INDEPENDENT INVESTIGATION REPORT

Ipswich & East Suffolk Clinical Commissioning Group

Patient

Prepared for Ipswich & East Suffolk Clinical Commissioning Group

Report Prepared by:

Registered Nurse

Cronin Ltd.

Company number 08514095

Date of Report: 15 September 2016

Contents

1. Instructions

1.1 I have been instructed by the Ipswich & East Suffolk Clinical Commissioning Group (CCG) to prepare an Independent Investigation Report in relation to patient a member of the family. In April 2016 a letter of complaint was received by the CCG from patient's father. Subsequent discussions with patient's father identified that the complaint related specifically to the honest belief that Ipswich Hospital had failed to undertake a full and thorough Serious Incident (SI) investigation into the care and treatment received by his daughter (Patient). Resultant from this alleged failing the Trust had not been able to identify all possible learning opportunities. Additionally it is alleged that Ipswich Hospital has failed to be open and honest with the family throughout the SI investigation process, in accordance with the Duty of Candour Regulations in place at the time of the index event, which is noted to be 2/3 August 2015.

1.2 My opinions within this report reflect my independence in this matter. I have not worked at Ipswich Hospital. I have not worked within the CCG. Prior to my meeting with the patient's family I have never had any contact with any of the family members. I have no conflict of interest with any parties in this matter.

1.3 Case Documentation

I have been sent copies of the following information:

- Patient consent dated 28 June 2016
- CCG Serious Incident closure 2015/26953 dated 5 November 2015
- CCG Reporting and Investigation Guidance for Serious Incidents V 0.2 dated July 2015
- Letter from CCG to father dated 10 June 2016
- Ipswich Hospital NHS Trust Serious Incident Requiring Investigation (SIRI) report dated 23 September 2015
- Final Terms of Reference (ToR) for independent investigation dated 12 July 2016
- Email from the Governance Manager at the Trust to the father of Patient - 11 December 2015 14:53
- Email from Mother to the Director of Governance 11 February 2016 22:13
- Numerous communications including emails, letters and voice recordings made by the family since the index event of 2 August 2015
- Numerous communications including emails, letters, and file notes by the Trust since the index event of 2 August 2015.

1.4 I have made it clear to the CCG and to the family that I am not in a position to review or pass comment upon the medical management of the patient in light of the events that unfolded within the index period of 2/3 August 2015.

1.5 My role is reserved to pass comment upon the areas with the agreed dated ToR dated 12 July 2016.

1.6 I reserve the right to alter my views and recommendations subject to further evidence, which may become available to me.

2. Overview A The Family Perspective

2.1 Patient delivered a live baby vaginally on 18 July 2015. On 2 August 2015 patient self presented to the Accident and Emergency (A&E) unit of Ipswich Hospital at 23:47 in the company of her mother.

2.2 Patient's presenting symptoms included breathlessness. The contemporaneous clinical records suggest that Patient presented with palpitations. The family of patient dispute the assertion that Patient presented with palpitations. Patient's mother recalls advising the treating clinicians that Patient had an irregular heartbeat. Patient's mother recalls advising the treating clinicians that Patient had a history of a pulsating vein in her neck and that this was present throughout her pregnancy. Furthermore Patient's mother recalls advising the treating clinicians that Patient presented with a generalized non-productive cough that was more pronounced when patient was speaking. Patient's mother recalls advising the treating clinicians that there was a family history of Deep Vein Thrombosis.

2.3 Within the following overview of the events that unfolded on and after the 2/3 August 2015 the family of patient dispute the timeline of events. I refer the reader to both the chronology of the family and the chronology of the SI investigation report author, as outlined below within the next section.

2.4 Triage was undertaken at 00:30 on 3 August 2015. Triage was undertaken via the Manchester Triage System (MTS) and resulted in a Category 2 (Orange) being applied to patient.

2.5 At 00:48 on 3 August 2015 bloods were taken from patient. The family of patient allege that medications were administered to patient without her consent at an unknown time, thought to be at some time between 00:48 and 01:20.

2.6 In addition between 00:48 and 02:45 various other medications including Metoprolol, Adenosine and Verapamil were thought to be administered at this time.

2.7 At approximately 02:45 on 3 August 2015 patient's mother recalls being asked to leave the resuscitation room in light of the medical plan of care to carry out a cardio version. Patient's mother recalls being advised by the attending medical staff that cardio version was a novel procedure within the A&E department and that a number of clinical staff would be observing the procedure. At this point in time patient was accompanied by three doctors and 1 nurse within the resuscitation area of the A&E department.

2.8 A rapid sequence induction is said to have been performed on patient followed by cardio version.

2.9 Post cardio-version patient is said to have been in sinus rhythm and the cardio version procedure was considered by the medical staff to have been successful.

2.10 By 04:25 patient is thought to have been extubated.

2.11 At or around this time patient's mother was invited back to the resuscitation room, having been in the relative's room for approximately 1 hour and thirty minutes.

2.12 Patient's mother recalls seeing patient on her right side at this time, as she entered the resuscitation room. Patient's mother recalls that patient was facing patient's mother as she entered the resuscitation room.

2.13 Patient's mother recalls that patient was not responsive, specifically noting that patient did not grip her hand and that her eyes were closed at this point in time.

2.14 Patient's mother recalls that the medical staff advised her that patient would be groggy when patient woke up. Patient's mother recalls that the medical staff advised her that patient would be discharged home later in the day (3 August 2015)

2.15 Patient's mother recalls providing assistance to the nursing staff (n=2) to change Patient's clothes as she had been incontinent of urine. Patient's mother recalls that she had to hold Patient under her arms during this procedure, as otherwise patient would have slid down and off the A&E trolley. Patient's mother considers that patient was unconscious at this point in time.

2.16 Patient's mother recounts that two individuals came to the resuscitation room to carry out an x-ray on patient. Patient's mother recalls that the individuals were carrying what patient's mother describes as large metal plates.

2.17 A mobile telephone call was made by patient's mother to patient's father at 04:43. Patient's mother recalls leaving the bay where patient was located momentarily.

2.18 This call was inadvertently recorded by patient's fathers phone answering service. As patient's mother is leaving a voice mail for patient's father she notes a change in the tone of the voice of nurse(s) and comes back to the bay. Patient's mother describes finding patient in a collapsed state. She describes finding patient's body at the 1000 position and her legs at the 1600 position and arms were extended and her eyes were wide open.

2.19 The available audio recording provides and audio account of what appears to be machines bleeping and muffled sounds of individuals shouting in addition to patient's mother verbalizing her concerns to the individual(s) present.

2.20 Simultaneously patient's mother recalls the attending nurse(s) running away from patient and out of the resuscitation room in what has been described by patient's mother as a panic, leaving patient unattended in the resuscitation room.

2.21 Patient's mother recalls looking towards the open doors of the resuscitation room and seeing other people within the main department, including two paramedics.

2.22 Patient's mother describes a delay, unknown in quantity of seconds or minutes, in advance of medical assistance being provided to patient.

2.23 Patient is said to have suffered from a Pulseless Electrical Activity (PEA) cardiac arrest and was resuscitated by the attending medical staff.

2.24 Post the cardiac arrest the family had a meeting with the A&E staff on the 5 August 2015 and felt reassured at that point in time, in light of the events that unfolded on 2/3 August 2015.

2.25 The family of patient claim that there was no formal communication between the Trust and the family until 27 August 2015, when the father of patient contacted PALS requesting an update following the meeting of 5 August 2015.

2.26 Various communications were undertaken between the family and the Trust following the 27 August 2015.

2.27 The SI report was released to the patient family 59 days post the index event.

2.28 A meeting was held on 16 November 2015 with the Family and Trust to discuss the findings of the SI. The meeting was audio recorded by the family of patient. The patient family continued to protest in relation to SI report outlining a number (n=42) of concerns in relation to the SI management.

2.29 At an unknown date in November 2015 the Trust offered an external review to review patient's cardiology care. At an unknown date in January 2016 the Trust offered an external SI review but at this stage the family did not want an external SIRI as they had lost faith in the Trust.

2.30 By February 2016 the Trust met with the family and the Director of Governance offered to provide a medical review, then offered a sense check, then offered a review of the rapid sequence induction, a cardiology review and an anesthetic review.

2.31 On 31 March 2016 the father of patient wrote to the CCG advising of his concerns in relation to the care of patient.

2.32 On 2 April 2016 the Head of Nursing met the family of patient at the family home and provided an overview of the events leading up to and including the cardiac arrest. New witness evidence from the nursing staff involved, prepared in March 2016 by the Trust, many months after the index event, provided a significant level of new detail that the patient family considered to be contradictory to the data within the SI report and assurances provided historically by the Trust. The net result was that the family became suspicious of the validity of the new evidence base.

2.33 The patient's family set out the following concerns in relation to the SI investigation:

- Key data sets have been omitted
- Not everyone who was present was interviewed as part of the SI process
- The Trust time line of events is contradictory
- The Trust willfully omitted vital information
- The Trust failed to acknowledge that patient's mother raised the alarm at the point of patient's collapse/cardiac arrest and that the attending nurse(s) fled from the scene at or around 04:53
- The Trust failed to address the family's concerns or explore the family concerns that nurse(s) fled from the scene
- The Trust failed to explore the families concerns that the nursing staff who were caring for patient's post cardioversion were not appropriately trained particularly in airway management
- The SI report implies that patient was awake post extubation. This is disputed by the family

- The detail behind the presentation of patient was not picked up by the SI process

- That this was an avoidable Cardiac Arrest was not noted

- The SI investigation report failed to make reference to the family history of DVT

- Key index witness (Mother of patient) was not formally interviewed by SI author

- No formal witness evidence was secured by the Trust with regards to what the mother of patient observed on 2/3 August 2015

- No data from vitals (pulse/Blood pressure/ECG etc.) machines was examined by the Trust as part of the SI process

- There is missing data from ECG's with regards to the subsequent cardiac arrest of patient

- The family were not involved in the SI process

- There has been a lack of objectivity by the SIRI author

2.34 The patient's family conclude that this was a rushed SI investigation and that there has been a cover up post the index event by the Trust.

2.35 The patient's family are of the view that the Trust tried to impress upon the family the pre-existing illness (thought to be Cardiomyopathy) of the patient prior to the cardiac arrest and that this the reason why the patient had a cardiac arrest.

2.36 The family state that they are looking for the truth in relation to the events that unfolded on 2/3 August 2015.

2.37 The family state that they are looking for disciplinary actions to be taken against those involved in the pre-cardiac arrest care of the patient.

2.38 The family state that they are satisfied with the post cardiac arrest care received by the patient.

3 Overview B The Trust perspective

3.1 The events that unfolded on 2/3 August 2015 in relation to patient were formally raised as a SI on STEIS on 12 August 2015.

3.2 A Serious Clinical Incident Group (SCIG) was convened on 1 September 2015. The purpose of the SCIG was to:

- Corroborate if the adverse event is a SIRI
- Agree if immediate mitigating actions are required defined within the policy
- Appoint an Investigating Officer
- Approve the final report and recommendations
- Agree appropriate action plans and identify the appropriate lead person(s)

3.3 Debate was undertaken at SCIG if the care of patient should be raised as a SI as the Trust was of the view that at this point in time patient may not have survived the key index events. The Trust considered that the care of patient was going to be the subject of a maternal death independent enquiry.

3.4 Nevertheless the Trust formally declared the index event as a SI.

3.5 The Trust is of the view that its main focus with regards to the subsequent SI investigation was focused on the medical management of patient.

3.6 The Trust accepts, with the benefit of hindsight that communications between the family and Trust occurred outside of the normal process.

3.7 Normally the Head of the Patient Advice and Liaison Service (PALS) becomes involved in communications between the concerned family and the Trust. In the context of the patient the Head of PALS was connected to the family. The normal default process for the Trust to communicate with families was not followed in light of this family connection.

3.8 The net result was that communications between the Trust and family did not follow the normal process.

3.9 The Trust is of the view that in many respects it over-communicated with the family. The Trust accepts with the benefit of hindsight that the voluminous /numerous mainly verbal communications between the family and Trust were not as effective as they should have been. In part the breakdown in the normal process of communications is as a result of the family connections with the Head of PALS.

3.10 In addition the Trust is of the view that many of the communications were undertaken informally and outside of the normal process, which again with the benefit of hindsight were less than ideal. For example the Head of Nursing at the time made daily visits to patient and the family when patient was on ICU. Furthermore the Head of Nursing visited the family at the family home. The SI author recalls daily interactions with the patient's family when the patient was located on the ITU.

3.11 Although such actions appear to have been undertaken by Trust staff with the best of intentions the Trust recognizes that the majority of its communications fell outside of the normal and agreed processes. The Trust accepts that with the benefit of hindsight the communications between the family was less than ideal. Communication's that occurred fell outside of the normal processes. The family, in many respects were over-communicated with the net result of high volume low quality communications coming from the Trust to the family.

3.12 With regards to the SI investigation key lines of enquiry were identified at the SCIG meeting on 1 September 2015.

3.13 These included:

1. To investigate the clinical management of the Patient leading up to admission 2/3 August 2015 and the first 4 hours in critical care unit
2. To include a review of the obstetric care with specific focus on whether palpitations and possible anemia were known about
3. To review the demand in ED over period 2/3 August 2015 and whether this was (sic) contributed to the clinical management decision made for the patient

3.14 The SI report dated 23 September 2015 did not meet the agreed ToR in full for a reason unknown. ToR 2 was adjusted and not fully reported upon by the Trust.

3.15 With reference to involving the family in the SI investigation the Trust comment that it was not within the culture of the organization to involve the family in SI investigations in 2015, but their involvement was not purposely excluded. The Trust appears to have acted in a traditional paternalist way with regards to the involvement of family member in SI investigations in 2015.

3.16 With regards to the SI process, the investigation was led by the SI author who was allocated the SI to investigate by the SCIG.

3.17 Witness statements were secured from:

1. Dr A typed and signed statement dated 19 August 2015
2. Dr B undated statement hand written
3. Dr C typed but not signed dated 31 August 2015
4. Witness evidence from Nurse A in Charge (NIC) in ED via email dated 10 August 2015

3.18 The Trust is said to have discharged its Duty of Candour formally by letter dated 27 August 2015 making reference to meeting in the A&E department on 3 August 2015. Within this communication the family were advised that the Trust would contact "*you to arrange a follow up meeting to discuss the investigation findings and any actions that we need to take*". The Trust communications referred to above initially were reassuring to the Trust and family. However by early 2016 the Trust became enlightened in relation to the issues at hand.

3.19 The SI investigation report was internally routed through various internal Trust channels throughout September and October 2015, eventually being signed off by the Trust Medical Director on 4 November 2015.

3.20 The SI report was released to the family and by 6 November 2015 the Trust were aware that the family were unhappy and had numerous concerns with the SI report. The father of formally notified the Trust of his concerns outlining 41 questions on 9 November 2015. The family presented 41 questions that needed to be addressed post the production of the SI report. These were acknowledged by the Trust on 10 November 2015. A meeting between the Trust and family occurred on 16 November 2015. The Trust recall that on 1 December 2015 an email was received from the family requesting an external review of the SI report. This communication was acknowledged by the Trust on 2 December 2015 and escalated to the Director of Governance and Medical Director at the Trust. By the 11 December 2015 the Trust agreed via the Medical Director that an external review would proceed.

3.21 Post 11 December 2015 via email both parties were engaged in agreeing and disagreeing the process for external review.

3.22 The definition of an external review was never clarified. It appears that the family expected a fresh investigation. It appears that the Trust were offering an internal review.

3.23 In any event, terms of reference for the internal review or fresh investigation were never agreed by both parties.

3.24 Over the coming few weeks the relationship between the family and Trust deteriorated further.

3.25 By the 11 January 2016 an email was received by Trust from the family chasing the external review and making complaints in relation to a lack of communication. On 12 January 2016 this matter was escalated to the Director of Governance.

3.26 In February 2016 the Director of Governance met with the family, an external medical expert appointed by the family and the SI author. The Director of Governance describes this meeting as challenging in that the family appear to have been dissatisfied with the efforts of the Trust at this time.

3.27 The net result was that the family became increasingly suspicious that the Trust was attempting to cover up actions surrounding the key index events that unfolded on 2/3 August 2015. At this time, in February/March 2016 the Trust realized that there was a lack of consistency in the management of communications between the family and that the Trust position going forward was going to be very difficult.

3.28 Also at this point in time the Trust realized that the initial local investigation was not managed well. The Trust took some efforts to re-examine the key index event of 2/3 August 2015 and noted that local attempts were made to secure witness evidence from the key nurses on shift. It noted a letter from the A&E lead nurse to all staff on duty re the care of patient dated 4 August 2015 requesting statements in light of the events related to patient. However this local investigation was never completed.

3.29 The Trust then made efforts to secure witness evidence from key nursing staff involved in the care of patient in March 2016, some seven months post the index event.

3.30 Statements were secured from the nursing staff involved in the care of PATIENT, one unsigned and undated and one dated 10 March 2016 and signed stating that both nurses were present and with patient at the point of her collapse/cardiac arrest.

3.31 The Trust recognizes that the actions undertaken in March 2016 seven months post the index event could be interpreted as the Trust acting in a way to cover its earlier failings. The Trust rebuts all accusations that it has made any effort to cover up the events surrounding and after the 2/3 August 2015.

3.32 The Trust maintains its position that it has been and continues to be open and truthful with the family.

3.33 With regards to the SI process the completed SI investigation was routed back to SCIG. The completed report was accepted by SCIG and signed as complete. Shortly after this time the Trust recognized in November 2015 the family had a number of outstanding concerns.

3.34 With regards to sharing the lessons learnt from the completed SI report the normal process for sharing lessons learned from SI's in Medicine and Therapies is as follows:

3.35 The Trust advise that each month a division focused SI report is provided to the Division Quality meeting. This report covers potential SIs, cases under investigation, cases which have completed investigations but the action plan has not yet been completed, and the lessons learned from SI's which have been submitted to the CCG in the previous month. Also included are actions, which are overdue for completion and lessons learned from complaints in the appendix. This report is presented at the Division Quality meeting and acknowledged in the minutes, as it is the formal process used for giving assurance and updating the CDG leads on the progress of SIRI cases.

3.36 A copy of the Trust wide SI report is also shared at the Division Quality meeting (this is tabled at the Risk Oversight Committee) so the division can be aware of and share the learning from the Trust wide cases.

3.37 The Division Quality meeting is chaired by the Head of Nursing and each CDG is represented by at least one of their leads (clinical, nursing or operations). The expectation is that they can take the reports presented at this meeting and use them to share information at the CDG quality meetings which will then filter down to ward / individual level.

3.38 Periodically the Trust produces a newsletter, which is emailed directly to all staff in the division. The newsletter covers lessons learned from a selection of SI's, complaints and M&M meetings along with links to the latest NICE guidance and internal guidelines/ policies, which have been issued.

3.39 With reference to the learning from the SI related to patient the Trust discharged its lessons learnt from the medical management of the case to the junior doctor teaching sessions on 19 November 2015. The case was also presented to the Morbidity and Mortality group on 17 December 2015.

3.40 With regards to the balance of the issues raised by the SI report and the outstanding queries from the family, these have not been addressed.

3.41 Chronology

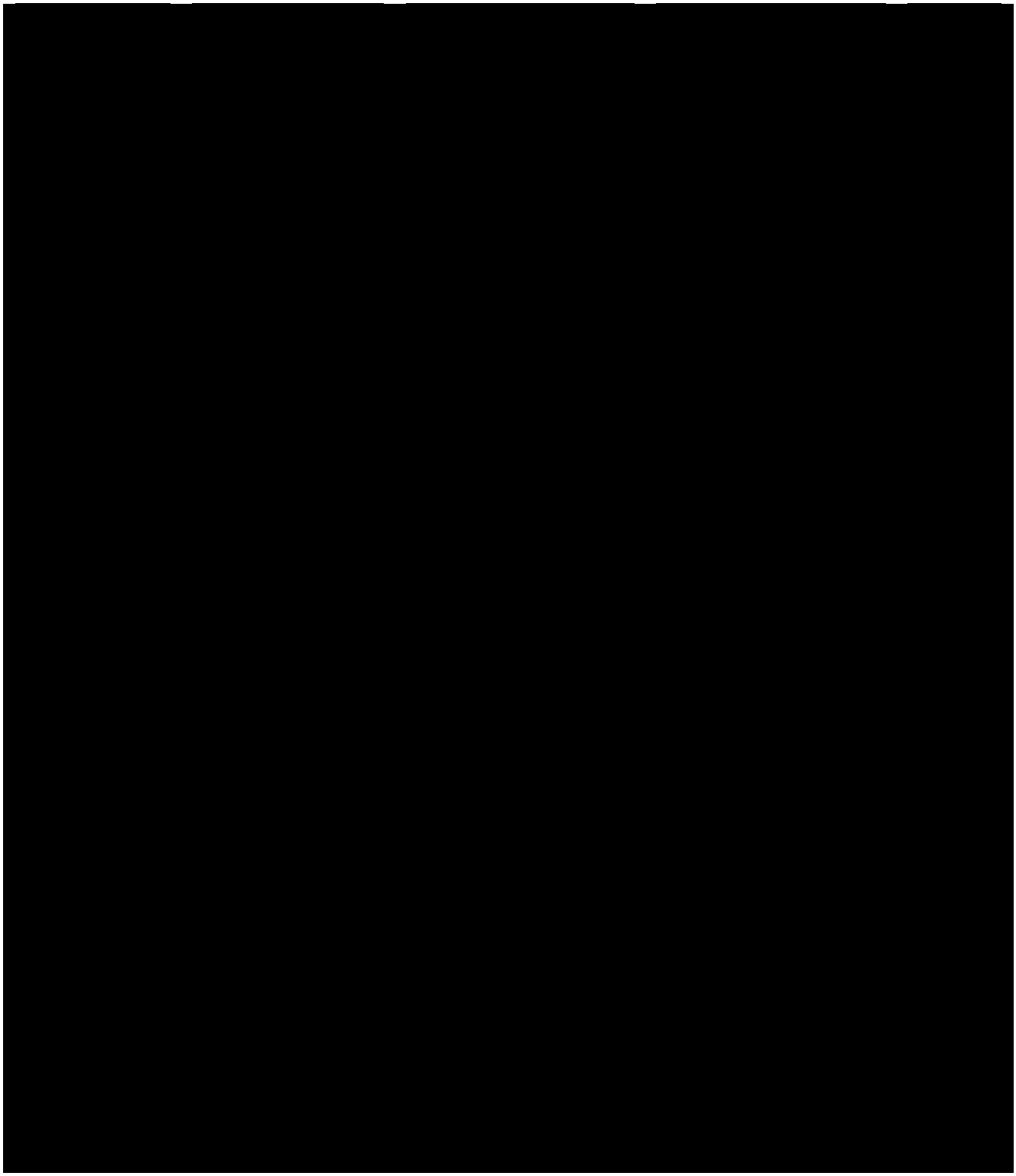
3.42 Conflicting chronologies available. There are areas of agreement and areas of conflict within both chronologies. Both chronologies are presented below over the following pages.

3.43 Patient family chronology

[redacted]

Event date / time	Event/activity	Person involved	Further information	Test Results
[redacted]				

3.44 Chronology from the Trust



4 Agreed ToR dated 12 July 2016

1. To review the original Serious Incident Investigation to assess and advise if the scope of the investigation has been sufficient to consider all the factors that may have contributed to the incident and specifically address the following points:

    - the root cause(s) of the incident
    - contributory factors
    - chronology of events
    - service delivery problems
    - care delivery problems
    - lessons learned
    - recommendations
    - action plan

2. Were the originally identified terms of reference broad enough to promote a comprehensive investigation?

3. Has the Lead Investigating Officer received Root Cause Analysis Training? If not was the Lead Investigating Officer supported through the investigation by an individual with the appropriate Root Cause Analysis Training and experience of investigating serious incidents?

4. Have all individuals directly or indirectly involved in the care of the patient, inclusive of the patient / relatives, been involved in the investigation process? If individuals involved directly or indirectly in the care of the Patient have not been involved in the investigation, what was the rationale for not including them?

5. Were the findings of the initial investigation appropriately drawn from the information gathered during the investigation and considered against local policy or procedures.

6. Is the rationale for the findings clearly documented in the report?

7. Was there sufficient engagement and openness with the family through the serious incident investigation; did the Trust appropriately discharge their responsibilities in the discharge of Duty of Candour?

8. In accordance with involving and supporting those affected (Serious Incident Framework 4.2) did the Patient's family have an opportunity to respond/comment on the SIRI findings and recommendations outlined in the final report. Were assurances provided by the Trust that the families' responses/comments would be considered as part of the quality assurance and closure process undertaken by the Commissioning Group.

9. To establish why the Trust deemed it necessary to request an independent medical review of the incident investigation report.

10. Was the appropriate evidence used (where it was available) i.e. Patients notes/records, written account?

11. Is there evidence that the Patient has been appropriately involved and supported?

12. To establish why the Ipswich Hospital NHS Trust did not inform the family that the SIRI was closed in November 2015, despite there being open dialogue / a complaint about its content?

13. Establish whether the Trust can demonstrate that robust systems were in place for reporting, investigating and responding to this serious incident so that lessons are learned and appropriate action has been taken to prevent future harm.

14. To establish what Quality assurance processes were in place at the CCG to ensure completion of high quality investigation reports and action plans to enable timely learning and closure of investigations and to prevent recurrence.

5 My Opinion

5.1 I offer below my opinion against each of the concerns as outlined in the agreed ToR dated 12 July 2016.

5.2 To review the original Serious Incident Investigation to assess and advise if the scope of the investigation has been sufficient to consider all the factors that may have contributed to the incident and specifically address the following points:

- the root cause(s) of the incident
- contributory factors
- chronology of events
- service delivery problems
- care delivery problems
- lessons learned
- recommendations
- action plan

5.3 Were the originally identified terms of reference broad enough to promote a comprehensive investigation?

5.4 Summary

5.5 SCIG identified the author of SI 2015/26953 to lead the investigation. Support was provided by a Cardiology Consultant who provided specialty advice of the cardiology aspects of the care and by an Obstetric Consultant who provided specialty advice with regards to the obstetric care.

5.6 The investigation of the index event was by root cause analysis involving a review of the notes and statements from staff involved, as well as notes from meeting with the family and lead consultant in the emergency department.

5.7 A comprehensive investigation is said to have been carried out in line with National Serious Incident Framework. A fishbone analysis tool was used to identify the contributory factors to the incident.

5.8 The date of index event was noted to be 3 August 2015. SI 2015/26953 was generated on 18 August 2005.

5.9 I have reviewed original Serious Incident Investigation and consider that the ToR set by the Serious Incident Review Group were not broad enough to encompass all of the events that are said to have occurred on 2/3 August 2015.

5.10 The agreed ToR at the Serious Incident Review Group meeting notes of September 2015 were not reflected in the final SIRI report. Adjustments were made to ToR (2) for a reason unknown.

5.11 The ToR agreed at the Serious Incident Review Group of 1 September 2015 set the investigator on a very narrow path to investigate the medical aspects of the events leading to the key index event occurring and the immediate medical management up to admission to the CCU.

5.12 The Trust lacked professional curiosity to further explore key lines of enquiry including those raised by the family with Trust staff, including SCIG members consistently from 5 August 2015 onwards.

5.13 The Serious Incident Review Group lost situational awareness of the events that unfolded on 2 August 2015 when setting the ToR.

5.14 Whilst the SI may have uncovered some aspects of the medical management of the care of PATIENT a large number of areas remain unexplored.

5.15 Detail

5.16 I have reviewed the Serious Incident Review Group meeting notes of 1 September 2015.

5.17 The construction of the Serious Incident Review Group was appropriate with representation from the key disciplines of Medicine and Nursing involved. There was significant debate in relation to the declaration of the key index event as a SI. The Trust took the view at this time that patient may not survive post cardiac arrest and that an external maternal death SI may have been necessary.

5.18 The Criteria identified for investigation of the adverse events that occurred on 2 August 2015 was " *Other…Unexpected post partum Patient*". This in my opinion reflected the group's narrow focus on the medical management of patient.

5.19 In my opinion the care of patient should have prompted a further category to be identified: *"Serious harm to one or more Patients… or where the outcome requires life saving intervention…permanent harm or will shorten life expectancy*".

5.20 In my opinion the Serious Incident Review Group lost situational awareness of the events that unfolded on 2/3 August 2015. In light of the focus on the medical management of patient the agreed ToR were never going to be broad enough to encompass all of the aspects of the events that unfolded on 2/3 August 2015. The SI investigator was instructed to follow the pathway identified by the SCIG group and did not defer from this pathway at any time.

5.21 I am mindful that as early as 5 August 2015 the family of PATIENT had raised various concerns with Trust staff. I am mindful that the SCIG group met on 1 September 2015 and for an unknown reason did not incorporate families concerns within the ToR. Key members of the SCIG were present both at the family meeting of the 5 August 2015 and at the setting of the SCIG ToR on 1 September 2015. At least two of the SCIG members were aware of the concerns of the family on 1 September 2015, as they were present at the meeting with the family on 5 August 2015.

5.22 I am unclear why the Trust did not accept and manage the families concerns at this point in time. I am mindful of the Duty of Candour letter sent by the Trust to family on 27 August 2015 making explicit reference to the meeting with the family on 3 August 2015 in A&E post patient cardiac arrest. The Trust formally wrote to the family on 27 August 2015 as part of the Duty of Candour advising that the Trust would contact "*you to arrange a follow up meeting to discuss the investigation findings and any actions that we need to take*". Further assurances were provided to the family at the meeting on 5 August 2015.

5.23 It is clear to me, having spoken with both the Trust and the family that the Trust raised the family's expectations of being involved and contributing to the SI investigation. The Trust verbally promised actions on numerous occasions and did not deliver on their promises.

5.24 The Duty of Candour requirements were not fully populated at the Serious Incident Review Group although reference is made to "*regular verbal contact with the Patients NOK has been in place since 2/3 August. Duty of Candour letter was given to the patients (sic) NOK 1/9/15*".

5.25 I have explored the culture of the Trust with regards to involving families in a partnership model in SI investigation in 2015. It is clear to me that the Trust took a paternalistic approach to the involvement of families in SI at this point in time. There is no evidence of any family involvement in the SI at any time, despite the willingness and eagerness of the family to become involved from 5 August 2015.

5.26 It may be concluded that the SI delivered upon some aspects in relation to the care of patient but it did so with a weighted focus towards medical care of patient with many aspects requiring investigation outstanding. Furthermore it may be concluded that some of the ToR were met, but not all.

5.27 Given that the course of the SI investigation was misguided from the outset, the end product (final SI report) remains unfulfilled. Although the SI may have answered a number of pressing concerns in relation to the medical management of patient, this focus was always going to be too narrow resulting in an incomplete investigation and an incomplete SI report.

5.28 Post SI investigation a number of questions, remain unaddressed and therefore unanswered including the following:

A contradictory chronology exists

Key witnesses were not interviewed including the mother of patient who was a direct witness and other medical staff for example one of the Doctors who performed CPR at the point of cardiac arrest

Furthermore key witnesses such as the Radiography staff were not interviewed who were present immediately prior to the cardiac arrest of patient

Dispute in relation to the actions of the nursing staff at the time of patient collapse/cardiac arrest

Concerns in relation to the training and competence of the nurses who attended Patient at the time of the index event

Disagreement in relation to the post cardio version state of patient

Missing data sets from vitals machines

5.29 Fundamentally I am mindful of the fact that least two members of the SCIG group were aware of the broader concerns of the family in August 2015 and failed to direct the SI investigator appropriately.

6.0 Has the Lead Investigating Officer received Root Cause Analysis Training? If not was the Lead Investigating Officer supported through the investigation by an individual with the appropriate Root Cause Analysis Training and experience of investigating serious incidents?

6.1 Summary

6.2 The lead investigating officer is said to be a highly experienced and highly respected clinician who retains the confidence of the Medical Director of the Trust. The level of experience in investigating SI's of the SI author remains unclear.

6.3 The Lead SI author received training in Root Cause Analysis (RCA) in February 2015. An external trainer trained the Lead SI author on a one-day internal training course at the Trust as part of a group training session. It remains unclear how large the group was that formed the training session. Previous training undertaken by the lead SI author is described as "*informal*". This was the first investigation the Lead SI Author undertook post the RCA training in February 2015. Previously the SI author is said to have undertaken two RCA investigations within the Trust.

6.4 The culture at the Trust was not one that supported a peer review process of completed SI investigations. SI's were managed in a process driven way that prioritised the completion of the report with regards to key target dates. The ultimate quality control checking process was a return of the completed SI investigation to the SCIG. There is evidence to support the SI report being distributed for comment internally and evidence of the final SI report being returned to the SCIG as the ultimate quality control mechanism.

6.5 Detail

6.6 My report above identifies that the SCIG agreed ToR were not broad enough to encompass all of the events that are said to have occurred on 2/3 August 2015. I am mindful that at least two members of the SCIG group were aware of the broader concerns of the family and failed to direct the SI investigator appropriately. As outlined earlier in my report the SI focused on the medical management of the events of 2/3 August 2015 at the expense of the surrounding issues, which remain unexplored.

6.7 It may be argued that the SI author made some attempts to examine the wider issues in relation to the care of patient on 2/3 August 2015 as there is reference to a fishbone analysis outlined in Appendix A.

6.8 However the fish bone analysis is lacking in detail and is insufficient to meet the needs of the investigation in my opinion. In summary the fish bone analysis reflects some efforts by the investigator to explore the wider issues it does not deliver on any level of detail.

6.9 In particular the investigator makes broad statements such as "*no staff issues identified*" and "*all those involved carried out their roles appropriately*" when the investigation methodology was not constructed to address these matters. In light of the family raising such concerns albeit in an informal way as early as 5 August 2013 with the Trust and mindful that at least two members of the SCIG group were aware of the broader concerns of the family, I remain perplexed why these concerns were never ever raised and/or discussed at SCIG at the point the ToR were agreed or when the final report was circulated for comment

6.10 My report above has identified that the SI investigation focused almost exclusively on the medical management patient. The Trust may argue that this was an appropriate and necessary step and I do not disagree with this. However the peripheral issues such as those outlined in the fishbone analysis have not been appropriately explored in any meaningful way. It may be argued that the peripheral issues that remain unexplored are as important as the medical issues address within the SI report.

6.11 Taking into consideration the culture of the Trust at the time of the index event and at the time of the SI report being prepared and subsequently released to the family there has been a missed opportunity to involve the family in the setting of the ToR of the investigation and involving the family in the investigation both as a key direct witness to the index event (mother of patient) and in the analysis of the findings post investigation, prior to sign off of the completed SI investigation.

6.12 However challenging it may appear to have been, the lack of involvement of the family in the investigation has been a missed opportunity for the Trust and for the investigator. I am not of the opinion that the Trust purposely and wilfully excluded the family from the investigation. Rather I am of the view that the SCIG group lost situational awareness and lacked professional curiosity in the matters that unfolded during the investigation. This matter added to the culture within the Trust at the material time and the high volume poor quality communication issues created a toxic mix that prevented the involvement of the family in contributing to the investigation in any meaningful way.

6.13 Finally the fact that the SI report did not fully address each of the agreed ToR at SCIG is reflective of a failure in process. Given that the final SI report was routed back to SCIG the matters above were never addressed. I am in no doubt that the powerful nature of the Trust culture and lack of situational awareness of the SCIG group contributed to the lack of focus on the issues at that time.

7 Have all individuals directly or indirectly involved in the care of the Patient, inclusive of the Patient / relatives, been involved in the investigation process? If individuals involved directly or indirectly in the care of the Patient have not been involved in the investigation, what was the rationale for not including them?

7.1 Summary

7.2 The Trust has failed to involve all of the individuals in the care of patient in the investigation process.

Detail

7.3 It appears that some local efforts were made by the A&E department to initiate some form of local investigation. Efforts were discharged to secure witness evidence from the staff who were on duty during patient's admission to the A&E department. A local A&E memorandum was issued to the A&E staff by the local management of the A&E department in regards to the care of patient dated 4 August 2015 requesting statements. However this local investigation was never completed.

7.4 It remains unclear if the SCIG group was aware of the local investigations of the A&E department in this regard. It also remains unclear if the SI author was aware of the local actions of the A&E department in this regard. The SI author does recall reviewing some nursing statements from the A&E nursing staff at the time of the index event and does not recall any issues coming to light that required further investigation.

7.5 Patient's mother as the key witness to the index event was never formally interviewed by the local A&E investigation or the author of the SI. Other staff such as the Doctor who undertook chest compressions at the point of cardiac arrest and the Radiography staff immediately prior to the cardiac arrest were not formally interviewed, and witness statements were not secured. No efforts were discharged by the Trust to secure a formal witness statement from the mother of patient. I am mindful of the subsequent efforts of the family in this regard.

7.6 Between August 2015 and March 2016 the family raised their concerns in relation to the Trusts failure to secure the witness evidence of the mother of patient on numerous occasions. In particular post the publication of the SI report and in light of the families broad concerns with regards to the SI investigation, on many occasions the Trust agreed to accept the witness evidence of the mother of patient. However the Trust failed to proceed to secure the witness evidence of the mother of patient in any meaningful way

7.7 Although the Trust may say that communications channels were available it is a matter of fact that the key witness to in the index event i.e. the mother of patient was not afforded an opportunity to contribute her witness evidence to the SI investigation process.

7.8 The Trust failure to include in any meaningful way the witness evidence of the mother of patient in particular and of all of the clinical staff involved in the care of patient is a key failure of the SI process. Although partly explained by the culture of the Trust at the time, the continued inability of the Trust to secure formal witness evidence from the key witness to the index events of 2/3 August 2015 remains current.

7.9 I am in no doubt that this key failure by the Trust compounded the current position.

7.10 Further criticism is leveled towards the SI process in relation to securing witness evidence of both of the nurses involved in the care of patient at the time of her collapse/cardiac arrest.

7.11 Although the Trust will say that the role of the investigator was to explore the medical management of the care of patient in my opinion the scope of the investigation plan was exceptionally narrow. The narrow ToR agreed at the SCIG led the SI investigator down a very narrow investigatory pathway. A lack of professional curiosity by the Trust compounded the narrow scope of the activities of the SI investigator. Fundamentally the fact that at least two members of the SCIG group were aware of the broader concerns of the family and failed to direct the SI investigator appropriately adds to compound the current position.

7.12 Although the SI investigator recalls reviewing some type of nursing statements from the A&E nursing staff at the time of the index event and does not recall any issues coming to light that required further investigation, it is clear to me that formal witness evidence from the nursing staff was not secured in 2015 as part of the SI investigation. In any event this nursing evidence, reviewed by the SI author does not appear to be available at present for a reason unknown.

7.13 In February/March 2016 when the Trust realized that key index witness evidence had not been formally secured the Trust took what may be interpreted as well-intentioned efforts to secure formal witness evidence from the nursing staff.

7.14 Efforts were made by the Trust some seven months post the index event to secure formal witness evidence form the nursing staff involved in the care of patient. This witness evidence was duly released to the family. I am in no doubt that this has caused significant distress as it provides a contradictory account of the recollections of the mother of patient and is inconsistent with the families' chronology of events.

7.15 As of August 2016 formal witness evidence has still not been secured from the mother of patient.

7.16 The reliability and validity of the witness evidence secured by the Trust in February/March 2016 in relation to events that occurred in August 2015 will inevitably be a source of contention between both parties.

8 Were the findings of the initial investigation appropriately drawn from the information gathered during the investigation and considered against local policy or procedures.

8.1 Summary

8.2 It may be argued that the findings of the local investigation were drawn from the information gathered during the investigation. However my report earlier has been critical of the narrow focus of the SI investigation and the failure by the SCIG group to provide the direction to assist the investigator in his task.

8.3 The SI investigation report has failed to follow some local policy and procedures

Detail

8.4 The investigator was directed by the SCIG group. The task at hand was primarily to investigate the medical aspects of the care of patient within the A&E department on 2/3 August 2015. My report earlier has been critical of the narrow focus of the SI investigation, the failure by the SCIG group to provide the direction to assist the investigator in his task and the lack of professional curiosity of the Trust during the investigation process.

8.5 Furthermore there have been significant failures by the SCIG group to provide oversight and to assist the investigator in his task. For example the agreed ToR at SCIG are not mirrored in the final investigation report.

8.6 Whilst the Trust may argue that the SI report had relevant clinical input from specialist clinicians and was adjusted in light of comments from various staff within the Trust clear failures in process and policy have been observed.

8.7 It has been said that the final SI report was routed via SCIG. The meeting took place on 24 September 2015, attended by

Trust Medical Director

Cardiologist

Governance Manager for Obstetrics

ED Consultant

Lead Nurse for ED

ED Consultant

SI Investigator

Governance Manager

8.8 There were minor changes made to the report and the ED consultants asked for more time to read the report before it was submitted. They were given a week but it was agreed at this meeting the report would be approved.

8.9 An email was sent by the Governance manager a week later to remind everyone that there had been no comments and the report would be considered approved. Some comments were received from and Governance Director and a revised report was prepared. The Medical Director provided executive director approval to the final version of the SI report on 4 November 2015.

8.10 It is clear to me that the membership of SCIG lost situational awareness of the inherent weakness in the SI report that I have identified earlier.

8.11 My report has earlier alluded to the failure to follow ToR 2 for a reason unknown. With regards to policy failure I am of the opinion that there has been a failure in the Trust to discharge its Duty of Candour, please note my comments on the following pages.

8.12 With reference to the membership of the sign off of the completed SI report it is clear to me that none of the members of the SCIG closure group were aware of the broader concerns of the family and failed to direct the SI investigator appropriately.

8.13 The ED consultant and ED lead nurse who were present at the SCIG closure meeting were not present at the meeting of 5 August 2015. It may be argued that this matter is reflective of a further lost opportunity by the Trust to become enlightened to the missing issues within the SI report and may be considered as further evidence of a lack of professional curiosity and lack of situational aware ness of the SCIG group.

9 Is the rationale for the findings clearly documented in the report?

9.1 Summary

9.2 The SI report is focussed on the medical management of patient on 2/3 August 2015.

Detail

9.3 As such I am not in a position to comment on the findings of the medical management, as I am not a medical practitioner. If I were to comment on the findings of the medical management of patient I would be stepping outside of my professional boundaries.

9.4 My observations are that the rationale for the findings are clearly documented in the report. However as noted earlier the scope of the investigation was exceptionally narrow and in my opinion did not explore all of the issues. In this regard although the findings may be clearly documented the scope of the investigation was too narrow rendering the rationale, findings and report redundant.

10 Was there sufficient engagement and openness with the family through the serious incident investigation; did the Trust appropriately discharge their responsibilities in the discharge of Duty of Candour?

10.1 Summary

10.2 The CQC has put in place a requirement for healthcare providers to be open with Patients and apologise when things go wrong. This duty applies to all registered providers of both NHS and independent healthcare bodies, as well as providers of social care from 1 April 2015. The organisational duty of candour does not apply to individuals, but organisations providing healthcare are expected to implement the new duty throughout their organisation by making sure that staff understand the duty and are appropriately trained.

10.3 The Trusts policy on Serious Incidents Requiring Investigation Version 8.0 dated 18 March 2013 in place at the time of the index event did not reflect the Duty of Candour requirements.

10.4 Nevertheless the clinicians involved had a professional duty of candour to patient and her family. I am mindful of the joint NMC and GMC guidance entitled Openness and honesty when things go wrong: the professional duty of candour published in April 2015.

Detail

10.5 Mindful of criticisms of the ToR set by the SCIG the Trust took some efforts to engage and be open with the family throughout and after the publication of the SI report.

10.6 My report earlier referred to high volume and low quality communications with the family particularly between the August and December 2015 period. Post January 2016 the communications between the family and Trust became more difficult and from the family perspective, mistrust and suspicion deepened. This was compounded by Trust staff promising to deliver on matters that were outside of their scope to act upon or agreeing to deadlines that were unachievable.

10.7 The movement of staff within the Trust and outside of the Trust compounded the challenges in communication at this time. The family report that they were passed from pillar to post due to staff movements. As time progressed particularly post January 2016 the family were experiencing severe challenges in communicating with the Trust, recounting numerous occasions where emails, letters and phone calls were not responded to.

10.8 It is clear to me that as matters progressed communication became even more challenged. Trust staff began to refer communications from the family to Director level staff to address either due to a lack of competence, confidence or possibly both. The net result was that difficulties in communication issues became compounded which in turn compounded the deep sense of suspicion that the family were developing of the Trust at this time.

10.9 Trust Director level staff met the family in early 2016. One of the meetings was described by a Director as challenging by the Trust. The Trust appears to have recognized at this point in time that the relationship with the family was damaged and took steps to attempt to redress this imbalance.

10.10 The Trust and family discussed either an external or an internal review of the care of patient. However the parameters to guide the external or internal review in the form of agreed ToR were never established.

10.11 In my opinion at this stage there was a significant amount of distrust between the family and Trust. The attempts of the Trust to gather new formal witness evidence from its staff, however well intentioned, was interpreted by the family in a suspicious manor.

10.12 Although the Trust made some efforts to discharge its duty of candour it was hampered and compounded by the lack of Trust policy in this regard, the limitations inherent within the SCIG agreed ToR, lack of professional curiosity by the Trust and the failures in quality control of the completed SI investigation.

10.13 The Trust may argue that there was sufficient engagement and openness with the family throughout the serious incident investigation, however my investigation has uncovered that the communication that occurred was broadly of poor quality, uncoordinated and ineffective. As time moved forward and in particular when the February/March 2016 time period is considered the family were reaching out to the Trust on a very frequent basis and Trust staff were referring communications up the management chain to Director level staff which compromised communications and/or compounded delays in communication.

11 In accordance with involving and supporting those affected (Serious Incident Framework 4.2) did the patient's family have an opportunity to respond/comment on the SIRI findings and recommendations outlined in the final report. Were assurances provided by the Trust that the families' responses/comments would be considered as part of the quality assurance and closure process undertaken by the Commissioning Group.

11.1 Summary

11.2 I am of the opinion that the culture of the Trust did not support the involvement of the family in the SI investigation in any meaningful way.

Detail

12.3 Verbal assurances were provided to the family alluding to their involvement in the SI investigation as early as 5 August 2015.

12.4 Little if any efforts were discharged by the Trust to involve them in the SI investigation. Communication difficulties identified earlier in my report compounded this position.

12.5 Once the SI report was prepared and completed it was presented to the family as a competed final document. This action, in light of the empty promises by Trust staff to the family of their involvement, led to anger and disappointment from the family.

12.6 The paternalistic approach taken by the Trust at this point in time as alluded to earlier in my report further compounded the relationship damage that further compounded the communication difficulties leading to the current position.

13 To establish why the Trust deemed it necessary to request an independent medical review of the incident investigation report.

13.1 Summary

13.2 The Trust and family interpreted the request for an independent medical review of the incident investigation report differently. Agreement was never reached in relation to the key ingredients that would culminate in the production of a review of the care of patient

Detail

13.3 The Trust notes that on 1 December 2015 an email was received from the family requesting an external review of the SI report. The Trust Medical Director agreed in principle that an external review would proceed on 11 December 2015.

13.4 It is clear to me that the definition of an external review was never clarified. The family expected a fresh investigation whereas the Trust had varying interpretations of what was agreed, despite the Trust Medical Director agreed in principle that an external review would proceed.

13.5 In any event, terms of reference for the internal review or fresh investigation were never agreed by both parties. I am of the opinion that the challenges in communication compounded this situation.

13.6 As noted earlier in my report over the coming few weeks the relationship between the family and Trust deteriorated further.

13.7 In early 2016 the Director of Governance met with the family an external medical expert appointed by the family and the SI author. This meeting was described as challenging by the Trust.

13.8 The Trust have pointed out that an email from the Governance Manager at the Trust to the father of 11 December 2015 14:53 agreed that the Trust will facilitate an external review. However an email from the mother to the Director of Governance on 11 February 2016 22:13 asks her to “park this for now”

13.9 It is clear to me that by early February 2016 the relationship between both parties had broken down. The Trust may be open to criticism for the earlier failures in communications and the communications that occurred outside of the normal process.

14. Was the appropriate evidence used (where it was available) i.e. Patients notes/records, written account?

14.1 Summary

14.2 My report above outlines my observations on the quality of the SCIG output that provided direction to the SI investigator. In summary in light of the on-going concerns of the family, known to the Trust and some of the SCIG members (n=2) as early at 5 August 2015, particularly in relation to the medical care prior to the cardiac arrest and the alleged actions/inactions of the nursing staff at the point of patient collapse/cardiac arrest the SI report did not consider all of the appropriate evidence.

Detail

14.3 My report above outlines the direction of travel for the investigation as set by the SCIG group. The subsequent investigation was dominated on the medical management of patient. I am not in a position to judge the conclusions reached in this regard.

14.4 In light of the events that unfolded within the index period of 2/3 August 2015 and were known by the Trust and/or SCIG group prior to the setting of the ToR on 1 September 2015 it is clear that not all of the issues in relation to the care of patient were appropriately explored by the SI.

14.6 As early as 5 August 2015 it was known by members of the SCIG group that the family had various concerns including missing ECG, cardiac monitoring strips, the position of patient at or immediately prior to the collapse/cardiac arrest, the actions/inactions of the nursing staff etc.

14.7 The SI investigation did not consider any of the supporting evidence in this regard.

15. Is there evidence that the patient has been appropriately involved and supported?

15.1 Summary

15.2 There is no evidence available that patient was involved and supported during the SI investigation. In my opinion, in light of the events that occurred on 2/3 August 2015 it would have been impractical to involve patient in the SI investigation.

Detail

15.3 Patient was acutely unwell post the events of 2/3 August 2015. It would have been inappropriate and impractical to involve patient in the SI investigation that followed as she remained unwell for a considerable period, post events of 2/3 August 2015.

16. To establish why the Ipswich Hospital NHS Trust did not inform the family that the SIRI was closed in November 2015, despite there being open dialogue / a complaint about its content?

16.1 Summary

16.1 My report above has outlined the direction of travel of the investigation, the lack of professional curiosity of the Trust, the culture of the Trust at the time of the index event and the subsequent communication difficulties that arose between the Trust and family. All combined to result in a toxic mix of circumstances at the time of the closure of the SI in November 2015.

Detail

16.2 By November 2015 the Trust was satisfied that the SI ToR had been met and that the SI was ready for closure. As noted earlier in my report although the final SI report was routed back to SCIG, the group appeared to lacked insight and professional curiosity to the matters hand. I am again mindful that members of the SCIG group that set the ToR were different to the SCIG group that reviewed and closed the completed report.

16.3 It does appear that the A&E consultants required further time post SCIG to consider the final SI report. It remains unclear if the A&E consultants provided any contributions post SCIG and post the closure of the SI.

16.3 The failure of the SCIG on two separate occasions, particularly on the first occasion when two of the SCIG members knew or reasonably ought to have known of the inherent weakness in the ToR agreed is a key issue. The fact that SCIG accepted a SI report in this regard is reflective of a key weakness in the Trust process.

16.4 The family was very keen to review the SI report in late October/early November 2015. The Trust report daily communications to different people at the Trust chasing the final SI report from the family. In my opinion the Trust took actions that were over and above those that would have been considerable reasonable at this time to get the final copy of the SI report to the family.

16.5 The Trust report that a member of the Trust staff physically delivered a hard copy of the final SI report to the family home. This is in my opinion is highly unusual and may be considered as reflective of a further example where the Trust acted outside of the normal processes.

16.6 My previous references to over communications between the Trust and family are evident at this point also. Again the net result was high volume low quality communications coming from the Trust towards the family.

16.7 I am of the opinion that the Trust ended up reacting to the perceived pressures of the family with regard to accessing a final copy of the SI report. It is clear to me that expectations of the family were very high with regards to the SI investigation output. Within a few days of receipt of the SI report the family were back in communication with the Trust listing 41 outstanding queries that were not addressed by the original SI report in a satisfactory way.

16.8 I am of the opinion that the Trust did not inform the family that the SI was closed in November 2015, as there was an assumption that the communication from the Trust to the family was effective.

16.9 Communication between the Trust and family was fundamentally flawed due to the reasons I have identified earlier in my report.

17. Establish whether the Trust can demonstrate that robust systems were in place for reporting, investigating and responding to this serious incident so that lessons are learned and appropriate action has been taken to prevent future harm.

17.1 Summary

17.2 The Trust had established systems in place at the time of the index event. However due to the issues raised earlier in my report, this SI was not investigated appropriately with the net result being of a set of residual issues that remain unexplored.

Detail

17.3 The normal process for sharing lessons learned from SI's in Medicine and Therapies is as follows. Each month the Governance manager presents a division focused SI report to the Division Quality meeting. This report covers potential SI's, cases under investigation, cases which have completed investigations but the action plan has not yet been completed, and the lessons learned from SI's which have been submitted to the CCG in the previous month. The Governance manager also includes actions, which are overdue for completion and lessons learned from complaints in the appendix. This report is presented at the Division Quality meeting and acknowledged in the minutes as it is the formal process the Governance manager uses for giving assurance and updating the CDG leads on the progress of SIRI cases.

17.4 The Governance manager also shares a copy of the trust wide SIRI report at the Division Quality meeting (this is tabled at the Risk Oversight Committee) so the division can be aware of and share the learning from the trust wide cases.

17.5 The Division Quality meeting is chaired by the Head of Nursing and each CDG is represented by at least one of their leads (clinical, nursing or operations). The expectation is that they can take the reports presented at this meeting and use them to share information at the CDG quality meetings which will then filter down to ward / individual level.

17.6 Periodically, the Governance manager produces a newsletter, which is emailed directly to all staff in the division. The newsletter covers lessons learned from a selection of SI's, complaints and M&M meetings along with links to the latest NICE guidance and internal guidelines/ policies, which have been issued.

17.7 It may be the case that the Trust had established systems in place at the time of the index event. However due to the issues raised earlier in my report, this SI was not investigated appropriately with the net result being of a set of residual issues that remain unexplored.

18 To establish what Quality assurance processes were in place at the CCG to ensure completion of high quality investigation reports and action plans to enable timely learning and closure of investigations and to prevent recurrence.

18.1 Summary

18.2 The CCG had established systems in place at the time of the index event. However due to the issues raised earlier in my report, this SI was presented to the CCG for closure. The set of residual issues that remain unexplored were not identified by the CCG and could not have been identified by the CCG at the material time.

Detail

18.3 The CCG reply on the providers to populate the various request forms when closure is being considered.

18.4 The closure form that was presented to the CCG with regards to this SI has been relatively sparsely populated with text. I am of the opinion that this is not unusual set of circumstances to find.

18.5 The Quality assurance processes that were in place at the CCG at the material time focused on learning from SI's and challenging providers where appropriate. Action plans were regularly reviewed. Key Si's particularly those that fitted under the Never Event category were deeply explored with the CCG and at follow up quality review meetings with the providers. Site visits were common again with regards to Never Event SI's.

18.6 With regard to the closure form submitted by the Trust to the CCG this was routed via the CCG quality team who managed the SI closure form with due regard.

18.7 I am of the opinion that the CCG quality team were presented with a typical closure form that was duly considered by the CCG in light of the content and action plan as submitted by the Trust.

18.8 There was no indication that anything was amiss at this point in time from the CCG perspective. In a sense, the CCG did not know what it did not know. It would have been unreasonable to expect the CCG to be aware of the family concerns at the point the SI form was submitted for closure to the CCG.

18.9 In any event it is clear to me that the closure from was routed through the various CCG channels as per CCG process in place at the time. This SI did not raise any concerns in the eyes or minds of the experienced CCG staff who reviewed the Trust closure form and action plan.

18.10 The CCG only became aware of the wider issues of the family in 2016 when it was formally contacted and made aware of the issues of concern.

19 Conclusion

19.1 The family raised a number of serious concerns with senior Trust staff on 5 August 2015. Senior Trust staff accepted the family concerns of 5 August 2015 and for an unknown reason did not incorporate families concerns within the ToR that were set on 1 September 2015.

19.2 I remain confident of the fact that two members of the SCIG were present both at the family meeting of the 5 August 2015 and at the setting of the SCIG ToR on 1 September 2015.

19.3 The ToR set by the Serious Incident Review Group were not broad enough to encompass all of the events that are said to have occurred on 2/3 August 2015. The investigator was directed on a very narrow path to investigate the medical aspects of the events leading to the key index event occurring and the immediate medical management up to admission to the CCU. Adjustments were made to ToR (2) for a reason unknown.

19.3 The Trust lacked professional curiosity to further explore key lines of enquiry including those raised by the family with Trust staff, including SCIG members consistently from 5 August 2015 onwards.

19.5 The SI investigator was a relatively inexperienced investigator having been relatively recently trained in RCA. The inability or reluctance, for reasons unknown of the SCIG group to guide the investigator appropriately remains a central issue in this case.

19.6 The powerful nature of Trust culture contributed to the paternalistic approach taken by the Trust in relation to the SI investigation. High volume poor quality communication issues created a toxic mix that prevented the involvement of the family in contributing to the investigation in any meaningful way.

19.7 The Trust has failed to involve all of the individuals in the care of patient in the investigation process. Fundamental aspects of an investigation process, such as securing formal witness evidence from key index witnesses, as soon as possible after the index event is a key failure by the Trust. Furthermore it remains unclear if the SI author or if the SCIG group was aware of the local actions of the A&E department in this regard.

19.8 The Trusts efforts of February/March 2016 in securing witness evidence from nursing staff involved the care of patient, although well intentioned can be misinterpreted in light of the previous events. In any event the Trust has failed to secure timely witness evidence from key index witnesses such as the mother of patient, the radiography staff and other medical staff involved in the care of patient.

19.9 Mindful of the fact that the Trust was of the view that the care of patient on 2/3 August 2015 was going to lead to a maternal death review I remain critical of the SCIG group for not directing the SI investigator appropriately.

19.10 The SI investigation focused almost exclusively on the medical management patient. The peripheral issues such as those outlined in the fishbone analysis have not been appropriately explored in any meaningful way.

19.11 Although the Trust made some efforts to discharge its duty of candour it was hampered and compounded by the lack of Trust policy in this regard, the limitations inherent within the SCIG agreed ToR, lack of professional curiosity by the Trust and the failures in quality control of the completed SI investigation.

19.12 The final SI report was released in light of significant pressure from the family as a competed final document. The paternalistic approach taken by the Trust did not assist in the SI investigation or the events that followed.

19.13 With regards to the internal review or fresh investigation of the care of PATIENT, mindful of the communications challenges as outlined in my report, terms of reference were never agreed by both parties. As both parties entered into February/March 2016 Trust staff redirected communications from the family to Director level staff, compounding the frustrations of the family during this period.

19.14 From the CCG perspective the CCG could not have reasonably known about the family concerns at the point the SI form was submitted for closure to the CCG.

19.15 Once the CCG became aware of the family concerns it acted appropriately.

19.16 Post SI investigation a large number of questions related to the care of patient on 2/3 August 2015 remain unexplored and therefore unaddressed by the Trust.

Appendix A

In August 2016 the Trust has informed me of the following actions that have been undertaken since but not necessarily as a result of the events involving PATIENT and her family on 2/3 August 2015:

- Trained 7 staff members (majority governance managers in the divisions) in 'train the trainer RCA' to enable them to support and train staff following the commissioning of an external provider in December 2015
- Provided training to the Executive team on the criteria for SIRI and chairing a serious clinical incident group and onward immediate actions and reporting
- Changed the format of investigators to now include a panel in line with best practice (people identified to meet the specifics of the incident e.g. drug related incidents will have a pharmacist on the panel; a never event will have an Executive on the panel etc.)
- Each investigation panel now has one of the 7 trained people on the panel (to drive consistency through the process). The Trust are growing the number of people who have been through this process, which will enable the Trust to reduce the dependency on the 7 people in individual cases and enable them to be utilized in training sessions going forward.
- Redeployed a staff member 2 days a week to lead on Duty of Candour (this role is currently being extended to include being family liaison for those incidents declared as SIRIs).
- Established a Trust wide Patient safety lead (this required a service change within the corporate nursing structure to release the budget to establish this role). As this has been a staged change and was dependent in recruiting

into Corporate Nursing vacancies this role commenced July 2016. Part of the role is to oversee serious incidents management, training and development.

- Increased the involvement of staff involved in serious incidents and the clinical teams in aspects of the investigation process – e.g. in the accuracy of the timeline of events and designing the actions in response to the findings and recommendations.
- The extension of the lead for Duty of Candour role is in direct response to the patient case and also in light of the:
- CQC report June 2016, which cited that only 12% of reports included clear evidence of involvement of the patient and/or the family in the investigation. With a recommendation being the identification of a single person who acts as family liaison.
- PHSO report July 2016, which cited a lack of appropriate communication with the family.
- The Trust is in the process of finalizing a revised internal policy, which will be launched via awareness sessions to all clinical areas. Separate to the above the Trust has commissioned a new Datix system which will also help the Trust to manage its incidents more effectively.