

Report on improvement actions to meet Health and Social Care Act 2008, its associated regulations, or any other relevant legislation in relation to Maternity and Neonatal Services CQC inspections 2024/25

| | |
|-----------------------------|--|
| Account number | Provider ID RR801 & Provider ID RR813 |
| Our reference | LGI maternity service AP6481 & SJUH maternity service AP7399 |
| Location name and ID | Leeds General Infirmary RR801 & St James's University Hospital RR813 |
| Service | Maternity Services |

| |
|---|
| Regulation 12: Safe care and treatment |
| How the regulation was not being met? |
| <ol style="list-style-type: none"> 1. We found learning following incident reviews was not always recorded. In addition, we found action logs did not always include names, accountability or completion dates to drive swift improvement. 2. Staff were not able to provide examples of practice which had been changed as a result of learning following incidents. Staff meetings in which to share incidents were inconsistently attended. 3. Risks to mothers and babies were not always managed well. We saw key performance indicator compliance for decision to incision timeframes were below national expected targets. 4. Key performance indicator compliance was worse than expected against some national targets. 5. Medicines were not always stored safely in line with guidelines, and we found pre-drawn syringes in theatre, did not include the dosage of the drug prepared. 6. Infection prevention and control (IPC) procedures were not always followed, and clinical waste was not always stored or disposed of safely. |

| Action the Trust is taking to meet the regulation, including measures/assurance and resources required |
|--|
| <ol style="list-style-type: none"> 1. Develop and implement a learning log to capture key themes and lessons learned from incident reviews. The Quality, Safety and Learning Team will share immediate learning and feedback from incident reviews through a monthly pack of quality, safety and learning information, which will be delivered to all areas. All reviews that require actions will be identified and actions tracked via Datix, all actions will have clear responsible owners and target dates for completion. 2. Conduct weekly incident review meetings at each site to identify immediate learning, changes to practice and ensure timely dissemination. Meeting attendance to be tracked and reported monthly. Key staff will have protected time allocated to attend, contribute, and cascade learning. 3. <i>Removed by CQC during factual accuracy</i> 4. Conduct a review of ward-level, national, corporate, and local KPIs. Develop and launch an integrated KPI improvement dashboard. Establish a multi-disciplinary working group to oversee this process. 5. Complete review of medication storage completed in collaboration with Medicine Management to ensure storage is in line with guidance. Additional storage equipment procured, daily checklist and audit of compliance established. Assurance visits being conducted by medicines management with feedback and recommendations for improvement at the time of the visit. 6. Reinforce IPC roles and responsibilities regarding specifically use of I am clean stickers, uniform policy and hand hygiene. All areas decluttered, damaged furniture removed, and a “check and challenge” protocol established at entry points. Trust wide estates and facilities escalation of waste storage. |
| How the Trust will ensure that the improvements have been made, are sustainable and what measures are in place to ensure effectiveness of the action |
| <ol style="list-style-type: none"> 1. We will ensure the learning log is embedded into practice by assigning ownership within the Quality, Safety, and Learning Team, with monthly reviews to monitor completion and quality of entries. Governance teams in each service area will be held accountable for the timely sharing of key themes and lessons, evidenced through meeting minutes. All actions arising from reviews will be logged in Datix with named owners and agreed deadlines. A monthly audit of action status will be conducted by the governance team, with overdue actions escalated to divisional leads and reported via the Women’s Quality assurance Group (QAG). 2. Weekly incident review meetings will be scheduled in advance with standing agendas and attendance logs to ensure consistency. Attendance will be monitored monthly, and non-attendance escalated to relevant line managers. Key learning and messages will be included in daily handovers and monitored via spot-checks and staff feedback surveys. |

| | | | |
|--|--|---|---|
| Protected time for key staff will be confirmed with operational leads, and compliance will be monitored through monthly workforce reporting. | | | |
| <p>4. A working group will be formally commissioned with defined roles, terms of reference, and reporting lines. Progress will be monitored through fortnightly milestone reviews.</p> <p>Completion of the KPI deep dive and dashboard will be overseen by a dedicated project lead, with key deliverables tracked using a shared action tracker and status updates submitted monthly. The dashboard will be piloted and refreshed based on feedback.</p> <p>5. A joint action plan with Medicines Management will oversee all elements of the medication storage review. Daily compliance checklists will be signed off by nurse-in-charge and subject to weekly spot audits by pharmacy staff.</p> <p>Findings from assurance visits will be shared with ward managers at the time of visit, with any required actions logged and tracked centrally by Medicines management. Monthly compliance reports will be reviewed by the Medicines Management Governance Group, and persistent issues escalated through clinical governance structures.</p> <p>6. IPC responsibilities will be reinforced through mandatory team briefings, led by ward managers, with audit of completion rates. Compliance with hand hygiene, uniform, and sticker use will be checked weekly using a standardised IPC audit tool.</p> <p>All areas will maintain decluttering logs, and estates will receive monthly reports on waste storage issues for action. Check and challenge stations at entrances will be monitored via unannounced spot checks, and outcomes fed back in weekly IPC huddles. Recurring issues will be tracked and escalated through the IPC governance framework.</p> | | | |
| What resources (if any) are needed to implement the change(s) and are these resources available? | | | |
| <p>A highlight report on progress against the actions to address the regulatory breaches is presented to the Weekly Executive Meeting. As well as progress against the actions this also identifies prioritisation of resources, if required, to ensure the quality and safety of our services.</p> <p>Corporate support from Digital and Informatics Team, Estates and facilities and IPC team.</p> | | | |
| Lead Director | Lead Manager | Date all actions will be completed | Date all actions will be assured |
| Rabina Tindale, Chief Nurse | Andy Harding, General Manager Laura Walton, Head of Midwifery Tom Everett, Clinical Director Laura Wokes, Head of Nursing, Medicines Management | 30 September 2025 | 31 January 2026 |
| How we will ensure the safety of people who use the service(s) until this regulation is met? | | | |
| We have established robust systems to uphold and continually enhance patient safety across all services. These include: | | | |

- **Learning from Patient Safety Reviews:** A structured process is in place to capture actions arising from patient safety reviews. Immediate learning is identified, documented, and shared promptly with relevant teams to support continuous improvement and reduce risk.
- **Defined Roles in Infection Prevention and Control (IPC):** Clear roles and responsibilities for infection prevention and control practices are assigned. Regular ward and departmental environmental reviews are conducted to maintain high standards of hygiene and infection prevention.
- **Medicine Safety Audits and Checks:** Daily checklists and audits are systematically carried out to ensure the safe storage, handling, and administration of medicines. This supports adherence to best practice and regulatory standards, reducing the risk of medication-related incidents.

Regulation 17: Good Governance

How the regulation was not being met?

1. Staff told us there was lack of detailed understanding displayed by leaders from a midwifery viewpoint. Leaders did not always have the skills, knowledge, experience and credibility to lead effectively. Leaders of the service had not always considered as a priority, incidents regarding incivility which had impacted on the wellbeing of staff.
2. There was not adequate oversight and escalation processes in place to ensure risks to the health, safety and welfare of staff and people using the service were managed in a timely way. Staff reported a reluctance to raise concerns and incidents because the trust had a blame culture and displayed hostility at times.
3. Staff from ethnic minority groups did not believe that they had the same opportunities for career progression as white staff. This was demonstrated by the National NHS Benchmark survey 2023.
4. We did not see any action plans in place to specifically address staffing concerns within the service.
5. Oversight processes in place to ensure incidents were appropriately investigated, actioned and appropriately shared were not robust. We saw several gaps and staff we spoke with, were not aware of recent incidents. Staff were not provided with the appropriate support and time to ensure all incidents were reported. Nor were they able to easily access debriefing or mental health support following incidents.
6. We found that although systems or processes were in place to ensure quality and safety of care, these were not always operated effectively. For example, families were not always invited to give feedback and when they did, this was not always valued by the clinicians involved.

Action the Trust is taking to meet the regulation, including measures/assurance and resources required

1. Develop and implement Matron of the Day Model and out of hours escalation policy. Improve leadership visibility through scheduled walkarounds and designated out-of-hours contacts as part of Workforce review. Expand non-clinical, specialist and Management Posts to aid consistency of cover across site. Continue to develop and embed effective Team meetings and a Leadership Development Strategy.
2. Conduct open civility culture workshops focused on psychological safety and learning from incidents and patient experience. Promote the Freedom to Speak Up Guardian, champions and routes of escalating concerns anonymously. Implement anonymous reporting mechanisms (e.g., Speak Up Guardians). Share positive examples of improvements made due to staff feedback. Develop culture improvement KPIs within leadership performance metrics.
3. Equality, Diversity and Inclusion element of the Maternity Safety Support Programme completed in July 2025. Use feedback to further develop the Trust and CSU response to breaking barriers and improving inclusion. Ensure membership and participation within the Trust newly launched anti-discrimination working group and focus on improvement mechanisms within the CSU.
4. Immediate mitigation implemented through twice daily huddles and weekly staffing sitrep introduced to mitigate any gaps for the week and week ahead. In addition to further use of bank and agency staff to mitigate short term risk. Midwifery workforce proposal and work force operation plan developed to achieve Birthrate plus recommendations. Full review of clinical education, review of skills and implementation of competency framework to be completed for all areas. The Trust will also establish a process of enhanced oversight in order to oversee the quality and safety of care provision within maternity and neonatal services.
5. Develop and implement a learning log to capture key themes and lessons learned from incident reviews.
The Quality, Safety and Learning Team will share immediate learning and feedback from incident reviews through a monthly pack of quality, safety and learning information will be delivered to all areas.
All reviews that require actions will be identified and actions tracked via Datix, all actions will have clear responsible owners and target dates for completion. Conduct weekly incident review meetings at each site to identify immediate learning and ensure timely dissemination. Meeting attendance to be tracked and reported monthly. Key staff will have protected time allocated to attend, contribute, and cascade learning.
6. Develop and implement a consistent co-produced model to gather women, birthing people and families feedback, inclusively to ensure pathways meets all people's needs who use these services. Procure and implement training across the CSU for key staff to ensure communication following incidents, bereavement, complaints and concerns provides Trauma Informed Care. Supported by the MNVP embed listening to patients within PMRT and bereavement processes.

How the Trust will ensure that the improvements have been made, are sustainable and what measures are in place to ensure effectiveness of the action

| | | | |
|--|--|---|---|
| <p>1 & 2. The CSU will seek feedback on the implementation of systems and civility work via the triangulation of incidents reports, workforce data, staff survey data and feedback provided within team meetings. The Trust will seek feedback through Executive listening events, which have been scheduled for the coming 12 months.</p> <p>3 The outcome of the MSSP EDI visit (July 2025) will be built into the MSPP improvement plan and feedback used to develop work trust wide to support improvement within E, D, I for patients and staff.</p> <p>4 Improvement will be monitored via reporting against the workforce establishment via the perinatal assurance report to Women's Quality Assurance Group and to the Quality Assurance Committee. Once established the maternity and neonatal Improvement Board will oversee the activity within all workstreams.</p> <p>5 Immediate learning shared through weekly immediate incident review meetings established on each site and established monthly quality, safety and learning packs. Staff understanding and knowledge will be reviewed through staff surveys and feedback at staff listening events. Validation will be undertaken to ensure that actions have been added to DATIX from rapid reviews and DATIX reviews.</p> <p>6 Improvement will be monitored via reporting against the workforce establishment via the perinatal assurance report to Women's Quality Assurance Group and to the Quality Assurance Committee. Once established the maternity and neonatal Improvement Board will oversee the activity within all workstreams.</p> | | | |
| What resources (if any) are needed to implement the change(s) and are these resources available? | | | |
| <p>Resource will be required to fund short- and longer-term staffing mitigation.</p> <p>Support will be required from corporate teams in order to deliver improvements related to patient experience, quality governance and wellbeing support.</p> <p>A highlight report on progress against the actions to address the regulatory breaches is presented to the Weekly Executive Meeting. As well as progress against the actions this also identifies prioritisation of resources, if required, to ensure the quality and safety of our services.</p> | | | |
| Lead Director | Lead Manager | Date all actions will be completed | Date all actions will be assured |
| Rabina Tindale, Chief Nurse | Andy Harding, General Manager Laura Walton, Head of Midwifery Tom Everett, Clinical Director | 31/10/25 | 31/03/2026 |
| How we will ensure the safety of people who use the service(s) until this regulation is met? | | | |
| The Trust has implemented a process of enhanced oversight to ensure the consistent delivery of safe, high-quality care within maternity and neonatal services. This approach reflects a proactive commitment to identifying and addressing risks in real time. | | | |

- **Workforce Oversight and Risk Mitigation:** Midwifery staffing levels and associated safety risks are reviewed daily through structured staffing meetings. A defined escalation process is in place to ensure that any concerns regarding staffing or patient safety are addressed promptly and appropriately, safeguarding the continuity and quality of care.
- **Learning from Patient Safety Reviews:** A system has been established to capture key learning and actions arising from patient safety reviews. Immediate learning is disseminated across relevant teams to support rapid improvement and prevent recurrence.

This framework underpins the Trust's wider commitment to fostering a culture of safety, transparency, and continuous learning across all maternity and neonatal services.

Regulation 18: Staffing

How the regulation was not being met?

1. There were insufficient numbers of suitably qualified, competent, skilled and experienced staff deployed to meet peoples' needs and keep people safe.
2. There were gaps on medical rotas and challenges with consultants not always attending when requested or within 30 minutes.
3. Staff did not have protected learning time.

Action the Trust is taking to meet the regulation, including measures/assurance and resources required

1. Immediate mitigation implemented through twice daily huddles and weekly staffing sitrep introduced to mitigate any gaps for the week and week ahead. In addition to further use of bank and agency staff to mitigate short term risk.
Midwifery workforce proposal and workforce operation plan developed to achieve Birthrate plus recommendations.
Full review of clinical education, review of skills and implementation of competency framework for all areas.
2. Complete the Medical Workforce Paper outlining current staffing and future needs by September 2025, with implementation milestones defined through to March 2026. Finalize and embed the medical escalation process in alignment with BSOTS (BadgerNet Supported Obstetric Triage System) by October 2025, ensuring 100% MAC rostering compliance. Conduct a full review of consultant roles and responsibilities by November 2025, and introduce a monthly reporting cycle on escalation response effectiveness, incident trends, and staff feedback.
3. Risk assessment completed as current mitigation is impacting ability to prioritise training. Full service wide review of training to be undertaken and Training Needs Analysis developed for all staff groups aligned to workforce priorities and strategy.
As workforce plans implemented service will work towards set protected learning time for all staff groups.

| | | | |
|---|--|---|---|
| How the Trust will ensure that the improvements have been made, are sustainable and what measures are in place to ensure effectiveness of the action | | | |
| <p>Improvement will be monitored via reporting against the workforce establishment aligned to Birthrate Plus and RCoG guidance via the perinatal assurance report to Women's Quality Assurance Group and to the Quality Assurance Committee. Once established the Maternity and Neonatal Improvement Board will oversee the activity within all workstreams.</p> <p>Improvement will be monitored via reporting against the workforce establishment via the perinatal assurance report to Women's Quality Assurance Group and to the Quality Assurance Committee. Once established the maternity and neonatal Improvement Board will oversee the activity within all workstreams.</p> | | | |
| What resources (if any) are needed to implement the change(s) and are these resources available? | | | |
| <p>Additional resource will be required for the funding of short and long terms staffing mitigation.</p> <p>A highlight report on progress against the actions to address the regulatory breaches is presented to the Weekly Executive Meeting. As well as progress against the actions this also identifies prioritisation of resources, if required, to ensure the quality and safety of our services.</p> | | | |
| Lead Director | Lead Manager | Date all actions will be completed | Date all actions will be assured |
| Rabina Tindale, Chief Nurse Magnus Harrison, Chief Medical Officer | Andy Harding, General Manager Laura Walton, head of Midwifery Tom Everett, Clinical Director | 31 December 2025 | 28 February 2026 |
| How we will ensure the safety of people who use the service(s) until this regulation is met? | | | |
| <p>The Trust has implemented a process of enhanced oversight to ensure the ongoing quality and safety of care within maternity and neonatal services. This includes strengthened governance, risk management, and operational controls.</p> <ul style="list-style-type: none"> Midwifery Staffing and Risk Management: Midwifery staffing levels and the associated safety risks are reviewed and managed daily through dedicated staffing meetings. These meetings enable real-time oversight and decision-making to maintain safe service delivery. <p>A clear escalation process is in place to address any identified concerns related to staffing or patient safety. This includes the proactive deployment of bank and agency staff to support service continuity. Where safe staffing cannot be achieved and risks cannot be mitigated locally, the Trust activates a business continuity plan. This includes escalation to the Director on Call, who is responsible for co-ordinating mutual aid or, where necessary, initiating the diversion of services to maintain patient safety.</p> <p>These measures reflect the Trust's commitment to robust oversight, timely escalation, and the provision of safe, high-quality care across all maternity and neonatal services.</p> | | | |

| | |
|-----------------------------|--------------------------------------|
| Account number | Provider ID RR813 |
| Our reference | SJUH maternity service AP7399 |
| Location name and ID | St James's University Hospital RR813 |
| Service | Maternity Services |

| | | | |
|--|-------------------------------|---|---|
| Regulation 15: Premises and equipment | | | |
| How the regulation was not being met? | | | |
| <p>1. CTG machines were not readily available to staff when required to ensure mother and baby safety. Records held by the department were unclear as to the status of repair of CTG machines being held by medical electronics as there was no documentation.</p> <p>2. Maternity theatres estate was on the risk register, but the risk register was not up to date with actions the trust had taken.</p> | | | |
| Action the Trust is taking to meet the regulation, including measures/assurance and resources required | | | |
| <p>1. Additional CTG machines procured and distributed. In addition, the fetal monitoring team have implemented a CTG asset inventory and escalation process. Process for equipment procurement and repair to be reviewed in conjunction with Medical Physics, revised process to be documented, shared with staff and audited.</p> <p>2. The service has updated the risk, mitigation and controls and this is reviewed monthly by the General Manager.</p> | | | |
| How the Trust will ensure that the improvements have been made, are sustainable and what measures are in place to ensure effectiveness of the action | | | |
| <p>Confirmation that all new CTGs (and CTGs that were under repair) have been delivered/returned to respective clinical areas and asset lot kept via medical physics and locally by the fetal monitoring team.</p> <p>Audit results - revised process for equipment procurement and repair.</p> <p>Monthly review of the risk register by the General Manager established.</p> | | | |
| What resources (if any) are needed to implement the change(s) and are these resources available? | | | |
| Resource approved to procure additional CTG machines. | | | |
| Lead Director | Lead Manager | Date all actions will be completed | Date all actions will be assured |
| Rabina Tindale, Chief Nurse | Andy Harding, General Manager | 30/06/2025 | 03/07/2025 |

| | | | |
|---|---|--|--|
| | Laura Walton, head of Midwifery Tom Everett, Clinical Director | | |
| How we will ensure the safety of people who use the service(s) until this regulation is met? | | | |
| Actions completed. | | | |

| | |
|-----------------------------|-------------------------------|
| Account number | Provider ID RR801 |
| Our reference | LGI Neonate Service AP6482 |
| Location name and ID | Leeds General Infirmary RR801 |
| Service | Neonatal Services |

| |
|--|
| Regulation 12: Safe care and treatment |
| How the regulation was not being met? |
| <ol style="list-style-type: none"> 1. Staff were not proactively engaged in learning by sharing of incidents. We saw examples of repeated incidents. Learning was not always evident following incident reviews. We were not assured that all that was reasonably practicable to mitigate risks was done. 2. We were not assured there were sufficient specialty qualified nurses or higher-level specialty doctors to provide care for babies with complex needs. 3. There were out of date medicines, medicines for patients no longer on the unit and lack of clarity regarding medicines management roles amongst nursing and pharmacy staff. Medicines were not always managed or stored correctly. 4. The environment was not always safe and there was a lack of general stock management responsibilities amongst staff. 5. Babies were not always transferred in line with the neonatal unit criteria. 6. Staff did not always follow good hand hygiene practice during and after providing care to babies. We were not assured infection control practices kept babies safe. |
| Action the Trust is taking to meet the regulation, including measures/assurance and resources required |
| <ol style="list-style-type: none"> 1. Develop and implement a standardised, easily accessible platform or process for sharing key learnings from all incidents, near misses, and "good catches." This will be a dedicated section on the intranet, a regular "lessons learned" bulletin, and brief, focused team briefings 'huddles' which will happen every day. Strengthen Incident Review Processes with a Focus on Preventative Action. Refresh incident review protocols to support the neonatal team to explicitly require and document the identification of systemic contributory factors, not just immediate causes. Emphasise the development of robust, measurable, and assignable preventative actions for each review. |

2. By December 2025, ensure that 100% of medical rotas (Tier 1, Tier 2, and Consultant) in neonatal and perinatal services are fully compliant with BAPM standards. Conduct a comprehensive rota review by September 2025, identifying gaps and required adjustments. Monitor compliance through monthly reporting, with a documented impact on staffing optimisation, patient safety, and delivery of the QIS action plan outcomes. Include rota compliance as a standing item in governance meetings to ensure ongoing oversight.
3. Following the development and implementation of a weekly audit process for all medicine rooms within the neonatal units there will be a robust assurance process implemented to provide assurance standards are being maintained. Clinical Service Unit (CSU) Nursing Leads will meet with Medicines Management and Pharmacy Services (MMPS) Leads to formally establish and document clear, unambiguous roles and responsibilities concerning all aspects of medicines management across the neonatal units.
4. Implement a system to ensure all critical equipment is readily available, safe, and correctly stored, through comprehensive inventory, checks and storage including empowering staff through education on equipment management protocols.
5. Implement a daily multidisciplinary review process for all neonatal transfers (incoming, outgoing, and within-unit level of care changes), ensuring full compliance with the Transfer SOP and neonatal unit criteria. Audit compliance weekly for the first 3 months, then monthly, with documented actions taken where deviations occur. Track trends and improvements through quarterly governance reports to ensure sustained alignment with safety and quality standards.
6. Fully integrate a hand hygiene audit process into both the daily and monthly Matron Assurance frameworks across all clinical areas. Use this mechanism to provide real-time feedback and identify non-compliance trends, aiming for $\geq 95\%$ hand hygiene compliance by November 2025. Share results through monthly dashboards and include hand hygiene as a standing discussion item in clinical governance meetings.

How the Trust will ensure that the improvements have been made, are sustainable and what measures are in place to ensure effectiveness of the action

1. A documented process for incident sharing (both Children's Hospital and Neonatal), a designated communication channel-teams, and a schedule for regular dissemination of incident insights. Revised incident review templates/checklists that include sections for root cause analysis, "lessons learned" for broader application, and specific preventative actions with clear ownership and deadlines.
2. Regular reporting of neonatal staffing against BAPM guidance and mitigation to cover gaps and QIS action plan and improvement in QIS rate and staffing levels and mitigation through Perinatal Assurance Report.
3. A definitive framework established outlining accountability and tasks, eliminating ambiguities and fostering seamless collaboration between nursing and pharmacy teams in medication management. All neonatal unit staff will have a clear understanding of their individual and collective responsibilities in medication management, fostering a more accountable and safer environment evidenced through audit and staff feedback.

4. Established audit encompassing equipment, stores, medication management, and other relevant operational standards formally reported at each Neonatal Governance meeting.
5. Situation Report (SitRep) has been fully revised to proactively identify babies requiring transfer. This enhancement allows for earlier identification and planning. These changes, specifically highlighting HRG1 and HRG2 categories using the NNU specification have been communicated to all staff. The Trust continues to report HRG care days regionally and monthly to CQC for St James's University Hospital.
6. Monitored through Quarterly HCAI/IPC Board Assurance Framework board report to detail progress

What resources (if any) are needed to implement the change(s) and are these resources available?

Additional funding for QIS - agreed within CSU and in forecast.

A highlight report on progress against the actions to address the regulatory breaches is presented to the Weekly Executive Meeting. As well as progress against the actions this also identifies prioritisation of resources, if required, to ensure the quality and safety of our services.

| Lead Director | Lead Manager | Date all actions will be completed | Date all actions will be assured |
|---|---|------------------------------------|----------------------------------|
| Rabina Tindale, Chief Nurse Magnus Harrison, Chief Medical Officer | Colin Holton, Clinical Director Jo Haigh, General Manager Laura Walton, Head of Nursing Laura Wokes, Head of Nursing, Medicines Management | 01/09/2025 | 01/01/2026 |

How we will ensure the safety of people who use the service(s) until this regulation is met?

The Trust has established a comprehensive framework to ensure the delivery of safe, effective care within neonatal services. This includes proactive risk management, real-time learning, and responsive escalation procedures.

- **Daily Safety Huddles and Incident Learning:**

Daily multidisciplinary huddles are in place to facilitate the rapid sharing of learning from incidents and patient experience. This ensures that safety insights are disseminated quickly and embedded into practice to drive continuous improvement.

- **Medicines and Equipment Safety:**

Routine audits of medicines and equipment have been implemented to ensure compliance with safety standards. The Maternity and Neonatal Programme of Support (MNPS) has undertaken two assurance visits to validate safe clinical practice. All medication storage areas have been reviewed, and expired stock has been removed to maintain high standards of medication safety.

- **Staffing Oversight and Support:**

Neonatal staffing levels are reviewed daily through structured staffing meetings, with a clear escalation process in place to address any identified safety concerns. Where safe staffing cannot be achieved or mitigated locally, a regional escalation protocol is activated through the Operational Delivery Network (ODN), enabling mutual aid or the diversion of services to ensure ongoing safety.

- **Workforce Support and Supervision:**

To further enhance the quality of care, a Qualified in Specialty (QIS) nurse will be present in each clinical room to supervise and support non-QIS colleagues, ensuring safe and consistent practice across the unit.

These measures reflect the Trust's continued commitment to high-quality, responsive neonatal care through robust systems of oversight, escalation, and staff development.

Regulation 15: Premises and equipment

How the regulation was not being met?

1. Premises were not fit for purpose in line with national best practice. Cot side resuscitation equipment did not meet Resuscitation Council best practice guidance for all babies that were admitted to the unit leading up to the time of inspection.
2. Areas of the unit needed repair, for example, fire door on kitchen, office door that did not fit properly.
3. Equipment was not always stored correctly. For example, stock items had expired, food in the parents' fridge was not labelled.
4. There was no designated private space for mothers to express breast milk or for private consultations.

Action the Trust is taking to meet the regulation, including measures/assurance and resources required

1. Complete a comprehensive, independent assessment of the neonatal unit premises aligned with national best practice guidelines (e.g., BAPM, NHS Estates). In parallel, conduct an immediate unit-wide audit of all cot-side resuscitation equipment to ensure 100% compliance with Resuscitation Council UK standards. Re-audit quarterly and track findings in the unit's governance reports. The CSU successfully closed all jobs identified during the recent inspection, ensuring premises are in a significantly improved state. A new Standard Operating Procedure (SOP) for Estates Evacuation has been developed and is now actively in use hospital-wide, including within the Neonatal Unit.
2. Confirm closure of 100% of estate related jobs identified in the recent inspection, with documented evidence of completion. Implement a system to ensure all equipment is readily available, safe, and correctly stored, through comprehensive inventory, checks and storage including empowering staff through education on equipment management protocols.

| | | | |
|---|---|---|---|
| 3. Implement process of equipment management to include inventory, checking processes and storage review. 4. LGI- Has breast feeding room and is currently open and in use. | | | |
| How the Trust will ensure that the improvements have been made, are sustainable and what measures are in place to ensure effectiveness of the action | | | |
| 1. Following completion of the action a detailed report identifying every cot space and its resuscitation equipment status, highlighting any deficiencies against Resuscitation Council UK guidance will be produced and a business case developed if additional equipment is required. 2. Complete and ongoing assurance as below. 3. Estates Jobs for escalation discussed every perfect ward meeting monthly. 4. No further action required. | | | |
| What resources (if any) are needed to implement the change(s) and are these resources available? | | | |
| A highlight report on progress against the actions to address the regulatory breaches is presented to the Weekly Executive Meeting. As well as progress against the actions this also identifies prioritisation of resources, if required, to ensure the quality and safety of our services. | | | |
| Lead Director | Lead Manager | Date all actions will be completed | Date all actions will be assured |
| Rabina Tindale, Chief Nurse Magnus Harrison, Chief Medical Officer | Colin Holton, Clinical Director Jo Haigh, General Manager Laura Walton, Head of Nursing | 30/09/2025 | 31/01/2026 |
| How we will ensure the safety of people who use the service(s) until this regulation is met? | | | |
| <p>Emergency equipment for neonatal resuscitation and stabilisation is currently available and accessible at St James's Hospital. In addition to the standard emergency provision, supplementary emergency trolleys have been deployed to ensure immediate access to additional essential equipment.</p> <p>This enhanced provision supports timely and effective emergency response, contributing to the overall safety and preparedness of the neonatal team.</p> | | | |

| | | | |
|---|---------------------|---|---|
| Regulation 17: Good Governance | | | |
| How the regulation was not being met? | | | |
| <ol style="list-style-type: none"> 1. Leaders did not always have the skills, knowledge, experience and credibility to lead effectively. Senior nurses were not aware of incorrect storage of medicines or general items within areas of their responsibility. 2. We found that although systems or processes were in place to ensure quality and safety of care, these were not always operated effectively, including the transfer of babies with complex needs to St James University Hospital Special Care Baby Unit. | | | |
| Action the Trust is taking to meet the regulation, including measures/assurance and resources required | | | |
| <ol style="list-style-type: none"> 1. Equip leaders with the necessary skills, knowledge, experience, and credibility to lead effectively, and to ensure senior nurses are consistently aware of and address critical operational standards, through conducting a leadership capability baseline assessment, targeted leadership development programs and establishing a structured oversight and audit framework for senior nurses. 2. Optimizing Neonatal Transfers through Audits, Simulation, and Enhanced Communication through implementation of review of Standard Operating Procedures (SOPs) for neonatal transfers, transfer audit and compliance, enhances Sitrep for proactive transfers and escalation and clear communication of care levels. | | | |
| How the Trust will ensure that the improvements have been made, are sustainable and what measures are in place to ensure effectiveness of the action | | | |
| <ol style="list-style-type: none"> 1. A documented leadership development curriculum with specific modules, learning objectives, and scheduled training sessions. A dedicated module for senior nurses on regulatory requirements and best practices for medicine and item storage, including practical audit skills. A formal audit schedule and checklist for senior nurses, clear reporting lines for identified non-conformities, and an immediate corrective action process. 2. Monthly audits of transfers to be reported in neonatal governance. Triangulation of incident reporting, patient experience relating to transfer with audit data. | | | |
| What resources (if any) are needed to implement the change(s) and are these resources available? | | | |
| <p>CPD funding to support leadership days.</p> <p>A highlight report on progress against the actions to address the regulatory breaches is presented to the Weekly Executive Meeting. As well as progress against the actions this also identifies prioritisation of resources, if required, to ensure the quality and safety of our services.</p> | | | |
| Lead Director | Lead Manager | Date all actions will be completed | Date all actions will be assured |

| | | | |
|---|---|------------|------------|
| Rabina Tindale, Chief Nurse Magnus Harrison, Chief Medical Officer | Colin Holton, Clinical Director Jo Haigh, General Manager Laura Walton, Head of Nursing | 01/11/2025 | 31/01/2026 |
| How we will ensure the safety of people who use the service(s) until this regulation is met? | | | |
| <ul style="list-style-type: none"> • Ward Leader Training: Training for Ward Leaders has been successfully completed, ensuring they are equipped with the knowledge and skills required to lead safe and effective clinical environments. • Operational SitRep and Escalation Process: Enhancements to the Situation Reporting (SitRep) process have been implemented to improve real-time oversight of service pressures and risk. A clear escalation and reporting framework has been established to ensure timely decision-making and appropriate managerial response to emerging issues. <p>These measures contribute to strengthened leadership, improved situational awareness, and more responsive operational management across services.</p> | | | |

| |
|--|
| Regulation 18: Staffing |
| How the regulation was not being met? |
| <p>2. There were insufficient specialty doctors at night, at the level appropriate to care for babies with complex needs.</p> <p>3. There were insufficient Allied Health Professionals to complete all their duties and to meet the requirements set out in the Neonatal service specification.</p> <p>4. Not all nurses caring for babies with complex needs were suitably specialist qualified. We found some occasions where a nurse cared for more than one baby with complex needs. This was not in line with British Association of Paediatric Medicine guidance.</p> |
| Action the Trust is taking to meet the regulation, including measures/assurance and resources required |

| | | | |
|---|---|---|---|
| <ol style="list-style-type: none"> 1. Develop SOP for escalation and management of gaps on medical rotas Ensure all medical rotas (Tier 1, Tier 2, and Consultant) are reviewed against the British Association of Perinatal Medicine (BAPM) standards, thereby optimizing staffing levels, enhancing patient safety, and contributing to the overall objectives of the Quality Improvement System (QIS) action plan. 2. Undertake an urgent workforce review of Allied Health Professional (AHP) staffing levels at SJUH and LGI. Develop and implement a targeted recruitment and retention plan, including use of bank and agency support where needed, to ensure safe and effective service delivery. 3. Review the QIS action plan- to ensure year on year improvement of qualified neonatal staff. | | | |
| How the Trust will ensure that the improvements have been made, are sustainable and what measures are in place to ensure effectiveness of the action | | | |
| <ul style="list-style-type: none"> • Regular reporting through Perinatal Assurance Report of QIS action plan and improvement in QIS rate and staffing levels and mitigation, if required across all staff groups. | | | |
| What resources (if any) are needed to implement the change(s) and are these resources available? | | | |
| <p>Additional funding for QIS agreed within the Children's Hospital CSU and in forecast.</p> <p>Additional resource will be required for the funding of short and long terms staffing mitigation.</p> <p>A highlight report on progress against the actions to address the regulatory breaches is presented to the Weekly Executive Meeting. As well as progress against the actions this also identifies prioritisation of resources, if required, to ensure the quality and safety of our services.</p> | | | |
| Lead Director | Lead Manager | Date all actions will be completed | Date all actions will be assured |
| Rabina Tindale, Chief Nurse Magnus Harrison, Chief Medical Officer | Colin Holton, Clinical Director Jo Haigh, General Manager Laura Walton, Head of Nursing | 31/07/2026 | 30/10/2026 |
| How we will ensure the safety of people who use the service(s) until this regulation is met? | | | |
| <p>The Trust has implemented a comprehensive approach to ensure the safe staffing and clinical competence of neonatal teams, with robust oversight and escalation pathways in place.</p> <ul style="list-style-type: none"> • Clinical Supervision and Support: A Qualified in Specialty (QIS) nurse will be allocated to each clinical room to oversee care and provide direct support to non-QIS staff. This ensures high standards of clinical supervision and safe delivery of care throughout the unit. | | | |

- **Resuscitation Competency:**

Each room or bay will have, at all times, at least one member of staff fully trained and assessed as competent in Newborn Life Support (NBLS). This guarantees the immediate availability of staff capable of responding to neonatal emergencies.

- **Staffing Oversight and Escalation:**

Neonatal staffing levels and associated safety risks are reviewed daily during structured staffing meetings. A clearly defined escalation process is in place for instances where staffing or safety concerns are identified.

If safe staffing levels cannot be achieved and risks cannot be resolved locally, escalation is made through the Operational Delivery Network (ODN), which co-ordinates mutual aid or, where necessary, the diversion of services to maintain patient safety.

These measures reflect the Trust's ongoing commitment to delivering safe, responsive, and high-quality neonatal care through effective workforce planning, clinical competency, and regional collaboration.

| | |
|-----------------------------|--------------------------------------|
| Account number | Provider ID RR813 |
| Our reference | SJUH Neonate service AP7400 |
| Location name and ID | St James's University Hospital RR813 |
| Service | Neonatal Services |

| |
|--|
| Regulation 12: Safe care and treatment |
| How the regulation was not being met? |
| <ol style="list-style-type: none"> 1. Staff were not proactively engaged in learning by sharing of incidents. We saw examples of repeated incidents. Learning was not always evident following incident reviews. We were not assured that all that was reasonably practicable to mitigate risks was done. 2. There were no control measures in place to ensure visitors complied with IPC good practices. 3. There were out of date medicines, medicines for patients no longer on the unit and lack of clarity regarding stock management responsibilities amongst staff. |
| Action the Trust is taking to meet the regulation, including measures/assurance and resources required |
| <ol style="list-style-type: none"> 1. Develop and implement a standardised, easily accessible platform or process for sharing key learnings from all incidents, near misses, and "good catches." This will be a dedicated section on the intranet, a regular "lessons learned" bulletin, and brief, focused team briefings 'huddles' which will happen every day. Strengthen Incident Review Processes with a focus on Preventative Action. Revamp incident review protocols to support the neonatal team to explicitly require and document the identification of systemic contributory factors, not just immediate causes. Emphasise the development of robust, measurable, and assignable preventative actions for each review. 2. Develop and widely distribute concise, visually engaging IPC guides that are available in multiple languages and easy-read formats. 'How to keep my baby safe' sessions implemented; brief IPC orientation for all new parents/primary caregivers upon admission. This will cover critical information tailored to the neonatal environment, emphasising their vital role in infection prevention, facilitating and reinforcing hand hygiene |

| | | | |
|---|---|---|---|
| 3. Following the development and implementation of a weekly audit process for all medicine rooms within the neonatal units there will be a robust assurance process implemented to provide assurance standards are being maintained. Clinical Service Unit (CSU) Nursing Leads will meet with Medicines Management and Pharmacy Services (MMPS) Leads to formally establish and document clear, unambiguous roles and responsibilities concerning all aspects of medicines management across the neonatal units. | | | |
| How the Trust will ensure that the improvements have been made, are sustainable and what measures are in place to ensure effectiveness of the action | | | |
| 1. A documented process for incident sharing (both Children's Hospital and Neonatal), a designated communication channel-teams, and a schedule for regular dissemination of incident insights. Revised incident review templates/checklists that include sections for root cause analysis, "lessons learned" for broader application, and specific preventative actions with clear ownership and deadlines 2. New information booklet for parents and families has been fully developed and is now in active circulation. This resource provides vital guidance to help families understand their baby's care. Effectiveness will be measured through regular interaction with families, HCAI rate will continue to be monitored with these interventions tracked. 3. A definitive framework established outlining accountability and tasks, eliminating ambiguities and fostering seamless collaboration between nursing and pharmacy teams in medication management. All neonatal unit staff will have a clear understanding of their individual and collective responsibilities in medication management, fostering a more accountable and safer environment evidenced through audit and staff feedback. | | | |
| What resources (if any) are needed to implement the change(s) and are these resources available? | | | |
| A highlight report on progress against the actions to address the regulatory breaches is presented to the Weekly Executive Meeting. As well as progress against the actions this also identifies prioritisation of resources, if required, to ensure the quality and safety of our services. Support will be required from corporate teams, IPC and medicines Management. | | | |
| Lead Director | Lead Manager | Date all actions will be completed | Date all actions will be assured |
| Rabina Tindale, Chief Nurse Magnus Harrison, Chief Medical Officer | Colin Holton, Clinical Director Jo Haigh, General Manager Laura Walton, Head of Nursing | 30/09/2025 | 31/12/2025 |
| How we will ensure the safety of people who use the service(s) until this regulation is met? | | | |
| The Trust continues to embed robust processes to maintain a safe and hygienic environment within neonatal services, with a focus on communication, infection prevention, and continuous improvement. | | | |

| |
|---|
| <ul style="list-style-type: none"> • Daily Safety Huddles: Daily huddles are in place to ensure timely and consistent communication of key safety messages, operational updates, and learning. This supports team situational awareness and rapid information sharing. • Infection Prevention and Control (IPC): Ward staff and ward clerks actively support IPC compliance by reminding all visitors and staff to remove coats and perform hand hygiene upon arrival to the ward. In addition, IPC guidance is embedded into parent education sessions through the “How to Keep My Baby Safe” talks, promoting awareness and shared responsibility for infection prevention. • Audit and External Assurance: Routine audits are in place to monitor compliance with clinical safety standards. The Maternity and Neonatal Programme of Support (MNPS) has conducted two assurance visits to validate safe practices. As part of this process, all medication storage areas have been reviewed, and expired stock has been removed to uphold medicine safety standards. <p>These measures demonstrate the Trust’s commitment to infection prevention, open communication, and maintaining a safe environment for babies, families, and staff.</p> |
|---|

| |
|---|
| Regulation 15: Premises and equipment |
| How the regulation was not being met? |
| <ol style="list-style-type: none"> 1. We found areas with cluttered and dusty surfaces, excess equipment stored in cupboards, wardrobes, and in the decontamination room. 2. Equipment was stored within splash zones of sinks and hand wash basins. 3. Computers on wheels were not cleaned between patients. |
| Action the Trust is taking to meet the regulation, including measures/assurance and resources required |
| <ol style="list-style-type: none"> 1. Regular programme of decluttering developed and instigated. Effective programme of assurance of environment cleanliness and clutter being developed. 2. All equipment removed. Splash zone check added to the IPC audit and included in the Water Safety Education programme. 3. Cleaning process implemented. Wipes procured for each computer on wheels and attached. Compliance check added to the IPC observational audit. |

| How the Trust will ensure that the improvements have been made, are sustainable and what measures are in place to ensure effectiveness of the action | | | |
|--|---|---|---|
| All new processes have been built into the departments regular programme of audit and, where applicable, within education programs. | | | |
| What resources (if any) are needed to implement the change(s) and are these resources available? | | | |
| A highlight report on progress against the actions to address the regulatory breaches is presented to the Weekly Executive Meeting. As well as progress against the actions this also identifies prioritisation of resources, if required, to ensure the quality and safety of our services. | | | |
| Lead Director | Lead Manager | Date all actions will be completed | Date all actions will be assured |
| Magnus Harrison, Chief Medical Officer | Colin Holton, Clinical Director Jo Haigh, General Manager Laura Walton, Head of Nursing | 30/10/2025 | 31/01/2026 |
| How we will ensure the safety of people who use the service(s) until this regulation is met? | | | |
| Immediate action was taken following inspection to ensure that all clinical areas are free from clutter and maintained in a clean, orderly condition, in full compliance with Trust policy. These actions support infection prevention and control measures and ensure a safe and therapeutic environment for patients, families, and staff. | | | |

| Regulation 17: Good Governance |
|--|
| How the regulation was not being met? |
| <ol style="list-style-type: none"> 1. We found differences in staff's understanding of the level of need the unit provided for. We were not assured that there were effective systems in place for ensuring that babies were cared for in the correct environment. 2. We found areas of the environment in need of repair during inspection. We were not assured that there was adequate oversight and escalation processes in place to ensure risks to health, safety and welfare of staff and people using the service were managed in a timely way. |
| Action the Trust is taking to meet the regulation, including measures/assurance and resources required |

| | | | |
|--|---|---|---|
| <ol style="list-style-type: none"> 1. Optimizing Neonatal Transfers through Audits, Simulation, and Enhanced Communication through implementation of review of Standard Operating Procedures (SOPs) for neonatal transfers, transfer audit and compliance, enhances Sitrep for proactive transfers and escalation and clear communication of care levels. 2. The CSU has successfully closed all jobs identified during the recent inspection, ensuring premises are in a significantly improved state. A new Standard Operating Procedure (SOP) for Estates Evacuation has been developed and is now actively in use hospital-wide, including within the Neonatal Unit. | | | |
| How the Trust will ensure that the improvements have been made, are sustainable and what measures are in place to ensure effectiveness of the action | | | |
| <ol style="list-style-type: none"> 1. Monthly audits of transfers to be reported to the neonatal governance group. Triangulation of incident reporting, patient experience relating to transfer with audit data. 2. Complete. Estates Jobs for escalation discussed at every perfect ward meeting monthly. | | | |
| What resources (if any) are needed to implement the change(s) and are these resources available? | | | |
| A highlight report on progress against the actions to address the regulatory breaches is presented to the Weekly Executive Meeting. As well as progress against the actions this also identifies prioritisation of resources, if required, to ensure the quality and safety of our services. | | | |
| Lead Director | Lead Manager | Date all actions will be completed | Date all actions will be assured |
| Magnus Harrison, Chief Medical Officer | Colin Holton, Clinical Director Jo Haigh, General Manager Laura Walton, Head of Nursing | 01/04/2026 | 01/09/2026 |
| How we will ensure the safety of people who use the service(s) until this regulation is met? | | | |
| Enhancements to the Situation Reporting (SitRep) process have been completed, strengthening real-time visibility of service status and risks. A clear escalation and reporting structure has been established to ensure timely decision-making and appropriate leadership response to emerging operational or clinical concerns. | | | |

| |
|--|
| Regulation 18: Staffing |
| How the regulation was not being met? |

| | | | |
|---|--|---|---|
| 1. There were not sufficient numbers of suitably qualified, competent, skilled and experienced staff to meet peoples, needs. AHP provision did not meet the requirements set out in the neonatal service requirement. Adult basic life support and neonatal life support were not at compliant levels for all staff groups. There were gaps on medical rotas. | | | |
| Action the Trust is taking to meet the regulation, including measures/assurance and resources required | | | |
| <ul style="list-style-type: none"> Develop SOP for escalation and management of gaps on medical rotas. Ensure all medical rotas (Tier 1, Tier 2, and Consultant) are reviewed against the British Association of Perinatal Medicine (BAPM) standards, thereby optimizing staffing levels, enhancing patient safety, and contributing to the overall objectives of the Quality Improvement System (QIS) action plan. Review the QIS action plan- to ensure year on year improvement of qualified neonatal staff. Complete a baseline assessment of NBLS and complete targeted identification of non-compliance through increased NBLS training. Undertake an urgent workforce review of Allied Health Professional (AHP) staffing levels at SJUH and LGI. Develop and implement a targeted recruitment and retention plan, including use of bank and agency support where needed, to ensure safe and effective service delivery. Develop SOP for escalation and management of gaps on medical rotas | | | |
| How the Trust will ensure that the improvements have been made, are sustainable and what measures are in place to ensure effectiveness of the action | | | |
| <ul style="list-style-type: none"> Regular reporting through Perinatal Assurance Report to Quality Assurance Committee of QIS action plan and improvement in QIS rate. Implement weekly monitoring of NBLS completion rates against the 90% target. | | | |
| What resources (if any) are needed to implement the change(s) and are these resources available? | | | |
| <ul style="list-style-type: none"> Additional funding for QIS agreed within the Children's Hospital CSU and in forecast. Additional NBLS trainers have been identified but will need study time allocating on roster to deliver sessions. Additional resource will be required for the funding of short and long terms staffing mitigation. A highlight report on progress against the actions to address the regulatory breaches is presented to the Weekly Executive Meeting. As well as progress against the actions this also identifies prioritisation of resources, if required, to ensure the quality and safety of our services. | | | |
| Lead Director | Lead Manager | Date all actions will be completed | Date all actions will be assured |
| Magnus Harrison, Chief Medical Officer | Colin Holton, Clinical Director Jo Haigh, General Manager | 31/07/2026 | 30/09/2026 |

| | | | |
|--|-------------------------------|--|--|
| | Laura Walton, Head of Nursing | | |
| How we will ensure the safety of people who use the service(s) until this regulation is met? | | | |
| <p>To ensure the consistent delivery of safe, high-quality care within neonatal services, the Trust has implemented the following workforce and escalation measures:</p> <ul style="list-style-type: none"> • Qualified Clinical Supervision: A Qualified in Specialty (QIS) nurse will be assigned to each clinical room on every shift to lead care and provide direct support and oversight to non-QIS staff, ensuring safe and consistent practice. • Emergency Competency Coverage: Each designated room or bay will have at least one staff member per shift who is fully trained and assessed as competent in Newborn Life Support (NBLS), ensuring the team is prepared to respond to neonatal emergencies at all times. • Staffing Oversight and Regional Escalation: Neonatal staffing levels and associated safety risks are reviewed daily during structured staffing meetings. Where concerns arise, a clearly defined escalation process is followed. If safe staffing cannot be achieved locally, escalation is made via the Operational Delivery Network (ODN), which co-ordinates mutual aid or, if necessary, the diversion of services to maintain safe and effective care. <p>These measures reflect the Trust's commitment to maintaining safe staffing levels, supporting clinical competence, and ensuring rapid escalation when required to safeguard neonatal patients.</p> | | | |