Dr Suzanne Armitage

A re-audit of the Manchester Newborn Sickle Cell Screening Programme against national clinical referral standards

The College's Clinical Effectiveness Department wishes to encourage high-quality clinical audit. We therefore periodically publish interesting examples of audits that have been successfully evaluated through our clinical audit certification scheme.

Background

Screening for sickle cell disease has been included in the Newborn Bloodspot Programme in Manchester since 2005. Specific laboratory and clinical referral standards for newborn sickle screening are produced by the NHS Sickle Cell and Thalassaemia Screening Programme. In contrast to national standards for the other conditions screened for, these do not include laboratory turnaround targets (TAT) for each individual step of the pathway. Following a previous audit in 2012, which demonstrated a failure to meet clinical referral standards, we devised 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 (as defined by National Standard NP3).

The pathway for newborn sickle cell screening in Manchester is shown in Figure 1.

Aim and objectives

The aim of this audit was to re-assess the performance of the Manchester Newborn Screening (NBS) Programme against both revised national standards produced by the NHS Sickle Cell and Thalassaemia Screening Programme in October 2011 and local pathway standards introduced following the previous audit in 2012 (Table 1).

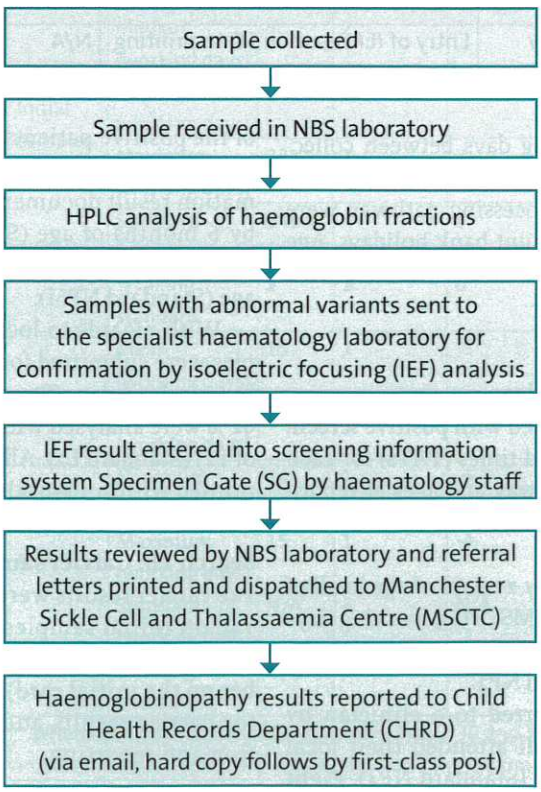

Figure 1: Pathway for newborn sickle cell screening in Manchester

Notes

Standard NP3 covers sickle cell disorders (FS, FSA, FSC, FSD, FSE, FSO^{Arab}) and other clinically significant haemoglobinopathies, detected by newborn screening (F only, FE, FEA). Standard NP2i is assumed to apply to all results not included under Standard P3, including carriers of sickle cell disorders.

MSCTC agreed to inform parents of positive screening results within five days of receiving the report. In order to meet Standard NP3, the NBS laboratory result needs to be issued before the baby reaches 21 days of age.

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.

Search 1A

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, FSD, FSA, FSE, FSO^{Arab}.

Search 1B

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.

Table 1: National and locally defined standards for newborn sickle cell screening

Standard	Acceptable standard	Achievable standard
1. National Standard NP2i: to report results of all screening including carrier results in a timely manner	95% screen negative results, including haemoglobinopathy carrier, available for communication by 6 weeks of age	98% screen negative results, including haemoglobinopathy carrier, available for communication by 6 weeks of age
2. National Standard NP3: timely communication of positive screening results (sickle cell disorder), including a review of parental results	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
3. National Standard 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	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
4.National Standard NP5: timely confirmation of diagnosis for infants with a positive screening result for specific conditions	90% attend local clinic by 3 months of age 90% of cases of Hb SS and Hb SC have confirmation of result documented in clinical notes by 6 months of age	95% attend local clinic by 3 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
5. National Standard NP6i: to ensure treatment is offered and parental education started in a timely manner for children with conditions as specified in the clinical standards	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
6. Local Standard L1: timely processing of samples by NBS laboratory	Receipt of sample in NBS laboratory to referral of sample for IEF: 3 working days	N/A
7. Local Standard L2: timely processing of samples by specialist haematology laboratory	Receipt of sample in Haematology laboratory to entry of IEF result in SG: 5 working days	N/A
8. Local Standard L3: timely reporting of abnormal results	Entry of IEF result in SG to printing of referral letters: 1 working day	N/A

The number of working days between collection and receipt of the sample and between each stage of the laboratory processing pathway were calculated taking into account bank holidays. Age at collection and age when results were reported were also calculated.

Results

Search 1A: Positive samples

Twelve babies were identified with positive screening results. The turnaround times (TATs) for each step in the screening pathway and ages at reporting, clinical referral and assessment are shown in Table 2.

Results were reported by 21 days of age in all of these positive cases giving MSCTC 5 working days to inform parents of the positive screening results in order to achieve standard NP3.

All patients were referred to a clinician by eight weeks of age and all attended their local clinic by 3 months of age (Standard NP4). Eight 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 (Standard NP5) and all had penicillin offered and prescribed by 3 months of age (Standard NP6i).

With regards to local TAT standards, all samples were submitted for IEF, when relevant, within 3 working days (Standard L1). Of these samples, 92% were analysed within 5 working days (11 out of 12) (Standard L2). All results had referral letters printed within 1 working day of IEF results being entered into SG (Standard L3).

Search 1B: Carrier samples

148 carrier results were confirmed and reported, 146 on initial samples and 2 on repeat samples (repeats required due to absence of NHS number on the initial card). Table 3 displays the TAT for carrier results and the mean age at collection and reporting.

Table 2: Laboratory TAT and clinical referral of positive screening results (failed standards in red)

Sickle cell/ other clinically significant disorders	Sample 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)	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	F1	5	1	2	6	1	0	9	19	2.7	6.3	3	N/A**	N/A**
	F2	7	2	2	4	0	0	6	19	2.7	10.3	5.4	N/A**	N/A**
	F3	5	1	2	1	1	0	4	12	1.7	6.9	2.2	N/A**	N/A**
Hb FE	FE1	5	1	2	4	1	0	7	15	2.1	9	ND*	N/A**	N/A**
Hb FS	FS1	6	1	2	4	1	0	7	19	2.7	8.7	4.8	1.7	1.9
	FS2	5	2	2	4	1	1	8	17	2.1	7.4	4.8	1.7	1.9
	FS3	5	1	2	5	0	0	7	15	2.1	7.1	3.9	2	1.9
	FS4	5	3	2	3	0	1	6	14	2.1	6.4	4.7	1.5	1.7
	FS5	5	1	2	2	1	0	5	15	2.1	6.7	5.1	1.6	1.9
	FS6	7	2	2	4	1	0	7	20	2.9	6.4	3.8	1.5	1.6
	FS7	6	2	2	1	1	0	4	14	2	8.6	2.1	2	2.1
Hb FSC	FSC1	5	1	2	1	1	0	5	14	2	9.6	2.6	1.9	2.6

* Not detected

**Not available; patients diagnosed with thalassaemia (HbF and HbFE) do not require penicillin treatment

Table 3: 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	N/A	N/A	N/A	N/A	N/A	<35 days old
	% failing standard	N/A	0	N/A	N/A	N/A	N/A	N/A	0

* When the two oldest babies, who 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.

Table 4: Compliance with national and local 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	95% screen negative results, including haemoglobinopathy carrier, available for communication by 6 weeks of age	98% screen negative results, including haemoglobinopathy 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	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)	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)	100% (12/12)	N/A
	90% attend local clinic by 3 months of age	95% attend local clinic by 3 months of age	100% (12/12)	100% (12/12)	N/A
4. NP5: timely confirmation of diagnosis for infants with a positive screening result for specific conditions	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)	100% (8/8)	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	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)	100% (8/8)	N/A
6. Local Standard L1: timely processing of samples by NBS laboratory	Receipt of sample in NBS laboratory to referral of sample for IEF: 3 working days	N/A	100% (148/148	100% (148/148	↔
7. Local Standard L2: timely processing of samples by specialist haematology laboratory	Receipt of sample in haematology laboratory to entry of IEF result in SG: 5 working days	N/A	96% (6/148)	96% (6/148)	↑
8. Local Standard L3: timely reporting of abnormal results	Entry of IEF result in SG to printing of referral letters: 1 working day	N/A	100% (148/148)	100% (148/148)	↑

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 (maximum time 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, the local standards are not applicable as the initial sample is sent for IEF, but the results are reported with the rest of the repeat sample's results.

Search 2: Normal samples

A total of 14 630 samples with the result code HBO-I-N were exported for the period October to December 2013. Samples where results weren't reported (sample insufficient or >14 days old, NHS number missing, baby <5 day old or transfused) were removed.

Of the remaining 14104 samples, 91 HBO-I-N results (0.6%) were reported >5 weeks of age. Of these, only 60 (66%) were first 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.

Summary and conclusion

In the previous audit in 2012, only 20% of positive screening results were reported in accordance with National Standards NP3 (95% results to be communicated to parents by 4 weeks of age). In this re-audit, all 12 positive cases were reported by 21 days providing MSCTC with 5 working days to provide these results to parents.

All positive patients 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. Eight patients were positive for sickle cell disease, all had a confirmation result documented in their clinical notes by 6 months of age and all had prophylactic penicillin treatment prescribed by 3 months of age (exceeding the achievable targets for standards NP5 and NP6i).

All samples requiring IEF analysis were referred to the haematology laboratory within 3 working days and 96% 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. Compliance with local TAT standards was, therefore, excellent.

99.4% of normal (screen negative) results were reported to CHRD by 35 days allowing sufficient time for CHRD to communicate these to parents by 6 weeks of age. Of the remaining results, only 66% (60/91 samples) were first 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.

This audit demonstrates the importance of defining targets for each element of the screening pathway and the power of cross-discipline collaborative working in achieving national targets for timeliness of referral and treatment of screen positive babies.

Suzanne Armitage, Lesley Tetlow and Claire Manfredonia
Manchester Newborn Screening Laboratory

Simone McLaughlin
CMFT Specialist Haematology Laboratory

Verna Davis and Sarah McDonald
Manchester Sickle Cell and Thalassaemia Centre

Central Manchester University Hospitals NHS Foundation Trust

Nicola Hancock

National Laboratory Medicine Catalogue

Implementation of the National Laboratory Medicine Catalogue will be a key pillar of the emerging IT strategy for the NHS. Safe and reliable transfer of pathology-related data will contribute to quality by improving outcomes. Here Nicola Hancock explains.

The National Laboratory Medicine Catalogue (NLMC)[1] aims to standardise the requesting, reporting and analysing of pathology tests. It is a development by qualified pathologists under the governance of The Royal College of Pathologists, working in collaboration with NHS England and The Health and Social Care Information Centre.

Pathology in the UK

Over 70% of diagnoses in the NHS involve pathological tests.[2] Each year nearly 800 million tests are carried out with the majority of results reported within 48 hours.

Pathology data is required by all NHS organisations. Two-way communication takes place between users and laboratories, and between laboratories. Up until now, there has been no way of ensuring that pathology tests are reported in a consistent and standardised way across the NHS. This lack of standardisation extends to the report names, codes and units of measurement used for both the requesting of tests and reporting their results. There is potential for the wrong test to be undertaken or results to be misinterpreted, causing a risk to patient safety.

Current pathology reporting systems

There is no mandatory system for reporting pathology data within the NHS, however the majority of reporting uses the Pathology Bounded Code List (PBCL). The PBCL was developed as part of the Pathology Messaging Implementation Project to support a universal system of electronic reporting from pathology labs to GPs. The main principle behind the PBCL is that all pathology tests and profiles were allocated an individual 'read code' to allow for electronic reporting from laboratories to GPs.