Dear Sir

Regulation 28 Report - Response

We write in response to your Regulation 28 Report dated 28 June 2023 issued following the inquest into the sad death of Mrs Carol Hatch. Please consider this letter as Spire Healthcare Limited's formal response to the concerns raised in the report.

We would like to take this opportunity to offer our sincerest condolences to Mrs Hatch's family. Prior to the inquest, we conducted a thorough and candid Root Cause Analysis ("RCA") investigation into the circumstances surrounding Mrs Hatch's death and had identified the majority of the issues which were recorded in the Regulation 28 report. To that extent, we consider it important that it is acknowledged that that the concerns raised in the Regulation 28 report are comprised largely of concerns Spire had already highlighted and was taking steps to address prior to the inquest. Notwithstanding this, as an organisation we have considered the concerns raised in the Regulation 28 report with the utmost seriousness and have undertaken further work to address these concerns.

We have set out our response to the Regulation 28 concerns in the table below with reference to evidence in support of those actions both in the form of the evidence which formed part of Spire's RCA action plan as presented at the Inquest, as well as evidence of the further work undertaken since the hearing took place.

Coroner's Concern	**Spire's Response**	**Evidence**
Escalation to consultant 1. Mrs Hatch's condition deteriorated markedly during the night of 31 August/1September 2022 (some hours after surgery). Neither the surgeon nor the anaesthetist were alerted to this unexpected deterioration. The Surgeon only became aware of the position when he contacted the hospital and came in around 7 am.	The RCA investigation completed prior to the inquest clearly identified that, wholly regrettably, on this occasion, some of the staff involved in the patients' care made errors in clinical judgement in failing to appreciate the signs of the patient's deteriorating condition and sepsis was not considered during the night and up until the patient was reviewed by the consultant surgeon. As soon as the consultant contacted the hospital at 07:00 hours and received an update on the status of the patient he	**ADDITIONAL INFORMATION** • Integrated Quality Governance Team ("IQG") Review of Learnings from Serious Incidents in 2022 and Q1 2023 • Leeds Incident Review of Escalating to Consultants

Coroner's Concern	Spire's Response	Evidence
	responded promptly and attended the hospital. As a result of this incident, Spire conducted a full and thorough RCA identifying areas of concern putting in place an action to address those concerns. As stated above, the majority of the issues identified in the Regulation 28 report are matters which had already been identified and addressed. Notwithstanding this, Spire is committed to ongoing learning from this event and improving its systems and processes.	
Nursing/RMO care 2. Mrs Hatch was cared for during the night by an agency nurse who had not worked at the hospital previously. No records were produced to the Inquest to demonstrate she was (a) competent (b) had an induction to the hospital or (c) received a handover at the start of the shift. 3. The nurse took observations at times during the night but either omitted some elements or misinterpreted the information with the result that the NEWS scores were inaccurately portrayed. This resulted in missed opportunities to escalate concerns to a doctor, more senior colleagues, or the surgeon.	These points were addressed in the RCA with remedial action listed in action points 9, 10, 12, 13, 14, 17, 18, 19 and 20 and evidence on these actions was presented at the inquest. The agency staff hospital induction process includes a documented local induction based on a standard format for induction used across the group. The investigation identified that the agency nurse (who had worked at Spire Leeds on a previous occasion) received a verbal induction when she arrived on shift on 31.08.22. A documented record of this induction could not be located but from the evidence obtained during the investigation and the events that occurred, we are confident that the agency staff member was orientated to the hospital as she completed Spire's care plans and patient records during the shift, accessed the handover, knew where to locate equipment,	**RCA ACTIONS EVIDENCE** • Action No. 9 Refresher Training for NEWS 2 • Action No. 10 Heads Together Clinical Night Staff • Action No. 12 NEWS 2 Training for National Agency Supplier • Action No. 13 Online Training to Recognise a Deteriorating Patient • Action No. 14 Spot Audit of NEWS 2 Scores • Action No. 17 Departmental On-Call Service • Action No. 18 Updated Induction Checklist – Leeds • Action No. 19 Key Learning Points to Nursing Agency • Action No. 20 Completed Agency Induction **AGENCY NURSE & RMO INFORMATION** • Confirmation from Nursing Agency of Action Taken **ADDITIONAL INFORMATION** • Ward Handover 31.08.22

Coroner's Concern	Spire's Response	Evidence
4. No observations whatsoever were taken in the period between 3 am and 6.25am, despite the patient having been recorded as "crying in pain" around 10pm. 5. The records kept were inaccurate; for example, there was no record of oxygen being provided around 2 am.	and escalated her concerns to the Resident Medical Officer ("RMO") via a senior member of nursing staff for advice. Spire has a series of checks to ensure that agency staff are assessed as competent to care for patients, as follows: - The nursing agency screens the candidates via their CV and ensures that they meet Spire Healthcare's statutory and mandatory training requirements of BLS, Anaphylaxis, Safeguarding Adults and Children, Infection Prevention and Control, Information Governance and Manual Handling and provides a Proforma Confirmation Form to the hospital. - The hospital will then thoroughly review the information provided to them in the Proforma Confirmation Form before they accept the nurse for the shift. - In this case, it was documented that the nurse who cared for the patient overnight had "recent and credible experience in surgical nursing, Immediate Life Support ("ILS")/Advanced Life Support ("ALS") and had met the mandatory training requirements" and was suitable to care for patients at Level 1A+ per our policy for Safe Staffing. - If suitable, the hospital agrees to the placement of the candidate, but careful consideration is given in each case and it is not uncommon to reject a candidate based on insufficient skills and experience to meet the hospital's requirements.	• Agency Confirmation Form 31.08.22

Coroner's Concern	Spire's Response	Evidence
	As part of the learning from this event, the team at Spire Leeds have shared and discussed the findings in the RCA with this nurse's agency. The core supplier competency checklist includes requires that agency staff are competent in the management of the deteriorating patient. The new checklist must be signed by the candidate as well as the agency to ensure both are confirming the information is correct. In addition to addressing NEWS training with agency staff, the hospital have ensured that a NEWS update refresher has been provided to all relevant colleagues and have conducted regular audits to provide assurance in relation to compliance.	
6. The RMO was called to review Mrs Hatch twice during the night but failed to appreciate that the deterioration in her condition necessitated an escalation to the surgeon and/or anaesthetist.	As heard in evidence during the inquest, this point was identified in the RCA and was addressed in the action plan at point 8 and 11. The RMOs for the majority of Spire hospitals are provided by an external agency. The agency provides training before RMOs start with us and provide top-up training as required. The training provided includes on-line elements and a residential course. The Group Medical Director (GMD) has visited the training site to get assurance of the extent of training. RMOs' CVs are provided to a site before they commence. When RMOs are new to a site, they have a period of shadowing with a previous RMO. In addition, there is have a RMO handbook with an induction checklist.	**RCA ACTIONS EVIDENCE** • Action No. 8 to share the RCA with RMO and NES • Action No. 11 Recognising a gastric perforation complication **AGENCY NURSE & RMO INFORMATION** • Confirmation of RMO Appraisal • Clinical Policy 18 RMO Handbook • NES Resident Doctor Pre Checks

Coroner's Concern	Spire's Response	Evidence
	Spire Leeds has the appraisal for the RMO covering the period when the incident occurred. The appraisal for that year documented mandatory training including sepsis. We have the doctor's full CV which includes an NES Healthcare induction which covers ECGs, BNF Medication, NEWS, Medical Note Writing, Pharmacology, and clinical self-declaration of competencies dated 23rd January 2017. At the time of the incident the RMO was trained in Advanced Life Support and EPALS. Compliance was assured in accordance with the contractual Spire requirements. This matter was recognised in the RCA, has been discussed with the RMO and there is a plan in place for training to be delivered to RMOs on recognising signs of a deteriorating patient and recognising signs of gastric perforation. In addition, Spire has received confirmation that the RMO has undertaken a recent appraisal. We refer the Coroner to evidence file relating to the RMO which includes evidence of action taken in relation to this concern.	
<u>Enhanced monitoring/further investigations</u> 7. When Mrs Hatch was observed to be in pain there was a delay in moving her to an extended care unit ('ECU') bed or otherwise escalating the level of monitoring. This did not take place until 9.50 am.	Care provided in ECU is governed by Clinical Policy 80 – Elective Adult Surgical Admission – Level 1 Provision and Clinical Policy 88 – Critical Care Standards. Level 1 Care is described as "*Enhanced care provides care for patients requiring more detailed observations than level 0 (ward and HOC) or step down from Level 2-3 care*", examples of which are, patients requiring close physiological monitoring after major surgery – may have additional monitoring devices in situ e.g. arterial line, patients	**ADDITIONAL INFORMATION** • Clinical policy 80 Enhanced Care Service Provision • Clinical Policy 88 Critical Care Standards

Coroner's Concern	Spire's Response	Evidence
	requiring a single vasopressor support (peripheral or central) but otherwise stable and not deteriorating. E.g. post-op patient with a "saggy" blood pressure secondary to an epidural, patients stepping down from level 2 critical care whose needs are greater than those that can be met by ward level care, patients requiring ongoing interventions from critical care outreach teams. All colleagues across the group and at Spire Leeds undergo competency assessment, with colleagues working in Level 1 ECUs also undergoing the National Competency Framework for Registered Nurses in Adult Critical Care Step 1. Of the nine colleagues who work within Spire Leeds ECU two have additionally completed a Critical Care Degree and another has completed a Critical Care Certificate. In addition, Spire Leeds has close links with Spire Manchester, who provide Level 3 (ICU) care and an agreement with Leeds NHS Hospital where our colleagues can attend to maintain ongoing competence in specific areas, for example, arterial lines, inotropes, non-invasive ventilation, transfer training.	
8. When the surgeon sought an x ray at 8.35 am there was a delay until this took place at 10.09 am. There was a failure to appreciate the urgency of the situation in a patient who was displaying symptoms of septic shock.	As heard in evidence during the inquest, this matter was identified in the RCA and addressed in the action plan at points 1, 2, 11, and 21. When Consultants commence their practice at Spire Leeds, they undergo an induction process which includes out of hours provision. The hospital has improved on call service documentation and has	**RCA ACTIONS EVIDENCE** • Action No. 1 RCA to Consultant • Action No. 2 RCA to Anaesthetist • Action No. 11 Consultant Training on Symptoms and Signs of Gastric Perforation • Action No.17 Departmental On-Call Service

Coroner's Concern	Spire's Response	Evidence
	communicated this to all consultants practising at the hospital.	• Action No. 21 Per-operative Communication of Difficult Surgeries
9. It was not readily apparent to some of those involved at that time that an out of hours radiographer could have been called in. This was a further missed opportunity to investigate her condition before it deteriorated.	This matter was identified in the RCA and addressed in the action plan at point 17. When Consultants commence their practice at Spire Leeds, they undergo an induction process which includes out of hours provision. The hospital has improved on call service documentation and has communicated this to all consultants practising at the hospital.	**RCA ACTIONS EVIDENCE** • Action No. 17 Departmental On-Call Service
10. Blood samples taken at 8.02am were not delivered to the laboratory until 9.06 am and then not reported on until 10.21 am as they had not been marked as 'urgent'. This also reflects a failure to appreciate the gravity of the situation.	As heard in evidence during the inquest, this matter was identified in the RCA action plan at point 22. As stated in Spire's RCA, learning has been developed surrounding the appropriate labelling of bloods in relation to the urgency of a clinical situation. This learning has been shared with staff across the hospital	**RCA Actions Evidence** • Action No. 22 Labelling of Urgent Bloods
11. The RMO was the senior doctor at the hospital overnight. The RMO recorded a note at 8.45 am "feeling much better now". The Inquest noted a discrepancy between this comment and the fact that Mrs Hatch was deemed too unwell to be moved to the radiology department at 9.10am, some 25 minutes later. 12. Overall, the cluster of failings on 31 August/1 September brought into question the competence of the staff	This incident was escalated to the RMO's agency, NES Healthcare, at the time of the initial event. The agency reviewed the incident and considered it to be a learning opportunity rather than requiring referral to the GMC. At the time of the incident, the RMO had an in-date Sepsis training record (23/1/22) and he was asked to reflect on the issue in his appraisal. In his appraisal, he presented a case study about Upper GI surgery and its complications. He completed the GMC Medical Practice in Action in October 2022 to update himself on the GMC guidance for doctors. He also completed the EPALS course in December 2022 where a lecture and a practical case included sepsis training.	**AGENCY NURSE & RMO INFORMATION** • Confirmation of RMO Appraisal • Clinical Policy 18 RMO Handbook • NES Resident Doctor Pre Checks **RCA ACTIONS EVIDENCE**

Coroner's Concern	Spire's Response	Evidence
looking after Mrs Hatch on duty at the Spire Hospital that night. The Inquest was informed that such concerns had not been reported to the regulatory bodies of those involved, The RMO continues to practice at the Spire Hospital.	Evidence was heard at the inquest that consideration was given to referring the RMO to the GMC following this incident. The RMO's skill set, and competency were discussed at a Scrutiny Panel on 17th February 2023 attended by hospital and senior clinical and medical management at Spire. It was concluded that the findings of the RCA and the known practice of the RMO did not meet the threshold for referral to the GMC. It was agreed that the hospital team would share the RCA with the RMO's agency, which was completed on 16th March 2023. It was agreed that the RMO's agency were best placed to assist us in understanding whether this was an isolated episode or not, whether there were any wider performance concerns that needed to be addressed or matters requiring escalation to the GMC. We have a quarterly meeting with NES Healthcare and have strengthened the process to include case by case discussion if we have raised any concerns about an RMO, and vice versa if the RMOs have raised any concerns about our hospital. If we have significant or unresolved concerns, the RMO is replaced by the agency. The RMOs undertake annual appraisal with their employing agency, and our hospital Directors of Clinical Services meet regularly with them.	• Action No. 4 RCA to RMO's • Action No. 7 RCA Sent to Nursing Agency • Action No. 8 RCA Sent to NES Healthcare • Action No. 11 Recognising a gastric perforation complication
13. The Inquest was informed that Spire Healthcare Limited rely on agencies	As stated above, the agency staff hospital induction process includes a documented local induction based on a	**ADDITIONAL ACTIONS EVIDENCE** • Mandatory Training Planner

Coroner's Concern	Spire's Response	Evidence
who supply clinical staff to assess their competence (whilst retaining a power of veto any individual put forward). Given the importance of having competent nurses and doctors on duty overnight further consideration should be given to the methods by which professional competence is assessed and staff from agencies are engaged.	standard format for induction used across the group. The RCA identified that the agency nurse (who had worked at Spire Leeds on a previous occasion) received a verbal induction when she arrived on shift on 31.08.22. A documented record of this induction could not be located, but from the evidence obtained during the RCA investigation and the events that occurred, we are confident that the agency staff member was orientated and completed Spire's care plans and patient records during the shift, accessed the handover, and escalated her concerns to the RMO for advice. Current ILS compliance for registered colleagues at Spire Leeds is 77%, against the target of 90%. Colleagues who do not currently have ILS training are booked onto training in the near future. Sepsis training is part of ILS competency. We have 100% compliance in performing quarterly scenarios of which sepsis is included. In this case, the RMO had documented mandatory training which included sepsis assessment and management. Similarly, the agency nurse in this case was ILS/ALS trained, which includes the assessment and management of sepsis. Spire has a series of checks to ensure that agency staff are assessed as competent to care for patients. The nursing agency screens the candidates via their CV and ensures that they meet Spire Healthcare's statutory and mandatory training requirements of Basic Life Support,	• Oxylog Training • Resuscitation Scenarios **ADDITIONAL INFORMATION** • Spire Education TNA

Coroner's Concern	Spire's Response	Evidence
	Anaphylaxis, Safeguarding Adults and Children, Infection Prevention and Control, Information Governance and Manual Handling and provides a Proforma Confirmation Form to the hospital. The hospital will then thoroughly review the information provided to them in the Proforma Confirmation Form before they accepted the nurse for the shift. In the case, it was documented that the nurse who cared for the patient overnight had "recent and credible experience in surgical nursing, ILS/ALS and had met the mandatory training requirements" and was suitable to care for patients at Level 1A+ per our policy for Safe Staffing. As part of the learning from this event, the team at Leeds have shared and discussed the findings in the RCA with this nurse's agency. The core supplier competency checklist includes requires that agency staff are competent in the management of the deteriorating patient. The new checklist must be signed by the candidate as well as the agency to ensure both are confirming the information is correct.	
14. Evidence taken from a consultant surgeon at the Inquest indicated that the failings at Spire Hospital contributed (more than minimally) to the death of Mrs Hatch on 18 October. This view dovetails with the medical opinion obtained by Spire Healthcare Limited	This concern is a matter of evidence before the coroner. Based on the thorough and considered investigations undertaken by Spire (see file entitled Incident Management), the organisation formed the view that Mrs Hatch's death was regrettably avoidable.	**INCIDENT MANAGEMENT** • Datix Report DW-336489 (Transfer Out) 01.09.22 • PSIR DW-336489 01.09.22 • CQC Notification DW-336489 (DPL-1355306) 12.09.22 • Datix Report DW-343997 (Patient Death) 19.10.22

Coroner's Concern	Spire's Response	Evidence
themselves to the effect that this death was "avoidable".		• PSIR DW-343997 19.10.22 • Medical Examiner Report (Commenced 26.10.22 - Returned 04.01.23) • Central Scrutiny Panel 17.02.23 • RCA Report DW-343997 08.03.23 • Mortality Review Annual Report 2022 28.03.23 • Clinical Governance Leads National Meeting 28.04.23 • Structured Judgement Review 06.05.23 • Group Mortality Review Committee 16.05.23 **ADDITIONAL ACTIONS EVIDENCE** • Deteriorating Patient Stickers • ECU Equipment Stock Check • Agreement in Principle with Leeds Teaching Hospitals • NEWS 2 Posters • Additional CPAP Masks • Additional Chest Drains • Venous Blood Gas Process for Deteriorating Patients **ADDITIONAL INFORMATION** • MAC Q1 2023 Newsletter (legible documentation)

I hope this letter and evidence attached provides both you and Mrs Hatch's family with assurance that Spire has taken seriously the matters of concern raised in your report and has taken substantial effective steps to address those concerns.

Yours faithfully