Manchester University
NHS Foundation Trust

Audit of the linkage of antenatal and newborn screening results in the Sickle Cell and Thalassaemia Screening Programme in Greater Manchester, Lancashire and South Cumbria

Clinical Audit Report

Date Completed: May 2018

Clinical Audit Lead/s: Beverly Hird

Person/s responsible for action plan: Beverly Hird

Person/s responsible for dissemination: Beverly Hird

Green	Amber	Red	Assurance Level	Risk Ref
			Very Limited	

Contents

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Clinical Audit Report – Outcome Summary	
Audit Title	Audit of the linkage of antenatal and newborn screening results in the Sickle Cell and Thalassaemia Screening Programme in Greater Manchester, Lancashire and South Cumbria

Standard	Compliance (%)
1. Standard one The newborn screening laboratory should be informed of 'at-risk women' via an alert form ('at-risk' form) if 1) Pre-natal diagnosis (PND) is declined OR 2) If PND is accepted, the baby is affected by a major haemoglobin disorder and the woman is continuing with the pregnancy	58% (56/97)
2. Standard two The comments box on newborn screening sample cards from babies born to women identified as 'at-risk' of having a child with sickle cell disease or β-thalassaemia should contain details of the mother's antenatal screening results (and the father's where known) or details of the baby's PND	27% (26/97)

Clinical Audit Action Plan

Key Action	Action Co-ordinator	Target Date
Arrange for the report to be distributed to the Screening Co-ordinators at each Trust, the Screening Quality Assurance Service (North), the Screening and Immunisation Managers (NHS England) for Greater Manchester and for Lancashire and the Manchester Sickle Cell and Thalassaemia Centre	Beverly Hird	July 2018
Ask the Screening and Immunisation Managers to add to the agenda of the next Greater Manchester Antenatal Newborn Screening Board Quarterly Meeting and to the agenda of the Lancashire and South Cumbria ANNB programme board with a view to discussing and agreeing actions with Screening Co-ordinators from each Trust.	Beverly Hird	July 2018

Aim & Objectives

The aim of the audit was to determine the level of compliance against 'Service Specification 18: NHS Sickle Cell and Thalassaemia screening programme', with regards to linkage of antenatal and newborn screening results.

Background

The NHS Sickle cell and Thalassaemia Screening Programme is a linked antenatal and newborn programme offered to:

- all pregnant women
- fathers-to-be, where antenatal screening shows the mother is a genetic carrier
- all newborn babies

In the absence of electronic linkage of the antenatal results with the newborn screening results, a paper alert form exists. This is completed by maternity units, for pregnancies where there is a higher risk of the fetus being affected by a significant haemoglobinopathy, and then sent to the laboratory. The laboratory reviews the newborn screening results in conjunction with the parent's results.

According to the NHS Sickle Cell and Thalassaemia Screening Programme Standards (3rd edition)[1], 'at-risk women' include

1) those with a one in four chance or higher of the fetus being affected by a serious haemoglobin disorder (mother and biological father results known)
2) women who are carriers or affected with a clinically significant haemoglobin variant where the haemoglobinopathy status of the baby's biological father is unknown
3) pregnancies by donor egg or sperm where the haemoglobinopathy status of the donor is unknown and the biological partner is a carrier or affected with a clinically significant haemoglobin variant.

There are no specific standards regarding the use of 'at-risk' forms. For the purpose of this audit a standard has been devised to cover the directives and recommendations within 'Service Specification 18: NHS Sickle Cell and Thalassaemia screening programme[2]'. Relevant excerpts are reproduced below:

Declined pre-natal diagnosis (PND) (section 2, page 15): The programme recommends that maternity units have a robust system for recording information on at-risk couples declining PND testing, for example recording in maternity notes, on the blood spot card and on alert forms to be

sent to the newborn screening laboratory. There should be a named person in every maternity unit with the responsibility to ensure that newborn screening laboratories are informed of carrier women (or at risk couples) whose pregnancy is ongoing.

Accepted PND (section 2, page 16): Maternity units should notify newborn screening laboratories of women continuing affected pregnancies. Alert form to be sent to the newborn screening laboratory.

Public Health England Guidelines for Newborn Blood Spot Sampling (March 2016)[3] state that family history relevant to the conditions screened for and any known medical condition in the baby, should be recorded in the comments box on the blood spot card. The purpose of this is to assist the newborn screening laboratory with linking antenatal and newborn screening results. No standard exists so for the purposes of this audit a standard has been devised.

Standards

Standard 1: The newborn screening laboratory should be informed of 'at-risk women' via an alert form ('at-risk' form) if
1) Pre-natal diagnosis (PND) is declined
OR
2) If PND is accepted, the baby is affected by a major haemoglobin disorder and the woman is continuing with the pregnancy

Criteria: Proportion of at risk women who the newborn screening laboratory was alerted to via an 'at-risk form'
Numerator: Number of alert forms received by the Newborn Screening Laboratory, regarding at risk women
Denominator: Number of at risk women
Threshold: 90% selected arbitrarily for this initial audit.
Data source for numerator: newborn screening laboratory
Data source for denominator: screening co-ordinator/ midwife or other relevant person within each maternity unit

Standard 2: The comments box on newborn screening sample cards from babies born to women identified as ‘at-risk’ of having a child with sickle cell disease or β-thalassaemia should contain details of the mother’s antenatal screening results (and the father’s where known) or details of the baby’s PND.

Criteria: Proportion of newborn screening sample cards from babies born to women identified as ‘at-risk’ with a comment relating to the haemoglobinopathy status of the parents or baby
Numerator: Number of newborn screening samples from babies born to women identified as ‘at-risk’ with a comment relating to the haemoglobinopathy status of the parents or baby
Denominator: Number of newborn screening samples from babies born to women identified as ‘at-risk’
Threshold: 90% selected arbitrarily for this initial audit.

Method

This was a retrospective audit covering a 1 year period: 'at-risk' women whose babies were born 1st April 2016 to 31st March 2017 in Greater Manchester, Lancashire and South Cumbria (the area covered by the Manchester Newborn Screening Laboratory).

An Excel spreadsheet template was distributed to the maternity units listed in table 1, via the Regional Screening Quality Assurance team.

Table 1 – Maternity Units Requested to Participate

Blackpool Teaching Hospitals NHS Foundation Trust
Bolton NHS Foundation Trust
East Lancashire Hospitals NHS Trust
Lancashire Teaching Hospitals NHS Foundation Trust
Manchester University NHS Foundation Trust - St. Mary's Hospital
Manchester University NHS Foundation Trust Wythenshawe
Pennine Acute Hospitals NHS Trust
Southport & Ormskirk Hospital NHS Trust
Stockport NHS Foundation Trust
Tameside And Glossop Integrated Care NHS Foundation Trust
University Hospitals of Morecambe Bay NHS Foundation Trust
Wrightington, Wigan and Leigh NHS Foundation Trust

The Excel template comprised the following data fields: Mother's surname, Mother's forename, Mother's NHS number, Mother's date of birth, Mother's address, Mother's antenatal Sickle Cell & Thalassamia screening result, Father's results (if tested), Baby's surname, Baby's alternative surname (where applicable), Baby's date of birth, Baby's NHS number. Results of PND, if performed.

The spreadsheets from each maternity unit were combined and duplicates were removed. Babies born outside of the reporting period were also removed. Hard copy alert forms received by the newborn screening laboratory (see Appendix 1 for form template) were cross-checked against the spreadsheet and the presence/ absence of a form was recorded. The laboratory screening IT system was interrogated to obtain the newborn screening results for each baby and the laboratory sample number. A scanned copy of the screening card form for each sample was checked for handwritten comments. The proportion of at-risk women who the laboratory was alerted to was calculated and the results were presented by maternity unit. Any remaining at-risk forms received for babies born in the specified time period were also recorded in a separate spreadsheet tab.

Results

Completed spreadsheets were received from the following maternity units: Wigan, Pennine, Bolton, East Lancashire, Lancashire Teaching, Stockport and Tameside. A spreadsheet covering women from Manchester NHS Foundation Trust was received from the Manchester Sickle Cell Centre. Despite several reminders, no spreadsheets were received from Blackpool, Southport & Ormskirk and Morecambe Bay. It's not clear whether this is because there were no at-risk women or due to the lack of a system for recording details of this cohort.

Figure 1 is a flowchart describing the number of 'at-risk' women reported by maternity units or the Manchester Sickle Cell Centre, the number babies born to these women for whom newborn screening samples received by the laboratory and the number of 'at-risk' forms received by the laboratory.

Figure 2 displays the number of 'at-risk' women reported by maternity units or the Manchester Sickle Cell and Thalassaemia Centre and the proportion of at-risk forms received in the laboratory, by maternity unit.

Figure 1 – Flowchart describing numbers in each group

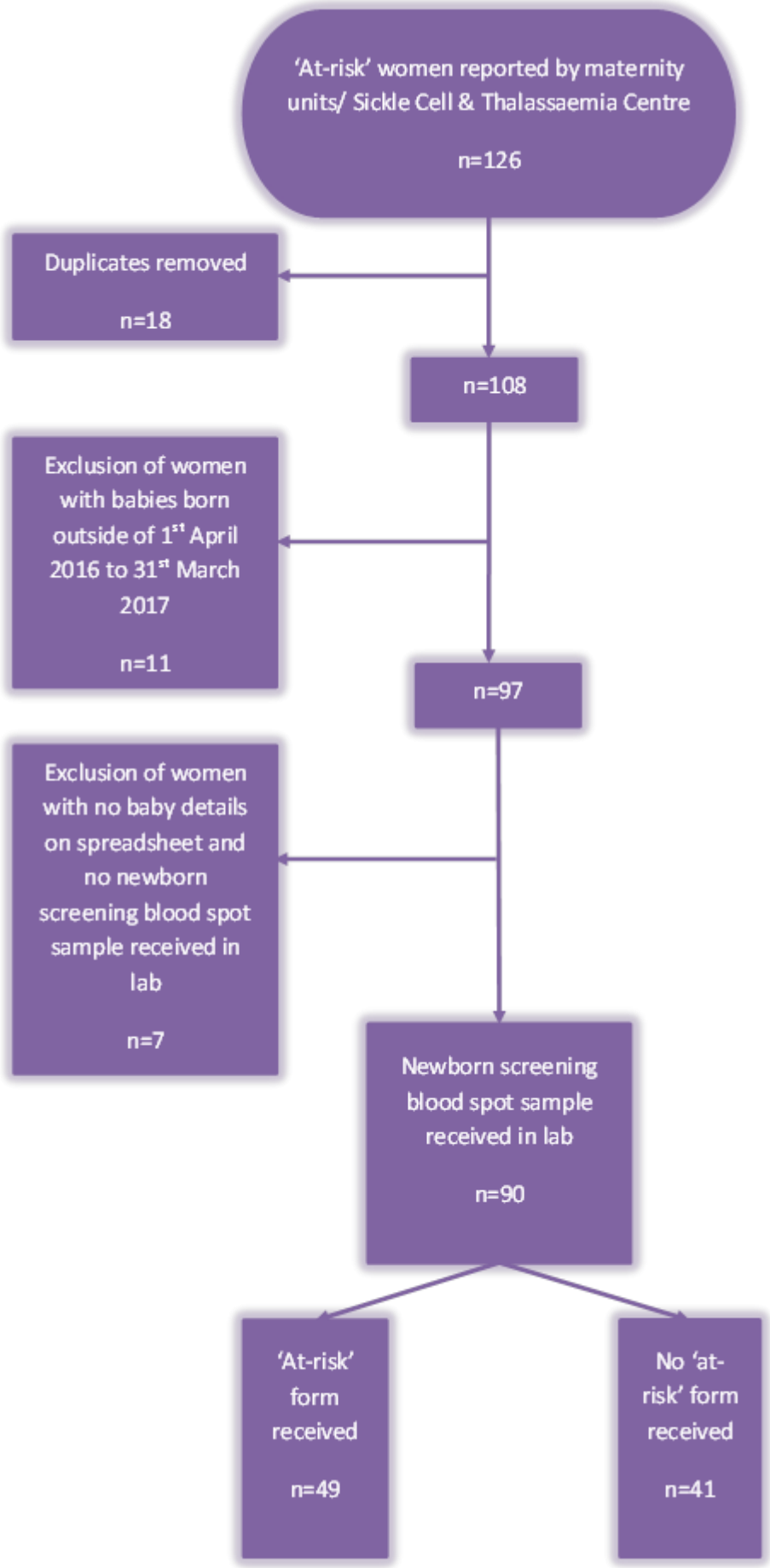
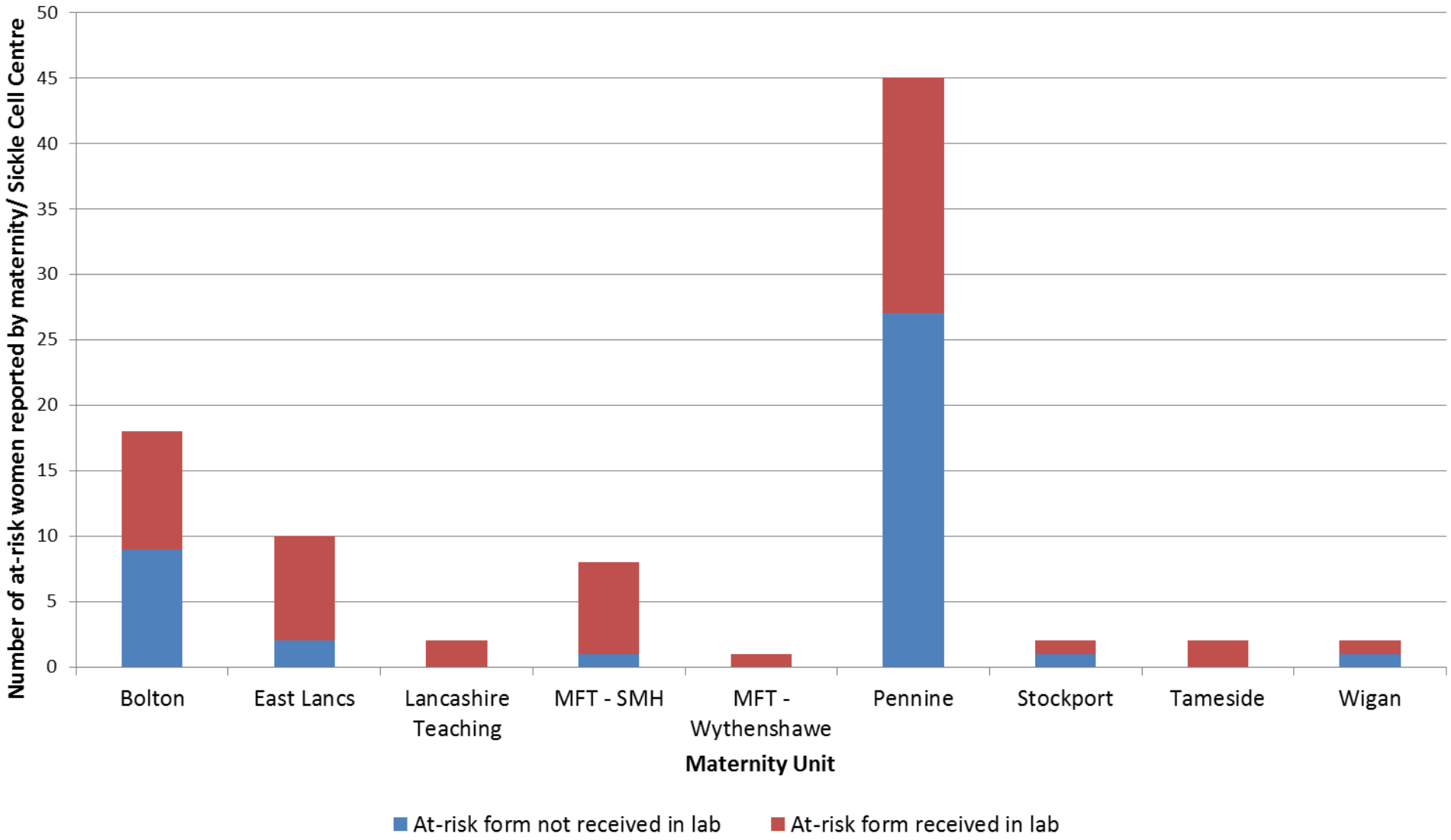


Figure 2: Proportion of at-risk forms received by the lab on at-risk women with babies born April 2016 to March 2017



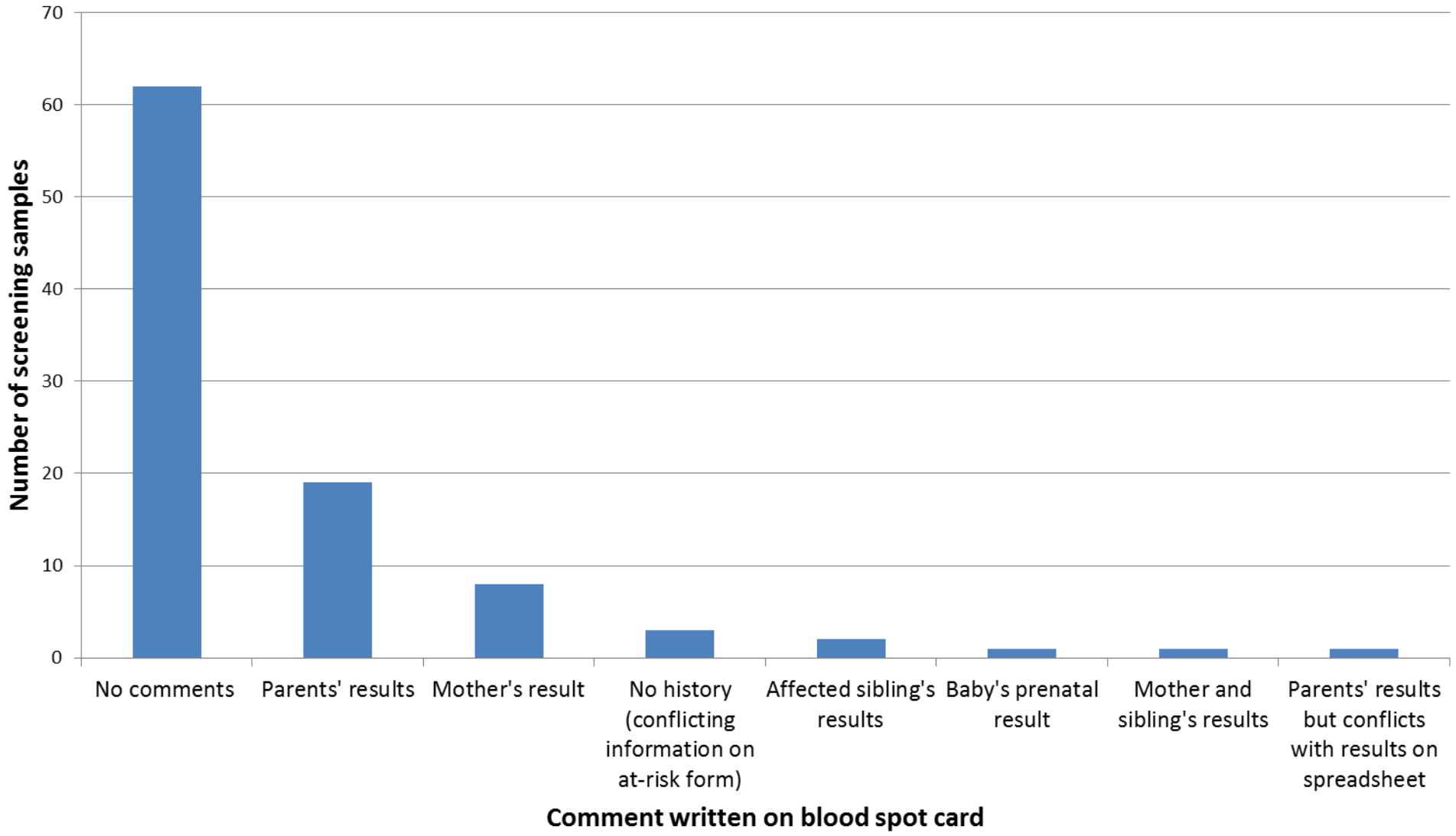
There were 56 ‘at-risk’ forms received by the laboratory for babies born from 1st April 2016 to 31st March 2017. 49/56 (88%) of these were included in the data returns from the maternity units or the Manchester Sickle Cell & Thalassaemia Centre. The 7 women missing from the spreadsheets were not cared for by the 3 Trusts not participating in the audit (Appendix 2). It’s possible that some of the women had PND and their babies were found to be unaffected; however, there was no indication of this on the ‘at-risk’ forms and two of the 7 babies were affected by sickle cell disease. This suggests that the cohort data provided by maternity units and the Manchester Sickle Cell and Thalassaemia Centre was incomplete and this is a limitation of the audit. There does not appear to be an independent source available for accurately identifying the number of ‘at-risk’ women.

An additional 7 ‘at-risk’ forms were received on women who had an expected delivery date between 1st April 2016 and 31st March 2017 but no newborn screening sample was received. This may be because the pregnancy did not continue or they may have moved away. These forms were excluded from the analysis.

The number of ‘at-risk’ women was calculated as the number identified by maternity (90) plus additional number of women identified by the ‘at-risk’ form only (7), giving a total of 97. In the specified audit period, forms were received on 58% (56/97) of at-risk women.

Figure 3 displays the type and frequency of the comments relating to sickle cell and thalassaemia written on newborn screening cards from babies born to ‘at-risk’ women (1st April 2016 to 31st March 2017). 27% (26/97) of cards had both parents’ sickle cell/ thalassaemia status (19) or the mother’s only if the father’s status was unknown (5) or an affected sibling (2; indicating at least carrier status for both parents). In 4 cases the comment on the blood spot card was misleading: ‘no history’ for two babies where the spreadsheet indicated that the parents were both β-thalassaemia carriers, ‘Hb variance NAD’ for one baby where the mother was a sickle cell carrier (father’s status unknown). For the remaining sample the comment was ‘Both parents sickle cell carriers. Beta thalassaemia trait’ but the spreadsheet indicated that the mother was a carrier for haemoglobin E (father’s result ‘abnormal variant’). The baby was identified as a carrier for haemoglobin E indicating that the spreadsheet was correct.

Figure 3: Comments relating to sickle cell and thalassaemia written on the blood spot cards of babies born to 'at-risk' women April 2016 to March 2017



The tables below illustrate the results of the audit.

Key:

Compliance ≥ 95%	Compliance 75% - 94%	Compliance ≤ 74%

Standard	Compliance (%)
1. Standard one The newborn screening laboratory should be informed of 'at-risk women' via an alert form ('at-risk' form) if 1) Pre-natal diagnosis (PND) is declined OR 2) If PND is accepted, the baby is affected by a major haemoglobin disorder and the woman is continuing with the pregnancy	58% (56/97)
2. Standard two The comments box on newborn screening sample cards from babies born to women identified as ‘at-risk’ of having a child with sickle cell disease or β-thalassaemia should contain details of the mother’s antenatal screening results (and the father’s where known) or details of the baby’s PND	27% (26/97)

Conclusions

The audit has provided very limited assurance.

Action Plan

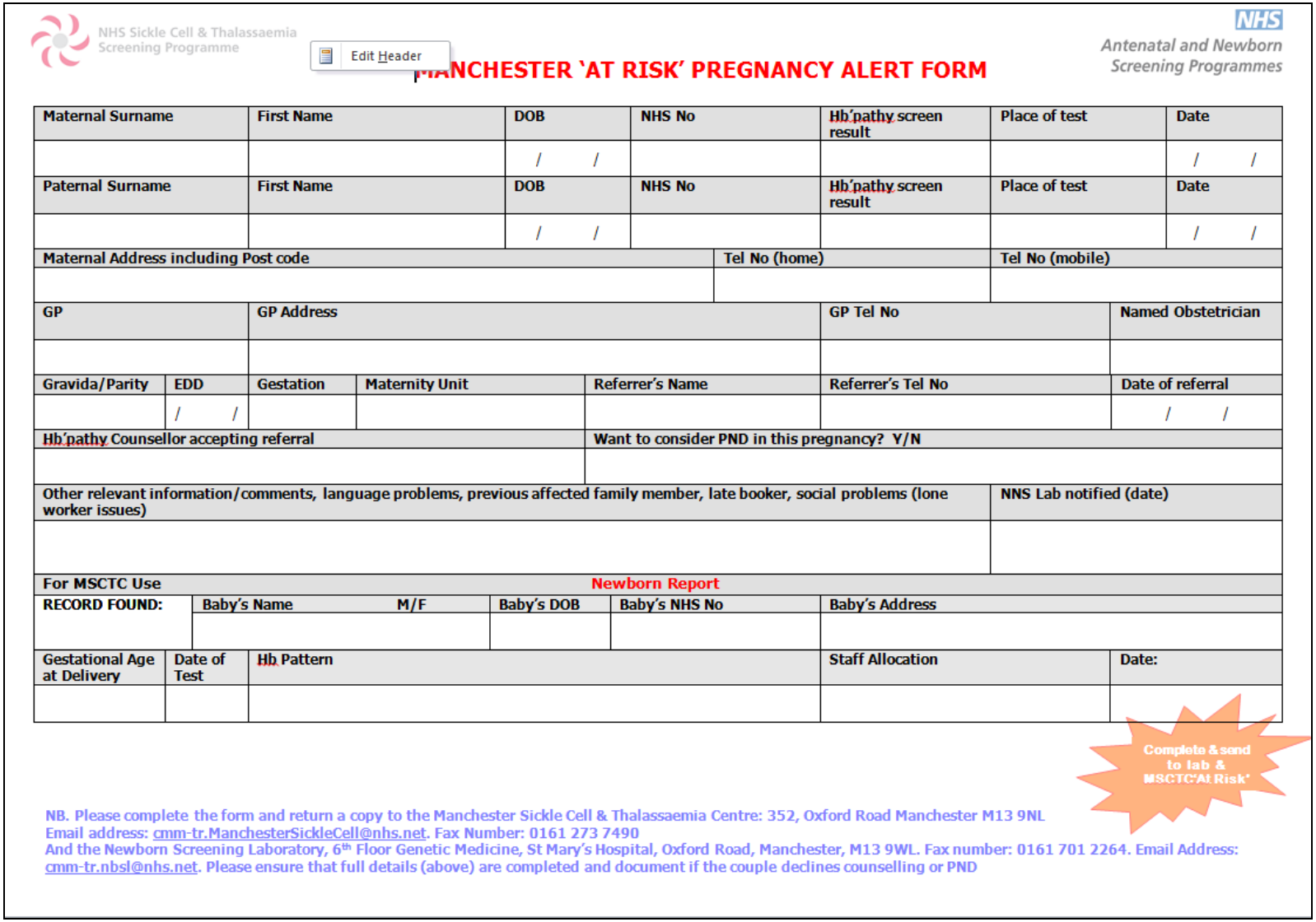
Clinical Audit Action Plan			
Key Action		Action Co-ordinator	Target Date
Arrange for the report to be distributed to the Screening Co-ordinators at each Trust, the Screening Quality Assurance Service (North), the Screening and Immunisation Managers (NHS England) for Greater Manchester and for Lancashire and the Manchester Sickle Cell and Thalassaemia Centre		Beverly Hird	July 2018
Ask the Screening and Immunisation Managers to add to the agenda of the next Greater Manchester Antenatal Newborn Screening Board Quarterly Meeting and to the agenda of the Lancashire and South Cumbria ANNB programme board with a view to discussing and agreeing actions with Screening Co-ordinators from each Trust.		Beverly Hird	July 2018
What were the main concerns that this audit identified?			
The newborn screening laboratory is not consistently informed of pregnancies at-risk of being affected by a major haemoglobin disorder.			
What are the main benefits, to patients or Trust processes, expected as a result of this action plan?			
Linkage of antenatal and newborn screening for sickle cell disease.			
Will there be a re-audit?	Possibly – depends if cohort can be identified more robustly	When will the re-audit take place?	-

References

1. NHS Sickle Cell and Thalassaemia Screening Programme Standards (3rd edition; https://www.gov.uk/government/publications/standards-for-sickle-cell-and-thalassaemia-screening , accessed 18/05/18)
2. Service Specification 18: NHS Sickle Cell and Thalassaemia screening programme (https://www.england.nhs.uk/publication/public-health-national-service-specifications, accessed 18/05/18)

3. Public Health England Guidelines for Newborn Blood Spot Sampling (March 2016; https://www.gov.uk/government/publications/newborn-blood-spot-screening-sampling-guidelines)

Appendix 1



NHS Sickle Cell & Thalassaemia Screening Programme

Edit Header

NHS
Antenatal and Newborn Screening Programmes

MANCHESTER 'AT RISK' PREGNANCY ALERT FORM

Maternal Surname	First Name	DOB	NHS No	Hb'pathy screen result	Place of test	Date
		/ /				/ /
Paternal Surname	**First Name**	**DOB**	**NHS No**	**Hb'pathy screen result**	**Place of test**	**Date**
		/ /				/ /

Maternal Address including Post code	Tel No (home)	Tel No (mobile)

GP	GP Address	GP Tel No	Named Obstetrician

Gravida/Parity	EDD	Gestation	Maternity Unit	Referrer's Name	Referrer's Tel No	Date of referral
	/ /					/ /

Hb'pathy Counsellor accepting referral	Want to consider PND in this pregnancy? Y/N

Other relevant information/comments, language problems, previous affected family member, late booker, social problems (lone worker issues)	NNS Lab notified (date)

For MSCTC Use — **Newborn Report**

RECORD FOUND:	Baby's Name	M/F	Baby's DOB	Baby's NHS No	Baby's Address

Gestational Age at Delivery	Date of Test	Hb Pattern	Staff Allocation	Date:

Complete & send to lab & MSCTC'At Risk'

NB. Please complete the form and return a copy to the Manchester Sickle Cell & Thalassaemia Centre: 352, Oxford Road Manchester M13 9NL
Email address: cmm-tr.ManchesterSickleCell@nhs.net. Fax Number: 0161 273 7490
And the Newborn Screening Laboratory, 6th Floor Genetic Medicine, St Mary's Hospital, Oxford Road, Manchester, M13 9WL. Fax number: 0161 701 2264. Email Address: cmm-tr.nbsl@nhs.net. Please ensure that full details (above) are completed and document if the couple declines counselling or PND

Appendix 2

'At-risk' forms received by the laboratory but not included in the data return from the maternity units or the Manchester Sickle Cell Centre

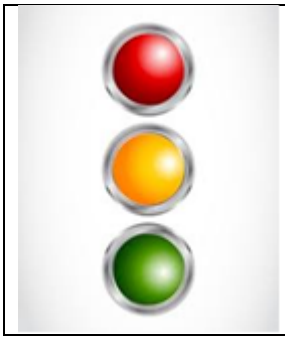
Maternity Unit	Parents' Results
Manchester NHS FT (St. Mary's)	AS/ AS
Manchester NHS FT (St. Mary's)	AS/ AS
Manchester NHS FT (St. Mary's)	AS/ AS
Manchester NHS FT (St. Mary's)	AS/ AC
Pennine Acute Trust	AS/AS
Tameside NHS FT	AS/ Unknown
Wrightington, Wigan & Leigh	AS/ Unknown

Key
AS=sickle cell carrier
AC=carrier of haemoglobin C

Appendix 3 – Assurance levels for Clinical Audit

Individual Standards

In the results of every audit, each standard measured is given a RAG rating. This will be one of Red, Amber or Green depending on how often the standard was met.

	Standard met in below 75% of cases
	Standard met in 75% to 94% of cases
	Standard met in 95% to 100% of cases

Assurance Level

Using the RAG ratings for all the standards measured in the audit we can calculate the overall assurance level.

Criteria	Assurance Level
Every standard is rated Green	Full
Each Standard is rated Green or Amber. If there are majority of amber rated standards the assurance may be reduced, on discussion, to limited.	Significant
There are more Amber and Red rated standards than Green	Limited
There are more Red rated standards than Amber and/or Green	Very Limited

- The appropriate level of assurance will be decided following a discussion between the clinical audit lead/s, sponsor and the clinical audit team.

- In the event that a decision cannot be reached, the Trust Clinical Audit Committee has the final word.

- The assurance level and a summary of the how the standards were rated then sits on the front page of the report, as can be seen above on Page 1.

- More information on assurance levels can be found in the Trust's clinical audit policy.

Appendix 4 – Dissemination list

For all Trust-Wide audits, copies of the completed report must be sent to the following:

- All Divisional Directors
- All Divisional Clinical Audit Leads
- All Divisional Clinical Effectiveness Leads
- Head of Nursing
- Clinical Audit team (via Facilitator for Division)
- Clinical Audit Supervisor
- Members of the clinical audit project team (if any)

For all Divisional audits copies of the completed report must be sent to the following:

- Clinical Head of Division
- All Directorate Managers
- Lead Nurse for Division
- The Divisional Clinical Audit Lead
- The Divisional Clinical Effectiveness Lead
- Clinical Audit team (via Facilitator for Division)
- Clinical Audit Supervisor
- Members of the clinical audit project team (if any)

For all local audits, copies of the completed report must be sent to the following:

- The Divisional Clinical Audit Lead
- The Divisional Clinical Effectiveness Lead
- Clinical Audit team (via Facilitator for Division)
- Clinical Audit Supervisor
- Members of the clinical audit project team (if any)
- Any Staff who may be affected by the audit report

For Divisional Contact Information please see the clinical audit website