Central Manchester University Hospitals NHS
NHS Foundation Trust

A re-audit of the turnaround time of samples for the Sickle Cell and Thalassaemia Newborn Screening Programme, in the Manchester Newborn Screening Laboratory

Clinical Audit Report May 2014

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Green	Amber	Red	Assurance Level

Contents

Clinical Audit Outcomes Summary		Audit number	4818
Audit Title	A re-audit of the turnaround time of samples for the Sickle Cell and Thalassaemia Newborn Screening Programme, in the Manchester Newborn Screening Laboratory		

Reason for audit

Re-audit of National Standards and new locally agreed standards

Standards

National standards: NHS Sickle Cell and Thalassaemia screening programme: Standards for the linked Antenatal and Newborn screening programme, October 2011.

NP2i: To report results of all screening including carrier results in a timely manner

NP3: Timely communication of positive screening results (sickle cell disease) – including a review of parental results

NP4: Effective follow-up of infants with positive screening results (sickle cell disease) – all babies to be registered with a local clinic / centre (or clinic working as part of clinical network)

NP5: Timely confirmation of diagnosis for infants with a positive screening result for specific conditions

NP 6i: To ensure treatment is offered and parental education started in a timely manner for children with conditions as specified in the clinical standards

NB. Standard NP2ii relates to 80% parents of carrier babies being given written information, ideally during a face-to-face discussion by trained healthcare professionals. A fax back form was introduced on 1st April 2014 in order to audit this standard. This standard is, therefore, not included in this re-audit but will be assessed in future audits.

Local laboratory turnaround time standards, agreed at the Haemoglobinopathy Quality Group.

L1: Receipt of sample in Newborn Screening (NBS) Laboratory to referral of sample for IEF (Haematology Lab): 3 working days

L2: Receipt of sample in Haematology Laboratory to entry of IEF result in SG IT system: 5 working days

L3: Entry of IEF result in SG to printing of referral letters: 1 working day

Results Summary Tables

The table below illustrates the results of the current audit compared with results of the audit in 2012, where applicable. NB. Only standards NP2i and NP3 were evaluated in the previous audit.

Key:

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

Results Summary Table – National Standards

Standard	Acceptable Standard	Achievable Standard	Compliance (%) 2013 (re-audit)	Compliance (%) 2011 (previous audit)	Change
1. NP2i: To report results of all screening including carrier results in a timely manner: (*Standards for Newborn Screening Programme, p42*)	95% screen negative results, including haemoglobin-opathy carrier, available for communication by 6 weeks of age	98% screen negative results, including haemoglobin-opathy carrier, available for communication by 6 weeks of age	99.4% (91/14104)	98.5% (210/14054) by 8 weeks of age (different National Standard targets applicable)	↑
2. NP3: Timely communication of positive screening results (sickle cell disorder) – including a review of parental results (*Standards for Newborn Screening Programme, P43*)	90% sickle cell disease results communicated to parents by 4 weeks of age	95% of sickle cell disease results communicated to parents by 4 weeks of age	100% (12/12)	20% (1/5)	↑

3. NP4: Effective follow-up of infants with positive screening results (sickle cell disease) – all babies to be registered with a local clinic / centre (or clinic working as part of clinical network) (*Standards for Newborn Screening Programme, P43*)	90% of babies identified are referred by 8 weeks of age to a designated healthcare professional	95% of babies identified are referred by 8 weeks of age to a designated healthcare professional	100% (12/12)	not measured	**N/A**
	90% attend local clinic by 3 months of age	95% attend local clinic by 3 months of age	100% (12/12)	not measured	**N/A**
4. NP5: Timely confirmation of diagnosis for infants with a positive screening result for specific conditions (*Standards for Newborn Screening Programme, p43*)	90% of cases of Hb SS and Hb SC have confirmation of result documented in clinical notes by 6 months of age	95% of cases of Hb SS and Hb SC have confirmation of result documented in clinical notes by 6 months of age	100% (8/8)	not measured	**N/A**
5. NP6i: To ensure treatment is offered and parental education started in a timely manner for children with conditions as specified in the clinical standards (*Standards for Newborn Screening Programme, P43*)	90% offered and prescribed prophylactic penicillin V (or alternative) by 3 months of age	99% offered and prescribed prophylactic penicillin V (or alternative) by 3 months of age	100% (8/8)	not measured	**N/A**

NB. There has been a change in the National Standards since the previous audit was performed in March 2012.

Results Summary Table – Local Standards

Standard	Compliance (%) 2013 (re-audit)	Compliance (%) 2011 (previous audit)	Change
1. L1: Receipt of sample in NBS Laboratory to referral of sample for IEF: 3 working days	**100%** (148/148)	**100%** (165/165)	↔
2. L2: Receipt of sample in Haematology Laboratory to entry of IEF result in SG: 5 working days	**96%** (142/148)	**0%** (147/147 initial samples)	↑
3. L3: Entry of IEF result in SG to printing of referral letters: 1 working day	**100%** (148/148)	**71%** (105/147 initial samples)	↑

Action Plan		
Key Action	**Co-ordinator for action**	**Timescale**
To share results of the audit with staff working in the Newborn screening and haematology laboratory and the Sickle Cell Centre and encourage continuation of good practice already in place.	Lesley Tetlow	April 2014
What was the main matter(s) of concern this audit identified?		
No areas of concern were identified.		
Please identify the main benefit(s) to our patient, or to hospital process that are expected to result from the action plan of this audit		
The aim is to continue good practice which is in place in order to continue to provide timely delivery of newborn screening results		

Will there be a re-audit?	*Yes*	When will the re-audit take place?	*April 2015*

Aim & Objectives

The aim of this audit was to re-assess the performance of the Manchester Newborn Screening (NBS) Programme against revised National Standards produced by the NHS Sickle Cell and Thalassaemia Screening Programme in October 2011. This audit was further to those previously performed in 2007, 2010 and 2012. The standards pertinent to the laboratory portion of the screening pathway relate to the timeliness of the reporting of the results. To help meet the national standards, local laboratory turnaround time (TAT) standards were agreed at the Haemoglobinopathy Quality Group (HQG) in January 2011 for incorporation into the City-wide Haemoglobinopathy Policy. Assessment of laboratory TAT against the new local standards was also performed.

Standards

National standards used: NHS Sickle Cell and Thalassaemia screening programme: Standards for the linked Antenatal and Newborn screening programme, October 2011.

Standards included in this re-audit:

NP2i: To report results of all screening including carrier results in a timely manner
NP3: Timely communication of positive screening results (sickle cell disease) – including a review of parental results
NP4: Effective follow-up of infants with positive screening results (sickle cell disease) – all babies to be registered with a local clinic / centre (or clinic working as part of clinical network)
NP5: Timely confirmation of diagnosis for infants with a positive screening result for specific conditions
NP6i: To ensure treatment is offered and parental education started in a timely manner for children with conditions as specified in the clinical standards

Standard NP3 covers sickle cell disorders, which have one of the following analytical results: FS, FSA, FSC, FSD, FSE, FSO^{Arab} and other clinically significant haemoglobinopathies, detected by newborn screening, with the following results: F only, FE, FA plus Hb Bart's.

Standard NP2i is assumed to apply to all results not included under Standard P3, including carriers of Sickle Cell disorders.

Local laboratory TAT standards, agreed at the HQG, for incorporation into the City-wide Haemoglobinopathy Policy:

L1: Receipt of sample in NBS Lab to referral of sample for isoelectric focusing (IEF; Haematology Lab): 3 working days (WD)
L2: Receipt of sample in Haematology Lab to entry of IEF result into SG: 5 WD
L3: Entry of IEF result into SG to printing of referral letters: 1 WD

At the HQG, the Manchester Sickle Cell and Thalassaemia Centre (MSCTC) agreed to inform parents of positive screening results within 5 days of receiving the results or sooner if the baby is approaching 4 weeks of age. This has not been included in this audit. However, in order to enable Standard NP3 to be met, the NBS laboratory should aim to report results to the MSCTC before the baby reaches 21 days of age.

Other relevant standards: UK Newborn Screening Programme Centre 'Standards and Guidelines for Newborn Bloodspot Screening' August 2008

- Standard 3 – Timely sample collection: 95% of first samples taken 5-8 days after birth (Core Standard)
- Standard 4 – Timely sample despatch: 100% of samples received by laboratory within 4 working days of blood sample being taken (Core Standard)

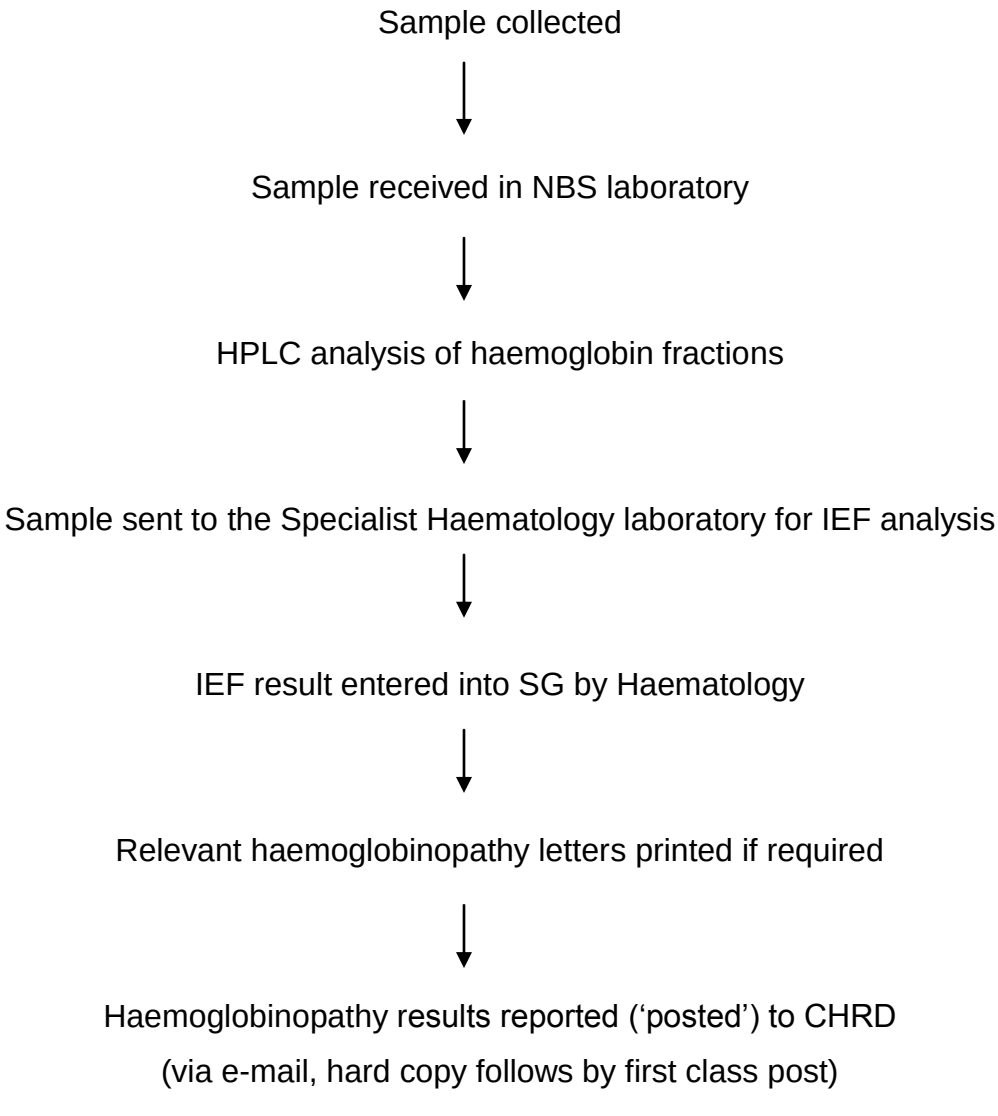
Background

The current UK Newborn Bloodspot Screening Programme consists of analysis of a heelprick filter paper blood sample, collected on day 5 for phenylketonuria, congenital hypothyroidism, cystic fibrosis, medium-chain acyl-CoA dehydrogenase deficiency and sickle cell disorders. Local performance against the standards produced by the UK Newborn Screening Programme Centre is audited by annual data submission to the Programme Centre.

The additional standards produced by the NHS Sickle Cell and Thalassaemia screening programme are not currently subject to National Annual audit. Furthermore, the Sickle Cell and Thalassaemia standards do not include laboratory TAT targets for each individual step within the pathway. In order to try to achieve the National standards, we devised local TAT standards at the HQG, held January 2011. We arrived at the local TAT standards by estimating the approximate number of days that each step in the pathway would need to take in order for the results to be reported to parents by the time the baby reaches 28 days of age. HQG meetings are attended by staff from the Haematology laboratory, the Consultant Paediatric Haematologist and the Service Lead for the Manchester Sickle Cell and Thalassaemia Centre.

Samples for the Sickle Cell and Thalassaemia screen are analysed by High Performance Liquid Chromatography (HPLC) within the Newborn Screening laboratory. All abnormal HPLC traces are then confirmed by isoelectric focusing (IEF) within the Specialist Haematology laboratory. The flowchart below describes the procedure for abnormal samples.

Samples for IEF analysis are hand-delivered to the Specialist Haematology laboratory at Manchester Royal Infirmary on a daily basis Monday to Friday. The term ‘posted’ refers to a completed and reported result in the Specimen Gate (SG) IT system. If a sample requiring IEF is insufficient for the other (quantitative) screening tests, the specimen is reported as insufficient for all tests, but the sample is sent for IEF analysis (provided there is enough blood on the card). When the repeat sample arrives, the IEF results from the first sample are entered against the repeat sample, to avoid further delay in issuing results. The pathway for reporting results to Child Health Records Departments (CHRD), health visitors (HV) & parents is displayed in Appendix 1.


Sample collected
Sample received in NBS laboratory
HPLC analysis of haemoglobin fractions
Sample sent to the Specialist Haematology laboratory for IEF analysis
IEF result entered into SG by Haematology
Relevant haemoglobinopathy letters printed if required
Haemoglobinopathy results reported (‘posted’) to CHRD
(via e-mail, hard copy follows by first class post)

Methods

Sample/Population

The SG IT system and the referral forms listing samples sent for IEF were used to gather data on the newborn screening samples received from 01/04/13 to 31/12/13.

Data Collection

Database searches were performed in SG and the results were exported to Excel. The data was collected in January 2014 and analysed in March 2014.

Result fields: Sample ID, NHS number, Last name, First name, Sex, Birth Date, Result Code, Specimen Count, Specimen Collected, Supervisor Reason, Specimen Collected, Specimen Received, Time Created, Time Measured, Time Accepted, Time posted, Address 1, Mother Birth Date and Ethnicity.

Search 1

A - To look for positive samples referred for testing by IEF: samples received: 01/04/13 to 31/12/13, test: Hb, result Code: HBO-IEF- *. Results with the following result codes were identified as positive samples: HBO-IEF-F / FE / FS / FSC / FSA / FSE / FSO^{Arab}.

B - To look for carrier samples referred for testing by IEF: samples received: 01/10/13 to 31/12/13, test: Hb, result Code: HBO-IEF- *. Results which have the following result codes were identified as carrier samples: FAS / FAE / FAD / FAC / FAO^{Arab}.

Search 2

To look for samples with an initial normal Hb (Hb FA) result code (HBO-I-N): samples received: 01/10/13 to 31/12/13, test Hb, result code: HBO-I-N

For each search, the number of working days between collection and receipt of the sample were calculated taking into account bank holidays. The number of working days between the following stages was also calculated: (i) receipt of sample to sent for IEF, (ii) sent for IEF to result entered on SG, (iii) IEF result entered to letter printed, (iv) letter printed to letter posted and (v) receipt of sample to posted. Age at collection and age when results were reported were also calculated.

It is important to note that, unlike the previous audit, we did not review HBO-R-N results. This is because, since the new HPLC integration parameters were introduced in August 2012, very few samples are identified with low A peaks (<3%).

Results

Search 1 A

A total of 12 babies were identified with positive screening results. The turnaround times (TATs) for each step in the pathway are shown in Table 1 below:

Table 1 - TAT of positive screening results (failed standards in red)

Sickle cell/ other clinically significant disorders	Lab Number	Age at collection (days)	Collected to Received (days)	Received to sent for IEF (days)	Sent for IEF to IEF result entered (days)	IEF result entered to letter printed (days)	Letter printed to result posted (days)	Received to Posted (days)
Hb F	13011892K	5	1	2	6	1	0	9
	13028761P	7	2	2	4	0	0	6
	13037197E	5	1	2	1	1	0	4
Hb FE	13021431Q	5	1	2	4	1	0	7
Hb FS	13000254Q	6	1	2	4	1	0	7
	13001797C	5	2	2	4	1	1	8
	13006409M	5	1	2	5	0	0	7
	13012215V	5	3	2	3	0	1	6
	13026593P	5	1	2	2	1	0	5
	13033468M	7	2	2	4	1	0	7
	13035380K	6	2	2	1	1	0	4
Hb FSC	13040942F	5	1	2	1	1	0	5

Sickle cell/ other clinically significant disorders	Lab Number	Age when result posted (days)	Age when referred to clinician (weeks)	Age when attend local clinic (weeks)	Age when confirmation result entered in clinical notes (months)	Age when penicillin offered (months)	Age when penicillin script collected (months)
Hb F	13011892K	19	2.7	6.3	3	N/A	N/A
	13028761P	19	2.7	10.3	5.4	N/A	N/A
	13037197E	12	1.7	6.9	2.2	N/A	N/A
Hb FE	13021431Q	15	2.1	9	not documented	N/A	N/A
Hb FS	13000254Q	19	2.7	8.7	4.8	1.7	1.9
	13001797C	17	2.1	7.4	4.8	1.7	1.9
	13006409M	15	2.1	7.1	3.9	2	1.9
	13012215V	14	2.1	6.4	4.7	1.5	1.7
	13026593P	15	2.1	6.7	5.1	1.6	1.9
	13033468M	20	2.9	6.4	3.8	1.5	1.6
	13035380K	14	2	8.6	2.1	2	2.1
Hb FSC	13040942F	14	2	9.6	2.6	1.9	2.6

NB. Patients diagnosed with thalassaemia (Hb F and Hb FE) do not require penicillin treatment.

The results were reported by 21 days of age in all of these positive cases. This then provides MSCTC with 5 working days in which to inform parents of the positive screening results, thus enabling us to achieve standard NP3.

All patients were referred to a clinician by 8 weeks of age and all attended their local clinic by 3 months of age; this shows achievement of Standard NP4. 8 of the positive patients were identified as having Hb FS or Hb FSC. All of these had their confirmation result documented in their clinical notes by 6 months of age, thus meeting Standard NP5. Of the 8 positive identified as requiring prescription of penicillin, all had this offered and prescribed by 3 months of age, thus illustrating achievement of Standard NP6i.

With regards local TAT standards, all samples were submitted for IEF, when relevant, within 3 working days. Of these samples, 92% were analysed for IEF within 5 working days (11 samples out of 12). All results had referral letters printed within 1 working day of IEF results being entered into SG.

Search 1 B

A total of 175 records were exported. One record was excluded as the initial sample was received outside of the time window under review in this audit (September 2013). A further record was excluded as it was an unnecessary repeat. A further 19 records were removed as the IEF result was reported as normal, leaving 154 records. If a baby had more than one sample, for example a day 0 sample and a day 5-8 sample, or an inadequate sample (such as no NHS number provided on original sample) and a repeat, then the sample where the Haemoglobinopathy (Hb) result was reported to the CHRD was retained in the spreadsheet (148 records) and any other samples were removed (6 records). The remaining records were divided into initial samples (146 records) and repeat samples (2 records). Table 1 displays the TAT of NBS samples requiring IEF, excluding positive samples, and the percentage which failed to meet local or national standards. Table 1 also displays the mean age at collection, age at reporting and the percentage of samples more than 35 days old at reporting.

All of the samples were referred to haematology within 3 working days. 96% of the initial samples met the TAT target for IEF analysis of 5 working days (receipt of sample in

Haematology Lab to entry of IEF result in SG IT system). The maximum time taken for IEF analysis was 7 working days. For initial samples, the target of 1 working day for entry of IEF result in SG to printing of referral letters was met in all cases. For repeats, for samples with no NHS number, this step may be delayed due to waiting for the repeat sample to arrive, as the initial sample is sent for IEF, but the results are reported with the rest of the repeat sample's results. With both of the repeat samples analysed in this audit, letters were printed within 4 and 8 days of IEF results being entered.

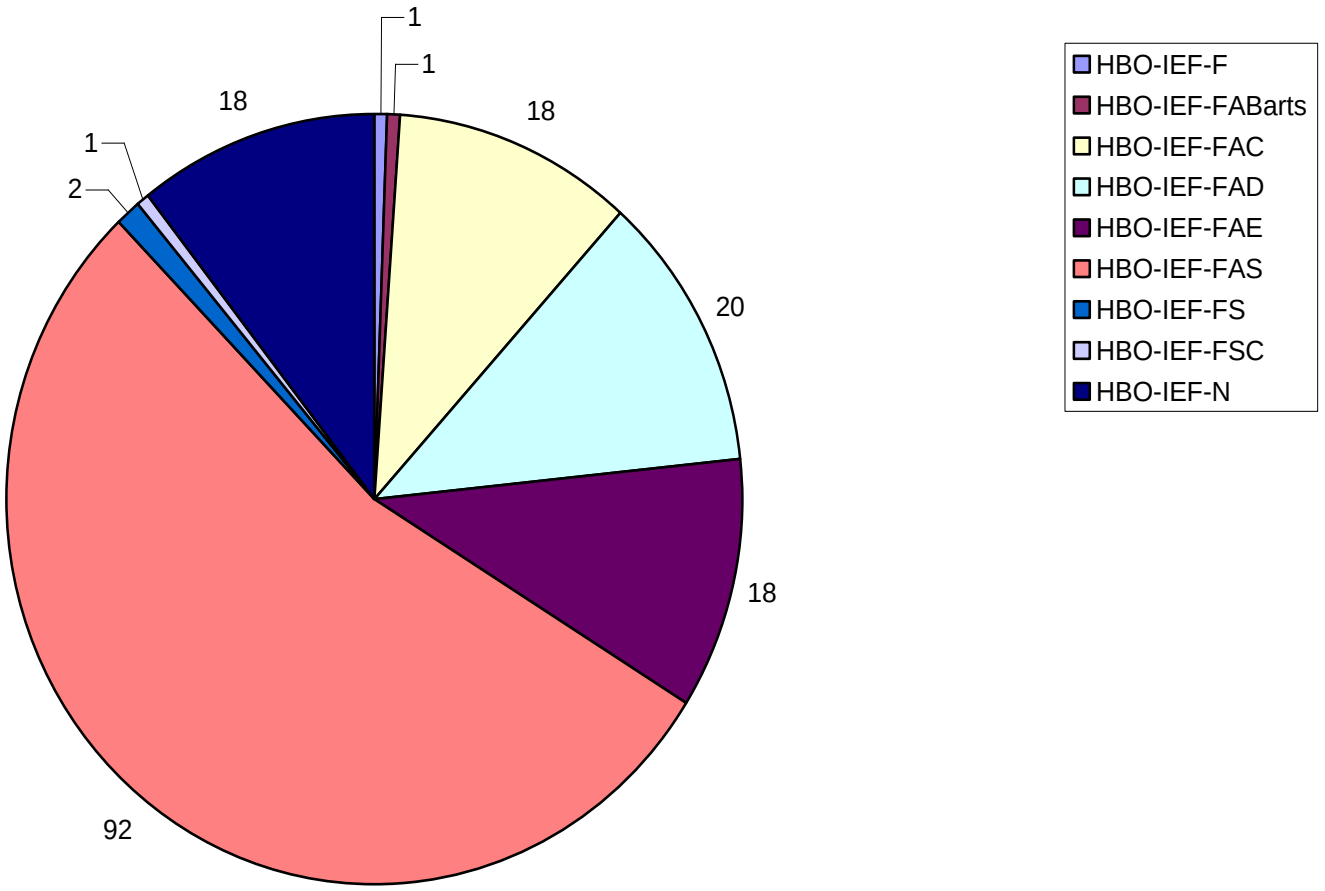
The haemoglobinopathy screening results for all samples undergoing IEF analysis during the audit period are displayed in Figure 1.

Table 1 – TAT of NBS samples requiring IEF and the percentage which failed to meet local or national standards

		Age at collection (days)	Collected to Received (days)	Received to sent for IEF (days)	Sent for IEF to IEF result entered (days)	IEF result entered to letter printed (days)	Letter printed to result posted (days)	Received to Posted (days)	Age when result posted (days)
Initial samples n=146	Mean (working days)	10	2	2	3	0	1	5	20
	Median (working days)	5	2	2	2	0	1	5	16
	Minimum (working days)	0	0	1	1	0	0	3	8
	Maximum (working days)	331*	7	3	7	0	2	9	360*
	Standard (working days)	5 to 8	4	3	5	1	N/A	N/A	<35 days old
	% failing standard	**2**	**1**	**0**	**4**	**0**	N/A	N/A	**1**
Repeat samples n=2	Mean (working days)	15	1	-5	5	6	0	7	29
	Median (working days)	15	1	-5	5	6	0	7	29
	Minimum (working days)	14	1	-5	5	4	0	5	25
	Maximum (working days)	15	1	-4	5	8	0	8	32
	Standard (working days)	N/A	4	3	5	1	N/A	N/A	<35 days old
	% failing standard	**N/A**	**0**	**0**	**0**	**0**	**N/A**	**N/A**	**0**

* When the two oldest babies, which were aged 330 and 331 days at collection, were excluded from this data, the maximum age at collection was 12 days and the maximum age when result was posted was 26 days.

Figure 1: Haemoglobinopathy screening results for all samples undergoing IEF analysis October - December 2013



Search 2

A total of 14630 samples with the result code HBO-I-N were exported for the period October to December 2013. Samples where results weren't reported were removed as follows: insufficient n=106 (0.7%), NHS number missing n=72 (0.5%), baby <5 day old n=335 (2.3%), sample >14 days old n=4 (0.03%), transfused n=9 (0.06%). A total of 14104 samples remained (96.41%).

91 HBO-I-N results (0.6%) were reported >5 weeks of age. Of these, only 60 (66%) were 1st submission samples. The youngest of these babies was aged 4 weeks 1 day at collection; this baby was born in the UK but outside the NW region.

Table 3 – Compliance with National standards, in comparison with previous audit (where applicable)

Standard	Acceptable Standard	Achievable Standard	Compliance (%) 2013 (re-audit)	Compliance (%) 2011 (previous audit)	Change
1. NP2i: To report results of all screening including carrier results in a timely manner: (*Standards for Newborn Screening Programme, p42*)	95% screen negative results, including haemoglobin-opathy carrier, available for communication by 6 weeks of age	98% screen negative results, including haemoglobin-opathy carrier, available for communication by 6 weeks of age	99.4% (91/14104)	98.5% (210/14054)	↑
2. NP3: Timely communication of positive screening results (sickle cell disorder) – including a review of parental results (*Standards for Newborn Screening Programme, P43*)	90% sickle cell disease results communicated to parents by 4 weeks of age	95% of sickle cell disease results communicated to parents by 4 weeks of age	100% (12/12)	20% (1/5)	↑

3. NP4: Effective follow-up of infants with positive screening results (sickle cell disease) – all babies to be registered with a local clinic / centre (or clinic working as part of clinical network) (*Standards for Newborn Screening Programme, P43*)	90% of babies identified are referred by 8 weeks of age to a designated healthcare professional	95% of babies identified are referred by 8 weeks of age to a designated healthcare professional	100% (12/12)	not measured	**N/A**
	90% attend local clinic by 3 months of age	95% attend local clinic by 3 months of age	100% (12/12)	not measured	**N/A**
4. NP5: Timely confirmation of diagnosis for infants with a positive screening result for specific conditions (*Standards for Newborn Screening Programme, p43*)	90% of cases of Hb SS and Hb SC have confirmation of result documented in clinical notes by 6 months of age	95% of cases of Hb SS and Hb SC have confirmation of result documented in clinical notes by 6 months of age	100% (8/8)	not measured	**N/A**
5. NP6i: To ensure treatment is offered and parental education started in a timely manner for children with conditions as specified in the clinical standards (*Standards for Newborn Screening Programme, P43*)	90% offered and prescribed prophylactic penicillin V (or alternative) by 3 months of age	99% offered and prescribed prophylactic penicillin V (or alternative) by 3 months of age	100% (8/8)	not measured	**N/A**

Table 4 - Compliance with local standards, compared with previous audit

Standard	Compliance (%) 2013 (re-audit)	Compliance (%) 2011 (previous audit)	Change
1. L1: Receipt of sample in NBS Laboratory to referral of sample for IEF: 3 working days	**100%** (148/148)	**100%** (165/165)	↔
2. L2: Receipt of sample in Haematology Laboratory to entry of IEF result in SG: 5 working days	**96%** (6/148)	**0%** (147/147 initial samples)	↑
3. L3: Entry of IEF result in SG to printing of referral letters: 1 working day	**100%** (148/148)	**71%** (105/147 initial samples)	↑

Comparison with 2011 previous audit

Data collection and analysis in this audit has been performed in the same manner as in the previous audit, such as taking into account differences in the procedure for initial and repeat samples and also calculation of working days have been included in calculation of TAT.

There has been a nominal improvement in reporting of screening results for normal and carrier patients, as performance was already 98.5% results being reported by 7 weeks of age in 2011 audit, in order to allow reporting to parents by 8 weeks of age. In this audit, 99.4% results were reported by 5 weeks of age, in order to allow reporting to parents by 6 weeks of age, as dictated in the amended National Standards.

A significant improvement was seen in reporting of positive screening results in this audit, where all of the 12 patients identified were reported within the expected standard of 4 weeks of age; this compared with only 20% in the previous audit.

Four additional standards have been included in this audit for which comparison can not be made against the previous audit.

Discussion

Unlike the other screening programmes, there is no annual national audit to assess performance against the clinical referral standards. The absence of laboratory TAT targets is also a major gap in the tools required to assess the quality of the service. We have taken the initiative of introducing local standards which will enable us to audit the programme on an annual basis. The first audit against these local standards identified parts of the pathway where the TAT could be improved and an action plan was produced.

In the previous audit in 2011, only 20% of positive screening results were reported within the National Standards of 95% results being communicated to parents by 4 weeks of age. Significant improvement in this standard has been exhibited in this audit; all 12 positive cases were reported within 21 days providing MSCTC with 5 workings days to provide these results to parents and thus meet this timescale. This improvement is a reflection of the local standards put in place by the laboratory in the action plan of the last audit as well as hard work by the laboratory staff in both the newborn screening and haematology laboratories.

All positive patients in this audit were referred to a clinician by 8 weeks of age and attended their local clinic by 3 months of age, exceeding the 95% achievable standard detailed in Standard NP4. Four of these positive patients were identified as having β-thalassamia Major. These patients do not require prophylactic penicillin prescribing (Standard NP6i) and are also not included in Standard NP5. All the remaining 8 sickle cell positive patients had their confirmation result documented in their clinical notes by 6 months of age, exceeding the 95% achievable standard in Standard NP5. It is appropriate for sickle cell patients to have prophylactic penicillin treatment prescribed by 3 months of age. All of the relevant patients in this audit met this requirement, achieving Standard NP6i.

In this audit, all samples requiring IEF analysis were referred to the haematology laboratory within 3 working days and 96% of these samples were then analysed for IEF and results entered into SG in 5 working days. All referral letters were printed within 1 day of IEF results being entered into SG. These meet the three local TAT standards.

It was considered appropriate in this audit for the NBS laboratory to report negative results to CHRD by approximately 35 days age, in order to allow CHRD to meet the National Standard of such results being available for communication by 6 weeks of age. In this audit 99.4% such results were reported to CHRD by 35 days of age. Of the remaining results, only 66% (60/91 samples) were 1st submission samples. The youngest of these babies was aged 4 weeks 1 day at collection; this baby was born in the UK but out of region.

In the previous audit, the target set was reporting within 49 days of age, as the National Standard at that time was for results to be reported within 8 weeks of

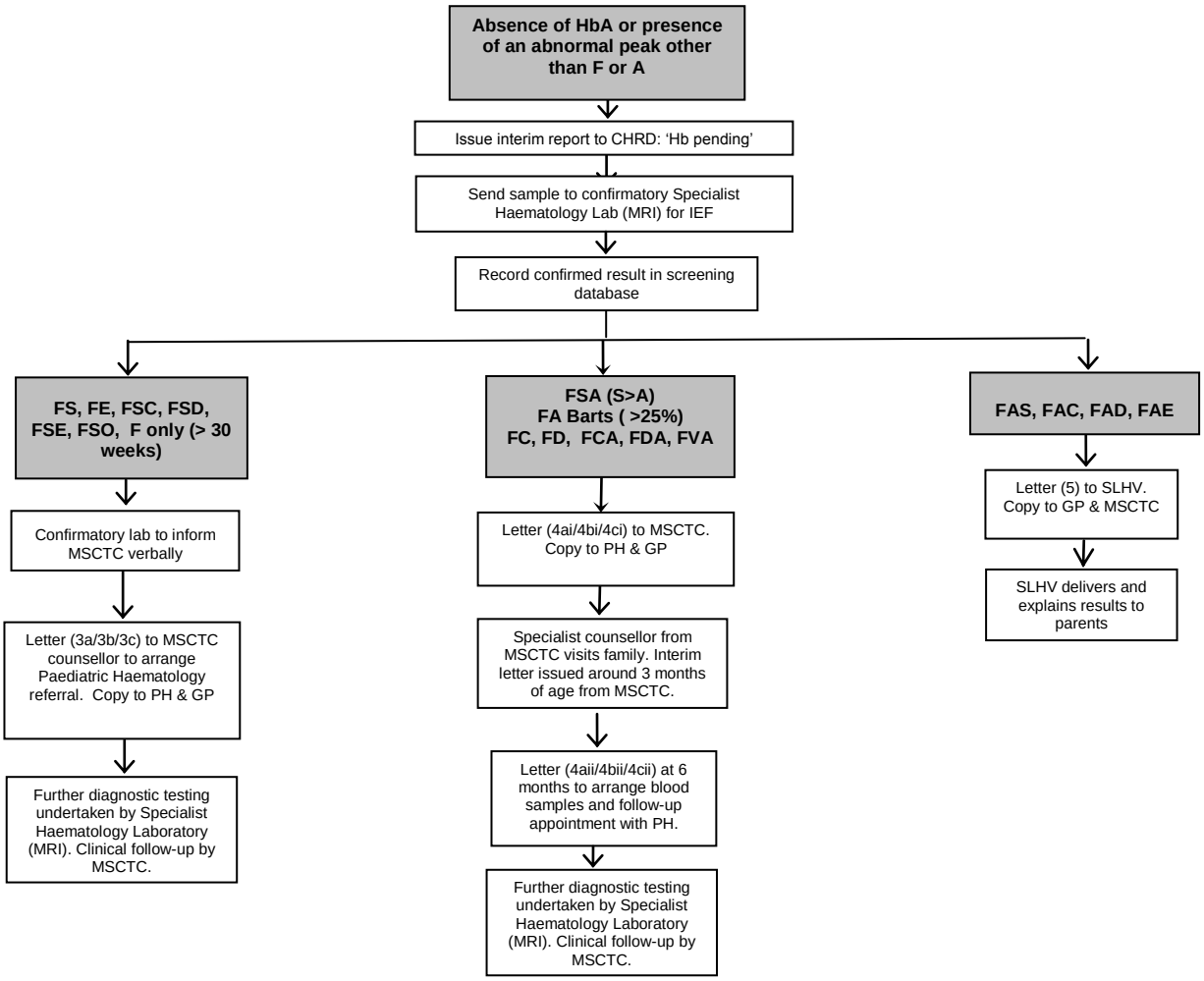
age. In the previous audit, 98.5% results were reported in this timescale. In this audit, 99.4% results were reported to CHRD by 35 days of age.

Action Plan

Action Plan		
Key Action	Co-ordinator for action	Timescale
To share results of the audit with staff working in the Newborn screening and haematology laboratory and the Sickle Cell Centre and encourage continuation of good practice already in place.	Lesley Tetlow	April 2014
What was the main matter(s) of concern this audit identified?		
No areas of concern were identified.		
Please identify the main benefit(s) to our patient, or to hospital process that are expected to result from the action plan of this audit		
The aim is to continue good practice which is in place in order to continue to provide timely delivery of newborn screening results		

Will there be a re-audit?	*Yes*	When will the re-audit take place?	*April 2015*

Appendix 1 – Extract from algorithm for screening for common haemoglobin variants: Manchester and NW Region



Appendix 2 – Assurance levels for Clinical Audit

For each clinical audit undertaken, an assurance rating is reported for each standard measured.

Step 1:

Each standard is given a rating of red, amber or green depending on how high, or low, it measured.

Calculation of individual ratings against standard	
Colour	Standard % measure
	95% and above
	75% to 94.9%
	74.9% and below

Step 2:

Once each standard has been rated, an overall level of assurance for the audit project can be determined using the matrix below.

Assurance Level	**Calculation of assurance**
Full	To be used when each standard has achieved a score ≥ 95% and is rated Green
Significant	To be used when there are only Green and Amber rated findings (although where there are a significant number of Amber rated findings, consideration will be given as to whether in aggregate the effect is to reduce the assurance level given)
Limited	To be used when there is a small ratio of Red and Amber to Green rated findings
Very Limited	To be used when the ratio of Red rated findings are greater than the Amber and Green

The appropriate level of assurance will be decided following a discussion between the clinical audit lead, or leads, and the clinical audit department. 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.

Appendix 3 – Dissemination list

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

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