NHS
Litigation Authority

NHS Litigation Authority Clinical Negligence Scheme for Trusts

Maternity Clinical Risk Management Standards 2012-13

Gloucestershire Hospitals NHS Foundation Trust

Level 3

January 2013

MANAGING RISK DNV

Contents

The comments and findings of the assessment recorded in this report reflect the opinions of the assessor(s) based on the evidence provided by the organisation in relation to the requirements contained in the relevant standards manual. They should not be read as approval or comment in any other context.

Executive Summary

Assessment outcome

Reference number	T619
Organisation assessed	Gloucestershire Hospitals NHS Foundation Trust
Date of last assessment	Wednesday, 20 January and Thursday, 21 January 2010
Assessment date	Monday, 14 January and Tuesday, 15 January 2013
Standards assessed	*CNST Maternity Clinical Risk Management Standards 2012-13*
Level prior to assessment	Level 2
Level applied for	Level 3
Level achieved	Level 3

Policy, practice and performance are assessed through a variety of outcomes. The assessment is performed using evidence provided by the maternity service.

At Level 3 the assessors examine whether the maternity service is monitoring its own implementation of the Level 1 approved documents. Monitoring tools utilised by the maternity service could include audits, as specifically required in some of the criteria, or reports, minutes or health records. The evidence provided by the maternity service is validated by the assessors when they perform spot checks on a random selection of criteria within each standard. A score is only awarded if the monitoring has identified a minimum of 75% compliance in each of the minimum requirements carried forward. The maternity service must supplement its evidence with an action plan to address weaknesses identified by the monitoring, and evidence of implementation of some of the required changes must be provided.

The maternity service was assessed against five standards each containing ten criteria giving a total of 50 criteria. In order to gain compliance at Level 3 the organisation was required to pass at least 40 of these criteria, with a minimum of seven criteria being passed in each individual standard. The organisation scored as follows:

Organisation	10/10	Compliant
Clinical Care	8/10	Compliant
High Risk Conditions	10/10	Compliant
Communication	10/10	Compliant
Postnatal & Newborn Care	8/10	Compliant
OVERALL COMPLIANCE	**46/50**	**Compliant**

Detailed scores can be found in the maternity service's evidence template which is a separate document that records the evidence reviewed and the compliance awarded at the assessment.

An overview of the risk areas covered by the assessment is provided within this report. Those criteria highlighted in green indicate the areas of compliance during the assessment. Those criteria highlighted in orange indicate the areas of non-compliance and those criteria not reviewed are highlighted in yellow.

Prior to formal assessment the maternity service was encouraged to conduct a self-assessment. The maternity service's self-assessment results are depicted below and plotted against the actual assessment results.

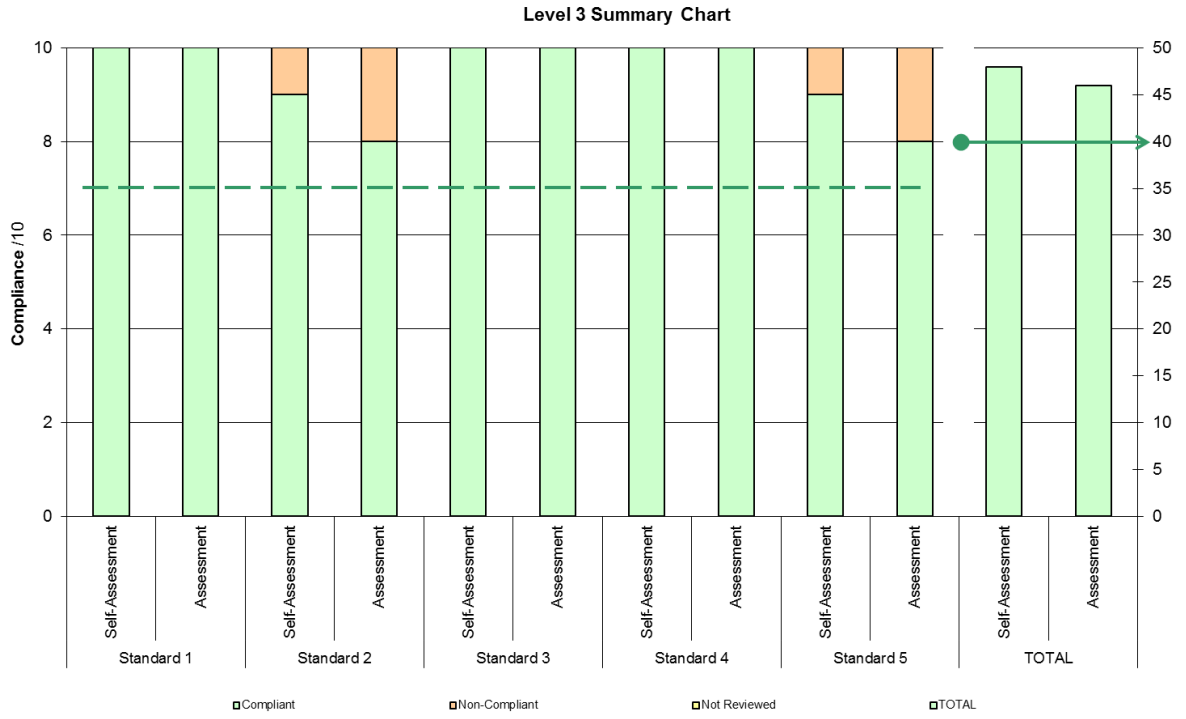

Chart 1: Comparison of the maternity service's self-assessment to actual assessment outcome

Key findings

The maternity service at Gloucestershire Hospitals NHS Foundation Trust is congratulated for achieving Level 3 against the CNST Maternity Clinical Risk Management Standards 2012-13. It was evident to the assessors throughout the assessment that the monitoring systems have been embedded in practice for a significant amount of time. Where monitoring systems had identified gaps in practice action plans had been developed, implemented and in many instances re-audits have been undertaken to determine the effectiveness of the actions taken. Ultimately this should have a positive outcome on patient care and safety. Through the internal monitoring the maternity service identified issues in relation to the maternity early warning system maternity and neonatal observations. As a result of this the maternity service openly declared non-compliant with these areas. The assessors were informed that a significant amount of work has been undertaken to improve clinical practice in these areas and improvements were evident in the health records seen.

As part of the assessment process the assessors review and spot check health records to ascertain if the approved guidelines are implemented in clinical practice. The standards of record-keeping and filing were found to be very high and at no time during the assessment were any loose documents found. The maternity service has introduced a number of clinical proformas and stickers to act as an aide memoir for clinical staff which have been incorporated into staff training programmes. The maternity service achieved full compliance for the health records reviews which is an outstanding achievement demonstrating that systems are well embedded in the clinical areas. Discussions with clinical staff also demonstrated that learning from monitoring processes translates into changes in clinical practice. Staff receive feedback and information from a comprehensive newsletter which is distributed to all clinical staff across all sites.

A spot check of ten clinical guidelines was also undertaken to ensure the guidelines presented are readily available across the maternity service and all the documents presented were current and accessible to staff electronically.

The audit reports were consistently comprehensive with evidence of the majority of identified actions completed. Minutes of the relevant committees demonstrated detailed discussion of the audits and proposed changes.

The assessors would like to thank the maternity service for the well organised and systematic approach to presenting both the live and pre-selected health records and monitoring reports and to thank everyone who participated in the assessment for their very open and transparent approach.

Overview of assessment outcome

Compliant | Non-compliant | Not reviewed | Not applicable

Standard ⇨	1	2	3	4	5
Criterion ⇩	**Organisation**	**Clinical Care**	**High Risk Conditions**	**Communication**	**Postnatal & Newborn Care**
1	Risk Management Strategy (Organisation)	Care of Women in Labour	Severe Pre-Eclampsia	Booking Appointments	Referral When a Fetal Abnormality is Detected
2	Risk Management Strategy (Leadership)	Intermittent Auscultation	Eclampsia	Missed Appointments	Newborn Life Support
3	Staffing Levels (Midwifery & Nursing Staff)	Continuous Electronic Fetal Monitoring	Operative Vaginal Delivery	Clinical Risk Assessment (Antenatal)	Admission to Neonatal Unit
4	Staffing Levels (Obstetricians)	Fetal Blood Sampling	Multiple Pregnancy & Birth	Patient Information	Immediate Care of the Newborn
5	Staffing Levels (Anaesthetists & Assistants)	Use of Oxytocin	Perineal Trauma	Maternal Antenatal Screening Tests	Newborn Feeding
6	Labour Ward Staffing	Caesarean Section	Shoulder Dystocia	Mental Health	Examination of the Newborn
7	Maternity Records	Induction of Labour	Postpartum Haemorrhage	Clinical Risk Assessment (Labour)	Bladder Care
8	Incidents, Complaints & Claims	Severely Ill Women	Venous Thromboembolism	Handover of Care (Onsite)	Support for Parent(s)
9	Training Needs Analysis	High Dependency Care	Pre-Existing Diabetes	Maternal Transfer by Ambulance	Postnatal Care
10	Skills and Drills	Vaginal Birth after Caesarean Section	Obesity	Non-Obstetric Emergency Care	Recovery

Assessment Results

Standard 1: Organisation

Overview

The promotion of good risk management, governance and assurance are integral components to the maternity service's working practices and help to ensure that quality assurance, quality improvement and patient safety are central to the service's activities. The maternity service cannot operate in isolation from the rest of the organisation and will need to share many systems and procedures with the wider organisation. This standard requires the maternity service to demonstrate good leadership, with an open and supportive culture, which provides a service that can fulfil the needs and expectations of women and their families. Positive leadership can contribute to the engagement of staff, support job satisfaction and raise morale. Communication is an essential component to ensuring good care and women's health records should provide all relevant information which may influence care. Therefore this standard also examines the process for the management of risks associated with health records. Requirements around staffing levels for professionals involved in the provision of safe care to women and their babies should demonstrate that the maternity service is working towards the recommendations within Safer Childbirth (RCOG 2007). The maternity service has a responsibility to ensure that all staff are appropriately trained, and skilled professionals are adequately equipped to work within the service to provide care. By ensuring effective, ongoing and updated training, education and support, the maternity service is promoting the delivery of high quality focused care.

A score of ten out of ten was awarded in this standard.

Key findings and recommendations

Criterion		Findings and recommendations
1.1 Risk Management Strategy (Organisation) The maternity service has an approved maternity service risk management strategy which reflects the organisation-wide strategy and is implemented and monitored.	Compliant	Where monitoring has identified deficiencies, there must be evidence that recommendations and action plans have been developed and changes implemented. The *Annual Clinical Governance Maternity Assurance Report April 2011 – March 2012* was presented in support of this criterion and details all of the required elements. It was noted in the report that the risk register was not presented at one of the Divisional Quality Committee meetings as the risk manager was on annual leave. There was no corresponding action relating to this gap within the

Criterion		Findings and recommendations
		action plan. As this could present a significant risk the maternity service is advised to review this process to ensure the risk register is presented on a monthly basis to the Divisional Quality Committee as detailed in the *Maternity Services Risk Management Operational Procedure*, Version 2 (December 2009).

Standard 2: Clinical Care

Overview

Central to the care provided to all pregnant women is the care provided in labour. This can be provided in a variety of care settings and at all times it must be appropriate to the needs of the woman, her level of risk and consistent with current national guidance. This standard examines the care provided around the time of labour and requires the maternity service to have in place approved documentation for such activities as the care provided to the woman during labour and monitoring of the fetal heart rate both by auscultation and by continuous electronic fetal monitoring. Additionally the standard looks at the care provided to women who are having a vaginal birth after a caesarean section and the care of women needing a Grade 1 caesarean section. The standard also considers other clinical interventions that can occur: the induction of labour; augmentation of labour with Oxytocin; fetal and cord blood sampling and the identification of and care provided to seriously ill women who need a higher level of dedicated care.

A score of eight out of ten was awarded in this standard.

Key findings and recommendations

Criterion		Findings and recommendations
2.3 Continuous Electronic Fetal Monitoring The maternity service has an approved system for improving care and learning lessons relating to continuous electronic fetal monitoring (EFM) in labour that is implemented and monitored.	Non-compliant	Where monitoring has identified deficiencies, there must be evidence that recommendations and action plans have been developed and changes implemented. The *Fetal Monitoring Guideline*, Version 5 (April 2012) states that 'It is recognised that an hourly review is acceptable within a ten minute time frame, if events such as epidural siting or visit to the toilet have delayed the interpretation'. On review of the health records the assessors found that review of the race frequently fell into the extra ten minute timeframe and in some instances no rationale was clear. Whilst the health records met the standard set by the maternity service the assessors were concerned about the frequency this occurred. Additionally the *Audit of CNST Standard 2 Criterion 2 Intermittent Auscultation* (December 2012) did not include whether the review of the trace had been

Criterion		Findings and recommendations
		undertaken hourly or within an hour and ten minutes. The maternity service is advised to review the current guideline and practice now a new centralised EFM has been introduced and if the decision to retain the additional ten minute timeframe is to remain in the guideline as this practice goes outside of NICE guidance the organisation's policy for this would need to be applied.
2.8 Severely Ill Women The maternity service has approved documentation which describes the process for ensuring the recognition of severely ill women either in pregnancy or the immediate postnatal period that is implemented and monitored.	Not reviewed	Following the monitoring process the maternity service declared non-compliance for this criterion.

Standard 3: High Risk Conditions

Overview

The provision of approved guidelines against which care should be provided and on which practice should be based is pivotal to the care women receive during the antenatal, intrapartum and postnatal periods. This standard seeks to address some of the high risk conditions that will occur within a maternity service including severe pre-eclampsia, eclampsia, operative vaginal delivery, multiple pregnancies and births and shoulder dystocia. Communication between a diversity of staff groups is required to enable care for women and their newborns to be precise, timely and responsive. This communication and the actions that follow are central to a positive outcome for all. Communication is assessed in high risk conditions such as postpartum haemorrhage, as well as in predisposing conditions that increase the risk to women and their babies, for example, pre-existing diabetes, venous thrombosis and obesity. Many women will be exposed to other risks associated with childbirth such as perineal trauma and this is also assessed in this standard.

A score of ten out of ten was awarded in this standard.

Key findings and recommendations

Criterion		Findings and recommendations
3.5 Perineal Trauma The maternity service has approved documentation which describes the management of all types of perineal trauma that is implemented and monitored.	Compliant	• maternity service's expectations for staff training, as identified in the training needs analysis The guideline *Perineal Repair Including Repair of Third and Fourth Degree Tears*, Version 3 (April 2012) details the training requirements of clinical staff undertaking all types of perineal repairs. On the review of the health records of women who had undergone perineal repair in some instances it was difficult to locate the corresponding clinicians training records. The maternity service informed the assessors that this issue had already been recognised and plans were in place to hold the training records centrally on a database for both medical staff and midwives. The maternity service is advised to implement this system at the earliest opportunity.

Criterion		Findings and recommendations
3.7 Postpartum Haemorrhage The maternity service has approved documentation which describes the management of postpartum haemorrhage that is implemented and monitored.	Compliant	Where monitoring has identified deficiencies, there must be evidence that recommendations and action plans have been developed and changes implemented. The *Audit of CNST Standard 3, Criterion 7 Post Partum Haemorrhage* (January 2013) details the minimum requirements and results from the continuous monitoring which are above the required 75%. However, the maternity service is advised to expand the detail within the report relating to the 'Management of women with PPH' as within the guideline the management includes several different elements of care. Compliance was awarded for the audit report as the proforma clearly detailed that each of the elements described had been captured, however without a detailed breakdown in the main body of the report if compliance levels fell in future audits to enable actions to be formulated a breakdown of each element of care would need to be identified.

Standard 4: Communication

Overview

Effective communication is the cornerstone of good clinical practice. The maternity service must ensure that approved procedures underpin these communication processes. Communication should occur between all team members in each discipline, as well as with women and their families. This standard guides the maternity service into setting up robust systems for both initial booking appointments and follow up appointments or visits in order to ensure that care is delivered in a timely manner and in an appropriate environment. It is expected that the maternity service has processes in place for the completion of appropriate clinical risk assessments during all stages of care. There should also be approved service wide systems for maternal antenatal screening tests. The maternity service must make sure that women and their families have access to unbiased information including the risks, benefits and alternatives, thus allowing them to make an informed choice regarding their care and treatment. The standard examines whether maternity services have processes in place for the effective handover of care and maternal transfer when necessary, and finally requires procedures to be in place to manage and minimise the risks pregnant women are exposed to when receiving care in a non-obstetric environment.

A score of ten out of ten was awarded in this standard.

Key findings and recommendations

Criterion		Findings and recommendations
4.6 Mental Health The maternity service has approved documentation which describes the process for ensuring that the mental health needs of women are met and is implemented and monitored.	Compliant	• process for identifying women during the antenatal period who have a current mental health problem, or who are at risk of developing a mental health problem The guideline *Maternal Mental Health*, Version 1 (July 2010) was presented in support of this criterion. Additionally in May 2012 the maternity service implemented the Gloucestershire Maternal Mental Health Care Pathway. Both the above documents appear to provide clear direction to clinical staff, however on review of the health records it was sometimes difficult to piece together the woman's care. The maternity service is advised to review the documentation of management and treatment plans to determine if a system could be introduced to provide clinical staff with a succinct overview of the woman's care.

Standard 5: Postnatal & Newborn Care

Overview

For most women and their newborn the postnatal period is uncomplicated but care during this period needs to address any deviation from the expected pathway after birth. This standard is concerned with care of women, their newborn and families during the first few weeks after birth and addresses key issues which may arise during this time. It includes issues such as giving women essential information to care for their newborn; postnatal care planning; infant feeding; routine examination of the newborn and recovery and bladder care for the mother. Also included are criteria relating to circumstances where problems are identified such as when a fetal abnormality is identified; neonatal resuscitation; and admission to the neonatal unit. Maternity services are expected to have guidelines in place for some of the key conditions which could affect the newborn in the first few hours of life. There is also a criterion about supporting parents when the outcome is not as they would expect.

A score of eight out of ten was awarded in this standard.

Key findings and recommendations

Criterion		Findings and recommendations
5.4 Immediate Care of the Newborn The maternity service has an approved system for improving care and learning lessons relating to the care of newborns in the first 24 hours of life that is implemented and monitored.	Not reviewed	Following the monitoring process the maternity service declared non-compliance for this criterion.
5.10 Recovery The maternity service has an approved system for improving care and learning lessons relating to the care of all women who have	Non-compliant	Where monitoring has identified deficiencies, there must be evidence that recommendations and action plans have been developed and changes implemented. A base line audit was completed in 2011 against the processes as described in the

Criterion		Findings and recommendations
received a general or regional anaesthetic in theatre for an operative intervention that is implemented and monitored.		guideline *Post-Operative Recovery in the Delivery Suite/Unit,* Version 2 (November 2009). Due to low levels of compliance 37% with the monitoring of the frequency of respirations a change from 5 to 15 minutes was agreed and implemented. The *Post-Operative Recovery in the Delivery Suite/Unit,* Version 3 (August 2012) guideline was revised to reflect the agreed change. On review of the guideline this frequency had also been applied to the monitoring of blood pressure (BP), pulse, respiratory rate, oxygen saturation and amount of inspired oxygen delivered, stating that these must be monitored every 15 minutes. The 2012 audit, results indicate improved levels of compliance. However, the report does not indicate whether all of the observations have been monitored every 15 minutes as per the guideline. The findings of the audit as presented to the Gloucester Birth Forum December 2012 via a written report and presentation indicated different levels of compliance. The maternity service, must review both audits and the agreed action plans, to make sure that there is a clear understanding of what the monitoring requirements are for all observations for women who have received general or regional anaesthetic following an operative intervention. Where the maternity service takes the decision to not monitor observations in line with the Royal College of Anaesthetists guidelines, this should be documented and managed in line with agreed governance processes.

Document Check

At all levels the evidence presented at assessment must be in use and reflective of day to day practice within the maternity service.

To test this, the assessor(s) randomly selected ten documents from the maternity service's evidence portfolio and asked to see evidence of their approval. Additionally, the assessor(s) reviewed the maternity service's intranet and/or policy folders to ensure that the ten documents are readily available for use by staff.

If the maternity service was unable to evidence that a document has been approved and is in use, compliance was not given for the criterion that it relates to.

	Name of approved document	Criterion	Format	Approval	Availability	Compliant
1	MSOP Policy B0564 09/12	3.1.1	Elec	Yes	Yes	Yes
2	Maternity Policy BO556 V2	3.1.7	Elec	Yes	Yes	Yes
3	A1068: Fetal Monitoring Guideline	3.2.2	Elec	Yes	Yes	Yes
4	A1035: Induction and Augmentation of Labour, Including the use of Syntocinon	3.2.7	Elec	Yes	Yes	Yes
5	A1049: Hypertensive Disorders Including Pre-Eclampsia and Eclampsia	3.3.1	Elec	Yes	Yes	Yes
6	A1042: Postpartum Haemorrhage Guideline	3.3.7	Elec	Yes	Yes	Yes
7	A2002: Routine Antenatal Care	3.4.1	Elec	Yes	Yes	Yes
8	A1101: Intrapartum Care Guideline	3.4.7	Elec	Yes	Yes	Yes
9	A1119: Maternal Antenatal Screening and Early Referral V2	3.5.1	Elec	Yes	Yes	Yes
10	A2012: Support for Parents in cases of Actual or Suspected Poor Outcome for the Newborn	3.5.8	Elec	Yes	Yes	Yes
				TOTAL compliant		10

Health Record Checks

Selected at random by the assessors

At Level 3 the assessors select criterion 1.7 and a further 16 criteria (four criteria each from Standards 2-5) and spot check health records, training records etc. to assure themselves of the validity of the maternity service's monitoring results. The assessors will spot check a maximum of eight records for each criterion.

For the spot checks of health records the assessors visit clinical areas and randomly select health records. At least half of the health records reviewed are selected from clinical areas on at least two sites during the assessment. If the health records available in clinical areas do not provide the required sample, the assessors supplement them by random selection from those pre-selected by the maternity service and included in the evidence portfolio.

The table shows whether the maternity service achieved compliance in these criteria.

Criterion Number	Criterion	Compliant
1.7	Maternity Records	Yes
2.1	Care of Women in Labour	Yes
2.3	Continuous Electronic Fetal Monitoring	Yes
2.6	Caesarean Section	Yes
2.9	High Dependency Care	Yes
3.2	Eclampsia	Yes
3.5	Perineal Trauma	Yes
3.7	Postpartum Haemorrhage	Yes
3.9	Pre-Existing Diabetes	Yes
4.2	Missed Appointments	Yes
4.4	Patient Information & Discussion	Yes
4.6	Mental Health	Yes
4.8	Handover of Care (Onsite)	Yes
5.1	Referral When a Fetal Abnormality is Detected	Yes
5.3	Admission to Neonatal Unit	Yes
5.7	Bladder Care	Yes
5.9	Postnatal Care	Yes

Appendix

Contacts

Assessment and Report enquiries

This report was prepared by Det Norske Veritas on behalf of the NHS Litigation Authority. Any queries regarding this report should be directed to:

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