. If the left internal jugular vein had not been tied off, only one element of the asserted obstruction would have been removed, ie venous drainage was not normal.
- (g) In your Supplementary Report to the Inquiry at page 16, you state that "[o]nce anaesthetised I would have given him enough intravenous fluid to bring the central venous pressure in the range 6 10 mm Hg. Prior to opening the blood supply to the transplanted kidney enough fluid should be given to increase the central venous pressure to 13-15 mm Hg."
 - (i) Explain what volume of fluid would be required to increase Adam's CVP from (say) 10 mmHg to 15 mmHg and what period

would be required, assuming that Adam had a normal cardiovascular system.

- <u>Response:</u> One cannot say precisely the volume of fluid required. A CVP of 10 mm Hg suggests a fairly full circulation the implication being that a fairly small volume of fluid would then cause a significant increase in CVP. I would have given 5 mls/kg (ie 100 mls) over 5 minutes and assessed the effect. If none, I would have given further aliquots of 5mls/kg until the desired effect was reached. I would suggest that between 5 and 15 mls/kg body weight should cause an increase in CVP from 10 to 15 mm Hg. In Adam's case this would have been 100 300 mls of fluid given over 10 minutes or so. Without a functioning CVP reading, one is guessing. Any fluid given should have been isotonic.
- (h) In your Supplementary Report to the Inquiry at page 17, you state "Obstruction to venous drainage of the head and neck will cause [the face to become swollen]. [...] The degree of facial swelling evident in [the photographs of Adam following his transplant procedure] suggests the presence of very high venous pressure in the veins draining the head this could be the consequence of partial obstruction of venous drainage and/or fluid overload."
 - (i) If Adam's body was generally swollen (i.e. diffuse oedema), rather than just his face, how would this affect your view that "there was obstruction to venous drainage from the head."

- It would suggest to me that there was another reason either in place of or in additon to cerebral venous obstruction to explain the facial swelling.
- (ii) If Adam had generalised oedema, what would you think the most likely cause? Please explain your reasoning.
- <u>Response</u>: For generalised oedema to occur, fluid has to be displaced from the circulation into the tissues – either as extracellular fluid (frequently termed "3rd space loss"), or as intracellular fluid. The following are mechanisms for fluid loss from the circulation:
 - Increased venous pressure in the tissues either locally caused by venous obstruction, or systemically caused by fluid overload.
 - A decrease in osmotic pressure of the blood relative to intracellular or extracellular fluid ie the plasma becomes hypotonic relative to either intracellular fluid or extracellular fluid
 - Loss of integrity of the capillary endothlium in the tissues allowing fluid to leak from the circulation into the extracellular

space. This can occur as part of a systemic inflammatory response –usually consequent to systemic infection

- Life threatening acute hypoxaemia will cause a degree of oedema there is no evidence that this was an issue in Adam's case.
- Regardless of the mechanism, fluid loss will be greater because of gravity in dependant areas – an example in normal life being swollen feet and ankles at the end of a long day spent standing.

For Adam to have had generalised oedema the likeliest cause is a combination of fluid overload and most importantly a decrease in the osmotic pressure of his plasma consequent to dilutional hyponatraemia

(iii) What evidence is there that Adam's swelling was confined to his head and neck?

Response:

Without having seen Adam around the time of his death (apart from the photographs provided by the Inquiry) I can only comment on the appearance of his body as informed by the descriptions provided in the various witness statements.

The photographs sent to me (093-005 008 to 13) show very marked swelling of Adam's head and arms – no other part of his body is seen. The swelling seen both when Adam was in PICU and following death is especially marked when compared to the two photographs of him at home.

Dr Armour in her post mortem report (011-010-040, last paragraph), states "The autopsy revealed gross cerebral oedema....It was the effects of this massive swelling of the brain which caused his death....There was no significant oedema of any other organ." She also states (011-010-041) that "The autopsy revealed ligation of the left internal jugular vein"

Debra Slavin on page 2 of her Inquiry witness statement describes Adam as being very bloated – but does not state if the observed swelling was confined to Adam's head and neck or noticeable everywhere.

(iv) What would be the significance for your view of the likely cause of Adam's oedema, if venous drainage of his head and neck was normal on the right side?

- If the venous drainage on <u>both</u> sides of the neck was normal, then my view would be that Adam's oedema was caused by dilutional hyponatraemia and fluid overload
- If the venous drainage on the right side was normal but there was a narrowing on the left, then my view would be that Adam's oedema was caused by dilutional hyponatraemia and impaired cerebral perfusion consequent to cerebral venous obstruction

- (i) In your Supplementary Report to the Inquiry at page 19, you state, "I get the impression that everything was hurried, that tensions had developed between the surgeon and anaesthetist, and that there was not adequate dialogue between those involved."
 - (i) Please explain the basis of your impression that "tensions had developed between the surgeon and anaesthetist".

- The operation was scheduled to start at 6 am, yet Adam was not anaesthetised until 7 am – for an operation to transplant a kidney that was known to already have a lengthy cold ischaemic time. Even in the most amiable circumstance this is likely to lead to tensions among the team.
- The tone of Dr Taylor's reponses, eg in his witness statement 008/3, para 32, 32c, 35 e,f,g, suggests to me that there was not much communication taking place between surgeon and anaesthetist.
- Dr Taylor implies that there was a lot of blood loss during the operation, Mr Keane refutes that. A proper discussion would have clarified the issue at the time the two individuals for whatever reason did not make the effort to discuss the difference in perceptions.
- Para 35 e in witness statement 008/3: Dr Taylor obviously encountered difficulties with central line placement yet he did not discuss this with the surgeon. Was this because the atmosphere was such that he did not feel comfortable doing so?
- Reading and re-reading the various witness statements does not reassure me that surgeon and anaesthetist were working effectively together as a team, communicating well with each other. This may be a misconception, but it is my perception.
- It is not clear to me if Dr Taylor visited Adam himself on the morning of surgery. In his witness statement 008/3 para 11 he states that he met Adam at 0545h. Mrs Slavin (WS 001/1 page 2 para 2) states "One of the first concerns I had was that Bob Taylor did not appear on the morning of the surgery to take Adam's blood"
- (j) In your Supplementary Report to the Inquiry at page 26, you state that you thought it likely that during transfer to PICU "Adam's position had altered and that blood was not able to drain freely from the head and neck – there being intermittent obstruction of the neck veins caused by narrowed veins consequent to previous central line insertion compounded by catheter placement in the internal jugular vein. Having noted the degree of swelling visible in the pictures of Adam's face at the time of death I believe that there was obstruction to venous drainage from the head."

(i) Please explain what you mean by "intermittent obstruction".

Response:

Obstruction which is not present all the time. In this case it may have occurred in a neck vein only when the head was turned to one side

(ii) Please explain what you mean by "*narrowed veins*", identifying the veins in question, stating when and explaining how you consider they became "*narrowed*".

Response:

Please see (e) above.

(iii) If the CVP decreased during transfer of Adam from theatre to PICU because "*Adam's position had altered*", would slight withdrawal of the catheter at the beginning of the case have been able to produce a more dynamic waveform and more accurate pressure?

Response:

It might have done so but one cannot say with certainty

- (k) In your Supplementary Report to the Inquiry at page 26, you state that *"*[*t*]*he chest x ray shows mild pulmonary oedema"*.
 - (i) What do you think was the cause of Adam's *'mild pulmonary oedema'* by the end of his surgery?

Response:

Excessive volumes of intravenous fluids being administered.

(ii) Is the severity of pulmonary oedema seen on his chest X-ray consistent with his oxygenation in the PICU and with his oedema elsewhere? If not, why not?

Response:

Yes. It correlates with the fact that he was ventilated with 50% oxygen, achieving adequate arterial oxygen saturation.

- (1) In relation to your analysis of Adam's fluid balance, including intake and output, at different stages on 27th November 1995:
 - (i) Analysis of Adam's fluid loss produced by overnight peritoneal dialysis on 70 nights in July to October 1995 showed variation from about 138 ml to 642 ml; average 290 ml. On one occasion when only

7 cycles were used, loss reduced to 82 ml. (Please find attached Adam's dialysis diary completed by his mother in the months prior to his death). On 27th November 1995, Adam had a shorter dialysis time than normal and was given only 8 cycles rather than his usual 15 cycles (Ref: 093-006-017). State whether these facts cause any re-evaluation of your fluid intake/output calculations/estimates, and if so, what re-evaluations are required.

Response:

- In my assessment I allowed 213 mls for fluid loss during dialysis the night before Adam's transplant. I am of the opinion that that is an accurate estimate. *However*, if one replaces that figure in my calculations of fluid balance with 90 mls, the net result will be that the cumulative fluid balance will be +ve 1871 mls rather than the +ve 1748 mls in my previous calculation.
- (ii) You calculated Adam's blood loss during surgery to be approximately 600 ml between 08.00 and 10.00 (time from start of surgery until vascular clamps), 200 ml between 10.00 and 10.30 (time when vascular clamps applied), and 328 ml between 10.30 and 11.00 (time from when clamps released until end of surgery). Please find attached schedule of haematology/biochemistry results from 26th November 1995 to 28th November 1995. Please indicate if these reports cause any re-evaluation of your previous blood loss calculations/estimates, and if so, what re-evaluations are required. Please calculate the operative blood loss as accurately as possible.

- The blood loss measured by the theatre nurses was 1128 mls. This total was reached at the end of the operation, and no record of the time line of this was kept, and is not usually kept. For the sake of ease of calculation I apportioned this loss according to the periods enumerated by the Inquiry, taking into consideration the time whn I thought that blood loss would occur. Mr Keane in his witness statement (006/3 para 23) suggests that approximately 600 mls of this was other fluids in the operative field. I suggest that the actual blood loss was between 528 mls and 1128 mls, most probably in the region 750 1000 mls.
- 500 mls of red cell concentrate (Hb concentration approx 24 g/dl) was given. The haemoglobin content of this is approximately that provided by 1200 mls of whole blood with an Hb concentration of 10 g/dl. Adam's haemoglobin concentration was approximately 10 g/dl both at the start and finish of the operation. Much of the other fluid given intraoperatively undoubtedly moved to the extravascular space, but a significant, but unknown proportion would have remained within the vascular compartment, thus diluting the haemoglobin content of the blood; thus on the face of

it, it seems that about the same amount of red cells were given as were lost, but if one accepts that the red cells in the circulation were diluted by an unknown amount, then more red cells were given than were lost. It remains an estimate, little better than an informed guess, but working out blood loss this way rather than relying on the loss noted by the theatre nurses suggests to me that the blood loss during the operation was less than 1200 mls – somewhat speculatively I suggest that 800 – 1000 mls would be a suitable estimate for this.

Simon R. Haynes: 1st November 2011