Bradford Teaching Hospitals
NHS Foundation Trust

Meeting Title	Board of Directors		
Date	13.9.18	Agenda item	Bo.9.18.11

CQC Puerperal Sepsis Outlier Notification

Presented by	Tanya Claridge, Director of Governance and Corporate Affairs	
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Lead Director	Tanya Claridge, Director of Governance and Corporate Affairs	
Purpose of the paper	This paper has been written to notify the Board of Directors that an outlier notification was received in relation to Puerperal Sepsis on the 31st July 2018 and to provide details of and assurance in relation to the response of the service in relation to the alert	
Key control	This paper is a key control for the strategic objective 1-to provide outstanding care for patients	
Action required	To note and gain assurance	
Previously discussed at/ informed by	Quality Committee (29th August 2018)	
Previously approved at:	**Committee/Group**	**Date**

Key Options, Issues and Risks

Puerperal sepsis is a severe infection of pregnant women around the time of labour or after delivery of their baby, resulting in a sepsis, a severe infection resulting in dysfunction of two or more major body systems. The CQC wrote to the Trust on 31st July 2018, informing that Trust had been identified as an outlier nationally for the diagnosis of puerperal sepsis in the period July to October 2017.

Analysis

The rates of puerperal sepsis attributed to the trust have been benchmarked against a figure calculated by the CQC, designed to reflect the size of the obstetric unit at Bradford and the obstetric workload. The benchmarked rate has been rising, however for the period under scrutiny, the rate of puerperal sepsis at the Trust was observed to rise more quickly, and remain raised over the period in question. The service has developed a strategy to respond to the alert and has identified some early findings relating to the coding of sepsis in the cohort of patients identified.

Recommendation

The Quality Committee should receive a summary of outcome of the actions taken to understand and mitigate any risks identified by the outlier notification with the full response provided to the CQC.

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Risk assessment						
Strategic Objective	**Appetite (G)**					
	Avoid	**Minimal**	**Cautious**	**Open**	**Seek**	**Mature**
To provide outstanding care for patients		g				
To deliver our financial plan and key performance targets			g			
To be in the top 20% of NHS employers			g			
To be a continually learning organisation				g		
To collaborate effectively with local and regional partners					g	
The level of risk against each objective should be indicated. Where more than one option is available the level of risk of each option against each element should be indicated by numbering each option and showing numbers in the boxes.	**Low**		**Moderate**	**High**	**Significant**	
	Risk (*)					
Explanation of variance from Board of Directors Agreed General risk appetite (G)	At present the risk assessed in relation to this alert is moderate as a full audit of the outcome of all the patients identified has not been completed and as such any harm has not been excluded.					

Risk Implications (see section 4 for details)	Yes	No
Corporate Risk register and/or Board Assurance Framework Amendments	▪	
Quality implications	▪	
Resource implications		▪
Legal/regulatory implications	▪	
Diversity and Inclusion implications		▪

Regulation, Legislation and Compliance relevance
NHS Improvement: (Risk assessment framework, quality governance framework, code of governance , annual reporting manual)
Care Quality Commission Domain: *(Safe, caring, effective, responsive, well led)*
Care Quality Commission Fundamental Standard: Regulation 12
Other (please state):

Relevance to other Board of Director's Committee:					
Workforce	Quality	Finance & Performance	Partnerships	Major Projects	Other (please state)
	▪				

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1 PURPOSE/ AIM

The CQC wrote to the Trust on 31st July 2018, informing that Trust had been identified as an outlier nationally for the diagnosis of puerperal sepsis in the period July to October 2017. This paper has been written to provide information to the Board of Directors relating to the actions being taken to understand and contextualise the alert and identify appropriate actions to mitigate any risks identified.

2 BACKGROUND/CONTEXT

Puerperal sepsis is a severe infection of pregnant women around the time of labour or after delivery of their baby, resulting in a sepsis, a severe infection resulting in dysfunction of two or more major body systems. Historically this was a major cause of maternal mortality and infection as an overall cause was cited in the National confidential Enquiry into Maternal Deaths as one of the leading cause of direct deaths in 2007. In the MBBRACE report of 2010-2012, a fifth of maternal deaths were due to all infective causes.

Following this, RCOG and NICE guidance, along with national sepsis recognition campaigns have all worked to address the treatment of sepsis overall and the treatment of sepsis and pyrexia in labour. Infection is now a minor contributor nationally to maternal death statistics.

The rates of puerperal sepsis attributed to the trust have been benchmarked against a figure calculated by the CQC, designed to reflect the size of the obstetric unit at Bradford and the obstetric workload. The benchmarked rate has been rising, however for the period under scrutiny, the rate of puerperal sepsis at BTHFT was observed to rise more quickly, and remain raised over the period in question.

The CQC derive their information from HES data, which in turn is principally generated by clinical coding within the trust.

3 PROPOSAL

The service has organised a team, composed of medical and midwifery staff, members of the departmental risk and management team, representatives from clinical coding and the informatics team. The team meets fortnightly and thus far has:

1. Identified 81 women from our own coding data who were coded as having puerperal sepsis in the period July to October 2017. This is very similar to the 78 Cases identified by the CQC for the same period. Small discrepancies at likely to be due to data collection differences.
2. The majority of these case notes have been collated and an audit commenced. The audit seeks to address the appropriateness of the clinical diagnosis and treatment, and the validity the subsequent coding.
3. Work is ongoing to ensure current local guidance for the treatment of suspected infection, sepsis or pyrexia in labour, reflect best national guidance, where available.

The audit has yet to be completed, however preliminary findings from audit of approximately the first 30 patient's notes suggest that a significant proportion of women with an infection or temperature in labour, have been coded as puerperal sepsis. Clinical auditors have reviewed these notes and in many cases restrospective clinical diagnosis by the auditor of an infection such as chorioamnionitis would be valid, but these women did not have puerperal sepsis.

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The view of the clinical auditors thus far is that the use of the term, sepsis (suspected or otherwise), is widespread in the clinical notes. Combined with the fact that the standard set of treatments and investigations when infection or sepsis is suspected, is labelled as the "sepsis bundle", many women are subsequently being labelled inappropriately as sepsis cases when undergoing these investigations and treatments and are subsequently inappropriately diagnosed and coded as such.

The auditors have opined that many of these women have had an infection and have been treated effectively and there is not a significant clinical risk we are failing to address, however a significant proportion are not sepsis and there has been a lack of clarity regarding an appropriate differential diagnosis.

It is likely that the excess cases of puerperal sepsis identified by the CQC will to be accounted for as a case of incorrect coding secondary to a lack of clarity of the clinical diagnosis and overuse of the term sepsis.

4 RISK ASSESSMENT

The outlier alert has been received during a period of ongoing scrutiny and review of the quality of maternity service provision by the Care Quality Commission. Whilst the preliminary audit findings have not identified any preventable harm to patients and identified that the excess cases are attributable to incorrect coding, until this audit is complete, the risk associated with patient safety as a result of the outlier notification is assessed as moderate.

5 RECOMMENDATIONS

- Based on preliminary findings, it is expected that communication to medical & midwifery staff will be required to remind them of the need for clarity in the clinical notes with the need to diagnose the cause of infection (e.g. chorioamnionitis) as opposed to a generic "diagnosis" of sepsis. Combined with this is the need for more senior oversight of the treatment plans and antibiotic duration of women with infections.

- Local guidance will be reviewed to ensure that this is an appropriate reflection of national guidance. If there is not a significant difference, we can use the audit data gathered to demonstrate that in the cases identified, these women have been treated appropriately or have been treated over cautiously, outside the recommendations of the guidelines.

- Completion of this audit and the actions outline above will address the CQC information requests.

- The alert notification also describes a lack of gestational data being submitted, informatics are unable to identify the cause for this, and further requests for information have been made to the CQC. This data quality issue is still under review

- The Quality Committee should receive the formal response which will be provided to the CQC in response to the outlier notification