Care Quality Commission

Royal Devon University Healthcare NHS Foundation Trust

Royal Devon & Exeter Hospital (Wonford)

Inspection report

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Ratings

Overall rating for this location	Requires Improvement
Are services safe?	**Requires Improvement**
Are services well-led?	**Requires Improvement**

Our findings

Overall summary of services at Royal Devon & Exeter Hospital (Wonford)

Requires Improvement ↓

Pages 1 to 3 of this report relate to the hospital and the ratings of that location, from page 4 the ratings and information relate to maternity services based at Royal Devon and Exeter hospital.

We inspected the maternity service at Royal Devon and Exeter hospital as part of our national maternity inspection programme. The programme aims to give an up-to-date view of hospital maternity care across the country and help us understand what is working well to support learning and improvement at a local and national level.

Maternity services include an outpatient department, labour ward / delivery suite, triage, midwifery led unit, antenatal & postnatal wards and one maternity theatre. Between April 2022 and March 2023 approximately 3497 babies were born at the Royal Devon and Exeter hospital.

This location was last inspected under the maternity and gynaecology framework in 2016. Following a consultation process CQC split the assessment of maternity and gynaecology in 2021. As such the historical maternity and gynaecology rating is not comparable to the current maternity inspection and is therefore retired. This means the resulting rating for Safe and Well-led from this inspection will be the first rating of maternity services for the location. This does not affect the overall Trust level rating.

We will publish a report of our overall findings when we have completed the national inspection programme.

We carried out a short notice announced focused inspection of the maternity service, looking only at the safe and well-led key questions.

Our rating of this hospital went down. We rated it as Requires Improvement because:

- Our rating of Requires Improvement for maternity services changed the ratings for the hospital overall. We rated maternity as Requires Improvement in safe and well led.

We also inspected one other maternity location run by Royal Devon University Healthcare NHS Foundation Trust. Our report is here:

The North Devon District Hospital– https://www.cqc.org.uk/location/RH801

How we carried out the inspection

We provided the service with 2 working days' notice of our inspection.

We visited labour ward / delivery suite, triage, midwifery led unit, antenatal & postnatal wards and one maternity theatre.

We spoke with 15 midwives, 4 doctors, 5 support workers, 2 women and birthing people. We received no responses to our give feedback on care posters which were in place during the inspection.

Our findings

We reviewed 12 patient care records, 5 Observation and escalation charts and 10 medicines records.

Following our onsite inspection, we spoke with senior leaders within the service; we also looked at a wide range of documents including standard operating procedures, guidelines, meeting minutes, risk assessments, recent reported incidents as well as audits and action plans. We then used this information to form our judgements.

You can find further information about how we carry out our inspections on our website: https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection.

Maternity

Requires Improvement

We rated it as requires improvement because:

- The service had issues with sickness absence. Staffing levels did not always match the planned numbers putting the safety of women and birthing people and babies at risk.
- Staff did not always use equipment and control measures to protect women and birthing people, themselves, and others from infection. Some equipment and areas of the premises were not always visibly clean.
- Leaders did not operate effective governance systems. They did not always manage risk, issues, and performance well. They did not consistently monitor the effectiveness of the service. Though staff were committed to improving services, they did not always have the skills and resources to do so. The service did not always manage incidents well and learn lessons from them.
- Staff were overdue completion of maternity mandatory training, including safeguarding and role specific training, putting women and birthing people and babies at risk.

However:

- Staff assessed risks to women and birthing people and kept good care records. They managed medicines well.
- Leaders ran services well using reliable information systems and supported staff to develop their skills.
- Staff understood the service's vision and values, and how to apply them in their work.
- Managers monitored the effectiveness of the service and made sure staff were competent. Staff felt respected, supported, and valued. They were focused on the needs of women and birthing people receiving care.
- Staff were clear about their roles and accountabilities.
- The service engaged well with women and birthing people and the community to plan and manage services.
- People could access the service when they needed it and did not have to wait too long for treatment and all staff were committed to improving services continually.

Is the service safe?

Requires Improvement

Mandatory training

The service provided mandatory training in key skills to all staff; however, not everyone had completed mandatory training updates or their role specific training.

Most staff were up to date with their mandatory multi-disciplinary PrOMPT (Practical Obstetric Multi-Professional Training) Study Day East (MPSD) training. Records showed 93% of midwifery staff, and 90% of maternity support workers were compliant, meeting the service compliance rate of 90%.

Maternity

Medical staff received and kept up to date with their mandatory training. Ninety three percent of consultants had completed all mandatory training courses, 87% of junior medical staff and 91% of anaesthetist's had completed their required mandatory training courses. The service education team had a proactive plan regarding the mandatory training for junior medical staff as their placements in the maternity department were only 12-weeks long.

The mandatory training met the needs of woman and birthing people and staff. Training included cardiotocograph (CTG) competency, skills, and drills training, the MPSD training included adult life support and basic neonatal life support training.

Training was up-to-date and reviewed regularly. There was an emphasis on multidisciplinary training leading to better outcomes for woman and birthing people and babies. Training included personalised care and an e-learning package for the National Bereavement Care Pathway.

Seventy-eight per cent of staff had completed fetal monitoring cardiotocograph training, below the services target of 85%, and fetal Growth Assessment Protocol (GAP) compliance October 2023 reported by the service as 36% below the service compliance rate of 85%. The service told us that 134 midwives were now out of compliance with GAP and stated there was insufficient time within the current study day provision for staff to complete this training. No further action plans have been provided by the service as to how this would be addressed. This meant the service could not be assured staff had the appropriate skills to keep women and birthing people safe.

Staff we spoke with reported that changes to their IT systems had made it difficult to monitor staff training records. Where leaders had identified staff non-compliance, we were told staff were sent reminder email alerts, so they knew when to renew their training. Staff we spoke with reported they had limited time away from clinical duties to complete the training. They were given 3 days per year and could not complete all the training because of staffing pressures. Infection prevention data provided by the service showed infection prevention & control level 2 annual training for registered staff in women & child health 80% below the trust compliance level of 85%.

Safeguarding

The service provided mandatory training to all staff however not everyone had completed their mandatory safeguarding training to the appropriate level.

Staff had not always kept up to date with training specific to their role on how to recognise and report abuse. The service told us the compliance rate for this training was 85%, however, training records sent to us in December 2023 showed 73% of maternity ward and labour ward registered staff had completed level 3 safeguarding children yearly training. Seventy-six per cent of maternity outpatient registered staff had completed Level 3 safeguarding children.

Medical staff level 3 safeguarding children level 3 compliance sent to us showed 27% compliance. A representative of the service told us they had identified errors in the mapping of training and from September 2023. The service confirmed they had provided the correct training information regarding staff child protection training. We had requested data relating to staff compliance for level 3 safeguarding adults training however this was not received for medical staff and midwifery staff. The lack of oversight suggested the service was not reasonably assured staff had the appropriate skills to safeguard children and vulnerable adults.

However, staff we spoke with could give examples of how to protect women and birthing people from harassment and discrimination, including those with protected characteristics under the Equality Act (2010). Staff could identify adults

and children at risk of, or suffering, significant harm and worked with other agencies to protect them, lateral checks would be made, and information could be shared via the Child Protection Information System (CPIS). Staff asked women and birthing people about domestic abuse. Where safeguarding concerns were identified women and birthing people had birth plans with input from the safeguarding team.

Staff we spoke with could explain safeguarding procedures, how to make referrals and how to access advice. The service had a safeguarding team who staff could turn to when they had concerns. Care records detailed where safeguarding concerns had been escalated in line with local procedures.

The hospital had not practised what would happen if a baby was abducted within the 12 months before inspection. Staff could not recall when the last baby abduction drill had taken place, and no data was submitted to show one had been recently competed. The baby abduction policy was expired from July 2023. When asked for further information the trust told us there was no evidence of a recent baby abduction drill at Royal Devon and Exeter hospital. While the security of the unit had not been tested, during our inspection, we noted that ward areas were secure, and doors were monitored.

Staff followed safe procedures for children visiting the ward.

Cleanliness, infection control and hygiene

The service did not always manage infection risks well. Staff used did not always use equipment and control measures to protect women and birthing people, themselves, and others from infection. Some equipment and some areas of the premises were not always visibly clean.

Maternity clinical areas were visibly clean and had suitable furnishings which were clean and well-maintained. Wards had recently been refurbished to the latest national standards.

However, we found store cupboards used by the antenatal & postnatal ward, triage, and the birthing centre to be disorganized, overstocked, and cluttered. We saw medical items had been left on the floor open inside a black bin type bag. Staff were unable to advise as to why this was there. We found a bag labelled ‘infant feeding grab bag’ on the cupboard floor, next to boxes of open items. Worktops were cluttered with boxes and other items.

Intravenous fluids (IV’s) had been stored within general store cupboards. Trolleys were found to be disorganized and over stocked. A yellow mop and yellow bucket were found to be stored in a birthing centre room bathroom inappropriately.

We observed the service using fabric cubical curtains; however, these did not have labels or information stating when they had been hung or when they should be replaced this was raised during the inspection with the matrons.

Cleaning records were up-to-date and demonstrated all areas were cleaned regularly.

The service generally performed well for cleanliness from the audit results the service have provided.

Staff followed infection control principles including the use of personal protective equipment (PPE). Leaders completed regular infection prevention and control and hand hygiene audits. We received evidence of hand hygiene audits carried out for months July, August, and September 2023 in all maternity areas. Results showed compliance being 94% July, 95% August, and 97% September above the service 85% compliance.

Data showed that cleaning audits were carried out weekly and between months October and November 2023, compliance was consistently above 98%. Staff told us they regularly cleaned equipment after contact with women and birthing people, equipment was visibly clean; however, we did not see evidence that cleaning had occurred, for example by using "I am clean stickers". We saw fetal heart monitoring machines which we were told had been cleaned and were ready to use, however, on inspecting the probes two machines each had one probe that we found to be dirty, and the stand for the CTG machine was found to have paint clearly peeling off and rust. These matters were escalated to the matrons during the inspection as a matter of concern.

We found baby resuscitaire on the birthing / triage area had been reported as clean but was found to be dusty, this was raised with staff at the time. Bed sheets, bath towels and blankets were found to be stored at the side of the door of the triage office uncovered.

We found a used orange mop and bucket had been left in a bathroom on the birthing centre inappropriately stored.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment mostly kept people safe. However, staff did not always carry out checks of specialist equipment. Staff managed clinical waste well.

Call bells were accessible to women and birthing people if they needed support and staff responded quickly when called.

The design of the environment followed national guidance. The maternity unit was fully secure with a monitored entry and exit system.

Staff carried out daily safety checks of specialist equipment. However, we found the labour ward post-partum haemorrhage (PPH) trolley was not tamper proof, and drugs could be removed from the trolley without staff's knowledge.

Records showed the resuscitation equipment on labour ward was not checked daily. From 1st to 29th November 2023 adult resuscitation trolleys checklist showed staff had not checked the equipment daily, there were 11 days when this had not been completed. We found resuscitation equipment (bag and mask) which had expired in January 2019 in a birthing room on labour ward. We found multiple packets of pairs of expired gloves, dressing packs, oral suction catheters, venepuncture blood collection vials, cannulas, and several items from "resuscitaire top up" box which we raised at the time of inspection with matrons.

Records showed that in the labour ward drug refrigerator, containing temperature sensitive medications did not have daily checks completed 7 days September 2023, 5 days October, 01 November – 18 November 4 days daily checks were not completed. Triage APN21 ward drug refrigerator, did not have daily checks completed, 17 days September 2023, 18 in days October 5 days October, -18 November on 12 days daily checks were not completed.

Staff regularly checked birthing pool cleanliness and the service had a contract for legionella testing of the water supply.

The service had suitable facilities to meet the needs of women and birthing people's families. The birth partners of women and birthing people were supported to attend the birth and provide support.

Maternity

The service had enough suitable equipment to help them to safely care for women and birthing people and babies. However, we found that on triage, and the birthing centre there were no suction units although suction points were available and built in. One mobile suction unit was found to be stored next to the adult resuscitation trolley at the postnatal ward area, this equipment was shared with triage and the birthing centre.

In the birth centre there were pool evacuation nets in all rooms and on the day assessment unit there was a portable ultrasound scanner, cardiotocograph machines and observation monitoring equipment.

The service had a mobile unit with a screen that could be used for women or birthing people wishing or needing to use sign language services.

Over the last 12 months the trust had to temporarily suspend maternity services twice due to there being a shortage of equipment.

Staff disposed of clinical waste safely. Sharps bins were labelled correctly and not over-filled. Staff separated clinical waste and used the correct bins. They stored waste in locked bins while waiting for removal.

The bereavement suite was based on the labour ward and had separate access. However, it was not sound proofed. If families were on the labour ward, they were in a room that was not sound proofed despite national guidance advising rooms being used as for the bereaved should be sound proofed.

Assessing and responding to risk

Staff completed and updated risk assessments and took action to remove or minimise risks. However, staff did not always identify nor quickly act upon women and birthing people at risk of deterioration.

There was a dedicated telephone line for access to triage, using a mobile telephone. However, there was no answer machine or divert on the phone if staff were unable to answer calls. This meant there was a risk women and birthing people may not be able to access information, advice or support in an emergency.

Leaders and staff monitored waiting times to make sure women and birthing people could access emergency services when needed and received treatment within agreed timeframes and national targets. Arrival times were recorded in the electronic care record and on a whiteboard in the triage team office. Following the inspection, the trust shared plans to optimise their electronic patient records system and install a digital triage whiteboard to ensure better oversight of patient journey to ensure women and birthing people could receive treatment within agreed timeframes.

Staff did not always escalate concerns when there were signs the condition of women and birthing people could be deteriorating. Staff used a nationally recognised Modified Early Warning Score (MEWS) tool to identify women and birthing people at risk of deterioration and direct staff when escalation may be appropriate. The trust had completed a recent audit between August and October 2023 of 10 records to check they were fully completed and escalated appropriately. The audit looked at maternity records from this hospital and maternity services at North Devon District Hospital. The audit showed that 50% of MEWS charts were completed. The results audit identified 50% of women or birthing people with abnormal scores had been escalated correctly. The service did not have a reasonable level of assurance all women or birthing people at risk of deterioration were escalated appropriately. However, during the inspection we reviewed 5 MEWS records and found evidence staff had completed 4 MEWS records escalating concerns to senior staff where appropriate. The audit found 4 out of 10 Newborn Early Warning Trigger and Track (NEWTT) charts were completed fully, 5 babies who had abnormal NEWTT scores were escalated appropriately.

Maternity

Staff used the fresh eyes approach to carry out fetal monitoring however, leaders did not have access to audit data on how effectively staff monitored women and birthing people during labour having continuous cardiotocograph (CTG). The audit had used a sample of 30 patients between June and November 2023 and showed 7 out of 30 cases had received hourly fresh eyes and 24 out of 30 had received hourly CTG assessments. Due to the small sample size of 30 women or birthing people over 5 months, the service could not ensure the effective use of fresh eyes audit. This raised concerns about whether leaders could promptly act on the results in accordance with Element 4 of "Saving Babies Lives" version 3, dated July 2023, which focuses on "effective fetal monitoring during labour." Such uncertainties increased the risk of undesirable outcomes, including serious harm to both women, birthing people, and their babies.

Staff knew about and dealt with any specific risk issues. Staff reviewed care records from antenatal services for any individual risks.

The trust conducted routine audits to assess compliance with surgical safety protocols. According to WHO audits on surgical safety, the organisation demonstrated full compliance with step 1, achieving an average of 95% compliance, while also maintaining 100% compliance in the remainder of the audit from June to November 2023.

The service had 24-hour access to mental health liaison and specialist mental health support. Staff explained when and how they could seek assistance to support women and birthing people with mental health concerns. Staff completed, or arranged, psychosocial assessments and risk assessments for women and birthing people thought to be at risk of self-harm or suicide.

Staff shared key information to keep women and birthing people safe when handing over their care to others. The care record was on a secure electronic care record system used by all staff involved in the woman or birthing person’s care. Each episode of care was recorded by health professionals and was used to share information between care givers.

Shift changes and handovers included all necessary key information to keep women and birthing people and babies safe. The trust completed 2 safety huddles each shift to ensure all staff were up to date with key information. Each member of staff had an up-to- date handover sheet with key information. Through both our observations on the day of the inspection as well as staff accounts, we found there was no standardised way to handover such as the nationally recommended information sharing tool such as SBAR, which describes the Situation, Background, Assessment, Recommendation for each person. Staff told us during the inspection SBAR audits were not in place and we did not see SBAR forms in use during the inspection. However, following our inspection we received a SBAR review completed by the trust for the period September, October and November 2023, where 10 sets of random notes were reviewed to per month, this evidenced overall, 80% of the sets of notes had not been signed or dated. The service also provided information that showed an SBAR tool was available on the electronic patient care record.

Staff completed newborn risk assessments when babies were born using recognised tools and reviewed this regularly.

Staff completed risk assessments prior to discharging women and birthing people into the community and made sure third-party organisations were informed of the discharge.

The triage waiting area was seen to be clean and to have plenty of seating, however a significant amount of the area was obscured from the view of the receptionist and others, the service had recognised the risk and put measures in place to ensure that if someone would need urgent assistance, they could be seen, and support provided.

Midwifery Staffing

Maternity

The service had issues with sickness absence. Staffing levels did not always match the planned numbers putting the safety of women and birthing people and babies at risk.

The service reported maternity 'red flag' staffing incidents in line with National Institute for Health and Care Excellence (NICE) guideline 4 'Safe midwifery staffing for maternity settings. A midwifery 'red flag' event is a warning sign that something may be wrong with midwifery staffing. Between November 2022 and November 2023, the trust reported 11 red flag incidents. Data provided following our inspection showed 654 red flag incidents in the first 3 quarters of 2023, 646 of these incidents were reported as delays between admission for induction of labour and beginning the process.

National Report and Learning System (NRLS) data did not specify time delay for perineal repair meaning it was unclear how long women and birthing people had to wait before receiving care, and the service could not be fully assured women and birthing people were not waiting longer than 60 minutes which should be being flagged as a red flag. Between 12/12/2022 and 11/3/2023 we identified 5 out of 301 incidents of women and birthing people required suturing following a 3rd or 4th degree tear, but no times were given to indicate if there was a delay. Recent audit data suggests 50% of MEWS had been completed, which indicates a level of under reporting. Data submitted to NRLS following March 2023 data had not been submitted as part of the right category.

Managers accurately calculated and reviewed the number and grade of nurses, nursing assistants and healthcare assistants needed for each shift in accordance with national guidance. They completed a maternity safe staffing workforce review in line with national guidance in April2021. This review recommended 180.25 whole-time equivalent (WTE) midwives, which was then uplifted to 206.2 WTE following the Ockenden report.

The Annual Staffing Review Maternity 2023 maternity reported 6.5% absence rate for midwives in September. Budgets for staffing showed a -0.25 WTE (80.30/80.05 WTE) variance for registered midwifery staff and -1.89 WTE (19.89/18.00 WTE) for midwifery care assistants. On the day of inspection, we noted that the coordinator was not supernumerary and was working clinically throughout the day affecting their ability to monitor and respond to staffing pressures, acuity, and capacity.

Staff were required to regularly update a staffing tool used to dynamically risk assess staffing in order to ensure there was a safe staffing establishment and skill mix allocation. However, during the inspection managers were not consistently updating this when prompted due to high levels of staffing pressure, meaning opportunities to reallocate staffing recourses could have been missed.

Managers requested bank staff familiar with the service and made sure all bank and agency staff had a full induction and understood the service.

Managers did not consistently support midwifery staff to develop through regular, constructive clinical supervision of their work and evidence provided on 29th November 2023 showed 203 out of 387 or 52% of midwifery staff across site had received their appraisal.

Medical staffing

The service had enough medical staff with the right qualifications, skills, training, and experience to keep women and birthing people and babies safe from avoidable harm and to provide the right care and treatment. Managers regularly reviewed and adjusted staffing levels and skill mix and gave locum staff a full induction.

Maternity

The service had a good skill mix and availability of medical staff. There were enough medical staff to keep women and birthing people and babies safe. The medical staff matched the planned number. The service had no vacancies for consultants and met establishment for middle tier medical staff during the day. There was 0.5 WTE vacancy for the on-call rota, meaning some locum cover was required to support with the on-call resident rota. They carried out a twice daily ward round.

Sickness rates for medical staff fluctuated over the past 12 months but decreased from 4.64% in May 2023 to 1.75% in August 2023.

Managers could access locums when they needed additional medical staff and made sure locums had a full induction to the service before they started work.

The service had a good skill mix and availability of medical staff on each shift and reviewed this regularly. The service always had a consultant on call during evenings and weekends. Managers told us medical staff were supported to develop through regular, constructive clinical supervision of their work. Eighty-eight per-cent of medical staff had received an annual appraisal.

The trust had not completed an audit of the maternity triage unit to review waiting times following a request for a medical staff member to attend, however staff told us it was sometimes difficult to have a patient reviewed in a timely manner as the doctors were not always available.

Records

Staff kept detailed records of women and birthing people's care and treatment. Records were clear, up to date, stored securely and easily available to all staff providing care.

Women and birthing people's notes were comprehensive, however some staff noted difficulties using the inpatient and outpatient versions of the electronic patient records. Staff were able to access both sets of records but some reported feeling more confident than others. We reviewed 5 electronic records and found records were clear and complete.

When women and birthing people transferred to a new team, there were no delays in staff accessing their records. Records were stored securely. Staff locked computers when not in use.

Medicines

The service did not always use systems and processes to safely prescribe, administer, record and store medicines.

Staff followed systems and processes to prescribe and administer medicines safely. Women and birthing people had electronic prescription charts for medicines which needed to be administered during their admission. We reviewed 10 prescription charts and found staff had correctly completed them.

Staff reviewed each woman's medicines regularly and provided advice to women and birthing people and carers about their medicines. The pharmacy team supported the service and reviewed medicines prescribed. These checks were recorded in the prescription charts we checked.

Staff did not always store or manage all medicines and prescribing documents safely. Controlled drugs were not always checked regularly with 6 instances between October and November 2023 where medicines had not been checked.

The clinical room where the medicines and medicine records were stored was locked; however unregistered staff were able to access these areas as well as the drugs fridge and drug safe. Not all medicines reviewed were in date and stored at the correct temperature. Staff monitored and recorded triage fridge temperatures. However. we found 47 instances where fridge temperatures September 2023 and December 2023 were unchecked. During this same period some temperatures were recorded as outside of their range with limited evidence of action following this variation other than repeat temperature check and reset.

The service used an electronic prescribing system. Midwives could access the full list of midwives' exemptions, so they were clear about administering within their remit.

Staff followed national practice to check women and birthing people had the correct medicines when they were admitted, or they moved between services. Medicines recorded on digital systems for the 7 sets of records we looked at were fully completed, accurate and up to date.

Incidents

Staff did not always recognise and report incidents. When concerns were raised or things went wrong, the approach to reviewing and investigating causes was too slow. There was little evidence of learning from events or action taken to improve safety, managers shared learning from incidents to prevent re-occurrence of similar incidents.

Staff knew what incidents to report and how to report them. However, they did not have time to complete incident reporting. Staff could describe what incidents were reportable and how to use the electronic reporting system. We reviewed 8 incidents reported in the 3 months before inspection and found them to be reported correctly. We could not triangulate all of the incidents with systems used by the service therefore, leaders could not be assured that staff raised concerns and reported incidents and near misses in line with trust policy.

Not all incidents were reported by staff as there were discrepancies noted in the reporting data. For example, incidents reported did not describe how long women and birthing people had to wait for 3rd and 4th degree perineal repair, removing the services ability to accurately ensure these were reported as red flags where appropriate. A trust MEWS audit carried out in June 2023 identified only 25% of women and birthing people had been escalated correctly where required. However, no failure to escalate incidents were reported between December 2022 and April 2023. Additionally, actions following this audit identified the need for a new MEWS observation chart to be implemented, however there was no completion date and no update had been completed.

Managers reviewed all incidents reported to the online incident reporting system at weekly huddles attended by band 8 midwives, quality and safety matron, governance lead, head of midwifery and governance lead obstetrician, to identify immediate actions and allocate any investigations required. Incidents which progressed to a 72-hour report or full investigation were reviewed at the monthly speciality governance meeting.

Managers investigated incidents thoroughly. They involved women and birthing people and their families in these investigations. Managers reviewed incidents potentially related to health inequalities.

Managers shared learning with their staff about never events that happened elsewhere. The service had a 'learning from incidents' midwife who was responsible for sharing learning from incidents with staff.

Maternity

Staff reported serious incidents clearly and in line with trust policy. Staff understood the duty of candour. They were open and transparent and gave women and birthing people and families a full explanation if and when things went wrong. Governance reports included details of the involvement of women and birthing people and their families in investigations and monitoring of how duty of candour had been completed.

There was evidence changes had been made following feedback. The service created action plans based on recommendations from serious incident reviews by the Health and Safety Investigation Branch (HSIB) now known as Maternity and Newborn Safety Investigation (MNSI). The action plans showed all the findings of the HSIB reports were acknowledged and where required managers implemented appropriate actions. Staff were also involved in feedback and learning as part of the process.

The maternal incident report review process required staff to fill out an electronic incident report which was then graded by governance team with any graded at or above moderate to be escalated to senior team and safety and risk team/ chief nurse as required. Notifications were sent to MNSI and MBRRACE where required and weekly governance meeting to discuss incident reports from previous week. Incidents graded at or above moderate were required to have a 72-hour review, duty of candor was completed and hot debrief was completed for staff involved. Further investigations were completed with families kept informed of investigation progress. Feedback was shared with staff and families and the final report and actions were documented electronically and tripartite meetings were then offered.

Trust incident data showed there were 24 incidents which were open for more than 60 days, and these included 6 that were reported between April to May 2023, 4 of which were waiting for a manager to complete the review. Therefore, we were not assured that incidents were reviewed within safe time frames.

We reviewed minutes from the services perinatal mortality review tool (PMRT) meetings which showed the service used a multidisciplinary approach to the reviews. However, we found that actions were sometimes overlooked, or gradings in care could not be completed due to lack of obstetric attendance at PMRT reviews for Royal Devon and Exeter hospital. For example, minutes from August 2023 showed the women and birthing peoples notes did not always record the woman or birthing persons perspectives on care. The PMRT report acknowledged common themes from the PMRT reviews however actions were not included in the report's actions.

We also reviewed submissions to the Perinatal Mortality Review Tool dated February 2023. In the initial summary of both reports, the relevant history of care and issues identified under social circumstances, and past obstetric history the report stated nothing significant identified however we known risk factors had been omitted.

In addition, minutes from the November 2023 PMRT meetings showed that not all cases were graded prior because of lack of obstetric input. Report 2 echoed report one with lack of information under these headings, but further on contained details of previous obstetric and medical history. Therefore, we were not assured that the hospitals PMRT process was robust or that incidents were appropriately reviewed was followed in line with the Health & Social Care Act (2008) regulation 20 Duty of Candour. The maternity dashboard showed 5 baby loses April 2023 – November 2023 however the service provided a copy of the services summary PMRT report which showed 11 baby losses. We have requested all copies of these PMRT's from the service, but they were not provided.

Is the service well-led?

Requires Improvement

Maternity

We rated it as requires improvement.

Leadership

Leaders were visible and supported staff. Leaders had the skills and abilities to run the service however their ability to accurately understand and managed the priorities and issues the service faced but were limited by systems used to monitor service provision.

Leaders were visible and approachable in the service for women and birthing people and staff. Leaders were well respected, approachable, and supportive. Staff told us they were well supported by their line managers, ward managers and matrons. The executive team visited wards on a regular basis. Staff told us they saw the executive team regularly and spoke of how accessible and encouraging they were.

The service was supported by maternity safety champions and non-executive directors.

They supported staff to develop their skills and take on more senior roles. Leaders encouraged staff to take part in leadership and development programmes to help all staff progress.

Leaders had the skills and abilities to run the service, they understood and managed the priorities and issues the service faced. They had responded to challenges to quality and sustainability within the service and had plans to manage them. However, leaders' ability to respond was limited by audit systems.

Vision and Strategy

The service had a vision for what it wanted to achieve and a strategy to turn it into action, developed with all relevant stakeholders. The vision and strategy were focused on sustainability of services and aligned to local plans within the wider health economy.

The service had a vision for what it wanted to achieve and a strategy to turn it into action, developed with all relevant stakeholders. The trust had developed the vision and strategy in consultation with staff at all levels in 2023 and covered a 3-year plan. The strategy identified key priorities which included: listening to women and birthing people to provide personalised care, retaining, and supporting staff, culture, and leadership, and improving compliance with national maternity safety initiatives such as the Clinical Negligence Scheme for Trusts (CNST) and the Saving Babies Lives care bundle.

Leaders had considered recommendations from the Ockenden 2020 and 2022 reports for the review of maternity services. The service had plans to revise the service vision and strategy to include recommendations however the service had not fully implemented changes in 2023 showing a slower than expected progression.

Culture

Staff felt respected, supported, and valued. They were focused on the needs of women and birthing people receiving care. The service promoted equality and diversity in daily work and provided opportunities for career development. The service had an open culture where women and birthing people, their families and staff could raise concerns without fear.

Maternity

Many quality improvement schemes revolved around staff satisfaction and wellbeing, recent culture surveys had been completed by the service to identify and implement improvements in staff culture. Leaders told us they believed staff who were well supported would be able to provide higher quality care to the women and birthing people they worked with.

The service fostered an open culture. Women and birthing people, their families, and staff could raise concerns without fear. Clear channels were established for women, and birthing people, relatives, and caregivers to express complaints or raise concerns. All feedback was addressed utilising the most appropriate and least formal methods available. Information on how to raise concerns was prominently displayed in women and birthing people's areas as well as visitor spaces. Staff understood the complaint policy and were adept at handling such matters.

The maternity staff survey 2022 reported staff felt involved in deciding changes which affected work and their immediate manager was supportive. The survey also reported staff did not always have access to adequate materials, supplies and equipment required for work. During the inspection we found items were not always available or in date grab bags used for pre-eclampsia did not contain all the items required to treat the condition and required items from other areas of the hospital. As a response to these, the trust implemented methods to discuss equipment and supply shortages including suggestion boxes and team reviews.

There were quarterly team building and social events, 1-to-1 conversations with managers, and surveys to support staff wellbeing. Staff we spoke with were positive about the department and its leadership team and felt able to speak to leaders about difficult issues and if things went wrong.

Staff we spoke with told us they worked in a fair and inclusive environment. The Workforce Disability Equality Standard (WDES) was a set of measures which enables NHS organisations to compare the workplace and career experiences of disabled and non-disabled staff. For the measure for staff with medical conditions reported more harassment, bullying or abuse, had limited opportunities for career progression and felt pressured to return from a period of sickness before they were ready. This was worse than the national average, however staff with a disability felt their employer had made reasonable adjustments to support them at work which was better than the national average.

Workforce Race Equality Standard (WRES) data collected as part of the NHS Staff Survey results for staff from all other ethnic groups were notably different to results for white staff, indicating poorer experiences for staff from all other ethnic groups. The results showed a higher proportion of staff from all other ethnic groups experienced harassment, bullying or abuse from staff and patients, relatives, or the public in the last 12 months. As well as a higher proportion of staff from ethnic minority groups experiencing discrimination at work within the last 12 months, with a lower proportion of staff believing the organisation provided equal opportunities for career progression.

The CQC Maternity Survey questionnaires were sent out between April and August 2023, responses were received from 201 people at Royal Devon University Healthcare NHS Foundation Trust. The CQC Maternity Survey 2023 reported mothers in labour and birth, staff caring for them, and care in hospital responded as “about the same” compared to other trusts.

Managers investigated complaints and identified themes and shared feedback with staff and learning was used to improve the service. This was a fixed agenda item on each regular team meeting. Staff could give examples of how they used women and birthing people's feedback to improve daily practice. Staff knew how to acknowledge complaints and women and birthing people received feedback from managers after the investigation into their complaint.

Governance

Maternity

Leaders did not operate effective governance systems. They did not always manage risk, issues, and performance well. They did not monitor the effectiveness of the service.

Maternity services were part of the clinical support and specialist services division. The service was managed by the divisional director in collaboration with the associate director of midwifery and clinical lead for obstetrics. There was a head of midwifery and a deputy head of midwifery (however this post was vacant at the time of the inspection). The associate director of midwifery reported to the divisional director operationally and professionally to the chief nurse. Staff did not have access to up-to-date policies reducing their ability to plan and deliver high quality care according to evidence-based practice and national guidance. Leaders monitored policy review dates on a tracker and reported there were currently 91 of 234 out of date. In response to concerns we raised following the inspection, the trust provided an action plan to review and implement updated policies with a target date of 31 March 2024, starting with those they deemed as high risk. They provided further information that the 234 guidelines were across site and included duplication of guidance as merging of documents was occurring as they became out of date. At the time of inspection, 39 of 135 guidelines were out of date.

Leaders regularly held meetings to maintain oversight of the trust and its governance processes. Where applicable worked with external partner organisations. Decisions made at these meetings would then be shared with frontline staff via leadership channels. Leaders monitored key safety and performance metrics through a comprehensive series of well-structured governance meetings.

Staff at all levels were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service. The service used a variety of methods to share learning with staff including case study discussions during practical obstetric multi-professional training (PrOMPT) sessions, direct feedback, and support for those involved in serious incidents, information shared through line managers and updates through internal communications such as email. Staff understood their role within the wider team and took responsibility for their actions. They knew how to escalate issues to the clinical governance meetings and divisional management team. Information was shared back to sub-committees and all staff.

Management of risk, issues, and performance

The approach to service delivery and improvement was reactive. was Audits were inconsistent in their implementation and impact, which limited effective planning processes and the management of risks. Risk registers and action plans were used, but there was a lack of pace for progress.

The local audit programme was not sufficient to monitor and improve performance over time. The trust had not recognised this risk as part of their maternity services active risk register submitted December 2023. We received limited evidence audits were being regularly completed or were based on limited patient sample sizes for, triage assessment and audit system, CTG monitoring and fresh eyes, SBAR audits. Staff we spoke with reported the trust did not complete SBAR audits or Sepsis audits. Additionally, gaps were identified through medicine records and fridge temperature checks outside of temperature ranges were not followed up.

Discrepancies were presented with regards to red flags, inconsistent use of staffing acuity tools as well as audit systems and their implementation, which tended to rely on small sample sizes. This impaired leaders' ability to effectively plan processes and manage risks.

Maternity

The service participated in relevant national clinical audits. Clinical outcomes were not in line (worse than) with the national average data from NHSD maternity Dashboard showed as of August 2023 babies with an Apgar score of between 0 and 6 was in the upper quartile with 22 per 1000 births. This was above the national average of 13 per 1,000 births.

National clinical audits also showed women who were current smokers at booking was 11.1% which was higher than the national average of 9% nationally. Additionally, data collected for women who were current smokers at delivery, failed the data quality checks and were therefore not available for august 2023.

According to the trusts "Meeting in Public of the Board of Directors of The Royal Devon University Healthcare NHS Foundation Trust 25 January 2023" The trust reviewed the presentation for Clinical Negligence Scheme for Trusts (CNST) and sign-off the evidence presented for compliance for Year 4. The Board noted there were still two separate returns presented, one for Northern services and one for Eastern, but for Year 5, this would have been amalgamated into one return. The audit report included evidence up to November 2023 and showed 4 out of 10 were compliant.

The service kept a live maternity risk register which identified insufficient midwifery and specialist midwives, and told us they use of band 2 support workers to provide theatre cover including training and vacancy rates, midwifery staff training and safeguarding provision as their highest risks. These risks were mitigated by a live action plan, actions are signed off to confirm steps had been taken to mitigate the risks.

Risks were identified through the incident management system and were reviewed and recorded in meeting minutes for the monthly risk assurance meeting. The leadership team took action to make change where risks were identified.

There were plans to cope with unexpected events. They had a detailed local business continuity plan. Staff contributed to decision-making to help avoid financial pressures compromising the quality of care.

Healthcare Safety Investigation Branch (HSIB) now known as the Maternity and Newborn Safety Investigations (MNSI) share findings with organisations with the opportunity to identify areas of learning from their findings and change that may impact in different circumstances, the service received a report June 2023 which reaffirmed the service was experiencing delays in care, delays in inductions, and immediate emergencies in labour were not always managed in line with national guidance. MNHI also reported the service Modified Early Warning Score (MEWS) chart was not in line with national guidance, leading to a lack of recognition of emerging or changing risk, and failure to escalate concerns although no affecting the outcomes in the two cases reported.

Caesarean section data provided showed 15 category 2 emergencies September 2023- December were longer than the target time of 75 minutes with one taking 230 minutes from decision to knife to skin, the service have not provided any plans on how to mitigate these delays with emergency caesarean sections.

Information Management

The service collected data to analyse, however key information used to evaluate performance and outcomes was not being collected. The information systems were integrated and secure. Staff could find the data they needed in order to make decisions.

The service collected data; however, key performance indicators were missing from the data added to the dashboard such as ward coordinator being supernumerary meaning it was not sufficient to effectively monitor and improve services at the time of inspection. They had a live dashboard of performance which was accessible to senior managers.

The information systems were integrated and secure**.** All IT systems were password protected and paper-based patient records were stored securely.

Data or notifications were consistently submitted to external organisations as required.

Engagement

Leaders collected information on women, birthing people and staff. They worked with public and local organisations to plan and manage services. They collaborated with partner organisations to help improve services for women and birthing people.

The service had links with the local Maternity and Neonatal Voices Partnership (MNVP). Leaders worked with the MNVP to help make decisions about care in maternity services. The MNVP reported a positive working relationship with the trust but had experienced different levels of engagements between hospitals. MNVP leaders described a limited ability to attend board meetings due to time limitations. A Patient Experience Committee Meeting was held quarterly where patient feedback could be discussed with the trust. The MNVP contained 2 split chairs, a co-chair, 4 vice chairs with a total of 84 paid hours shared between them.

Leaders understood the needs of the local population. Where possible the trust had set up outpatient hubs offering additional locations where women and birthing people could attend appointments. Services at these locations included intermittent auscultation where concerns may be identified and referrals for women to attend the local hospital were made.

The service always made available interpreting services for women and birthing people and collected data on ethnicity. Picture books were available to support communication for individuals who may be unable to read translated languages. The triage and birthing centre had a mobile screen that could be used to connect to language services including sign language.

Learning, continuous improvement and innovation

Evidence of quality improvement and innovation was limited. However, there was some limited evidence that staff were committed to continually learning and improving services.

The trust was involved in a limited number of improvement projects. In October 2023, the maternity governance group reported the second part of a staff culture survey had been completed with the plan to improve staff culture. In addition to this the trust supported staff by supplying them with QR codes which staff could scan to access guidelines. Staff had also completed unconscious bias training in an attempt to address some of the inequalities experienced by ethnic monitory groups. Training included the use of medical mannequins with darker skin tones. The trust had identified additional areas where services could be improved, work on these areas was in various stages of completion at the time of the inspection.

Leaders had taken the opportunity to discuss issues identified as part of the staff survey to engage with and encouraged staff to find solutions for the identified issues.

Maternity

Areas for improvement

Action Royal Devon and Exeter hospital MUST take is necessary to comply with its legal obligations. Action a trust SHOULD take is because it was not doing something required by a regulation, but it would be disproportionate to find a breach of the regulation overall, to prevent it failing to comply with legal requirements in future, or to improve services.

Action the trust MUST take to improve:

Maternity

- The service must ensure staff are up to date safeguarding adults' level 3 training. Regulation 12(1)(2) (c)
- The service must ensure women and their babies are effectively risk assessed and staff act upon women, birthing [people and babies at risk of deterioration. Regulation 12(2) (a)(b)
- The service must ensure systems are in place to effectively monitor and manage women and birthing people requiring an induction of labour and caesarean section, in particular, that they are carried out within a safe timeframe in line with national guidance. Regulation 12(2) (a)(b)
- The service must ensure risks are mitigated. Regulation 12(2) (a)(b)
- The service must ensure staff comply with systems for the accurate interpretation and escalation of electronic fetal monitoring and this is regularly audited. Regulation 12 (2) (a) (b)
- The service must ensure staff have access to up-to-date policies and guidance. Regulation 17 (2) (d)
- The service must ensure effective governance and oversight of audits and action plans are developed to improve performance. Regulation 17 (1) (2) (a) (b)
- The service must ensure there are effective systems in place to identify, monitor, manage and learn from incidents including baby loss and risks in a timely way. Regulation 17 (2) (a)
- The service must ensure ward coordinators maintain their supernumerary status in line with the maternity incentive scheme 2022 safety action 5. Regulation 18 (1)

Action the trust SHOULD take to improve:

- The service should ensure the security of the unit is reviewed in line with national guidance. In particular staff's ability to respond to a baby abduction.
- The service should aim to ensure recommendations made from Ockenden 2020 and 2022 are considered and changes made are done so within a timely manner.
- The service should ensure medicines are stored, managed, prescribed, and administered safely.
- The service should risk assess the need for suction units to be available and in working order in triage, triage 4 bedded bay and the birthing centre.

Our inspection team

The team that inspected the service comprised a CQC lead inspector, and 4 other CQC inspector. The inspection team was overseen by Carolyn Jenkinson, Deputy Director of Secondary and Specialist Care. Additionally, the team comprised of 2 Registered Midwifery advisors and one Obstetric Consultant advisor.