Manchester University
NHS Foundation Trust

Re-audit of the age at which newborn screening carrier results for sickle cell disease are given to parents

Clinical Audit Report: 11659

Audit Period: 1st April 2023 and 30th September 2023
Date Completed: 14th June 2024

Clinical Audit Lead(s): Beverly Hird (Initial audit performed by Claire Bradford; data collection assisted by Neera Jones)

Person(s) responsible for action plan: Beverly Hird

Person(s) responsible for dissemination: Beverly Hird

Clinical Audit Facilitator: Daniella Magalhães

Green	Amber	Red	Assurance Level
2	0	1	Limited

Contents

Clinical Audit Report – Outcome Summary	
Audit Title	Re-audit of the age at which newborn screening carrier results for sickle cell disease are given to parents.

Standard	Compliance Initial Audit	Compliance Re-audit	Change
1. Standard one Parents should be informed of their baby's carrier status by 6 weeks (42 days) of age.	63% (304/480)	64% (228/355)	↔
2. Standard two All carrier status audit forms should be completed and returned to the laboratory.* *N.B. Figures after laboratory has chased missing data.	89% (485/542)	99% (357/361)	↑
3. Standard three Carrier letters should be sent to the screening link health visitor by day 32.	99% (541/542)	99% (359/361)	↔

Clinical Audit Action Plan			
Key Action	Action Co-ordinator	Target Date	
Share the report with the Greater Manchester and Lancashire and South Cumbria NHS England Screening and Immunisation teams and ask for feedback if any actions are proposed as a result of this work.	Beverly Hird	July 2024	
What were the main concerns that this audit identified?			
More than one third of sickle carrier results from newborn screening were communicated to parents beyond the recommended timeframe.			
What are the main benefits, to patients or Trust processes, expected as a result of this action plan?			
Confirmation that newborn screening carrier results have been communicated to parents, by a suitably trained professional, in a timely manner.			
Will there be a re-audit?	No	When will the re-audit take place?	N/A

Aim & Objectives

The aim of the audit is to determine the age at which parents are informed of their baby's newborn screening carrier results for sickle cell disease. This will help inform us of the implications of national plans to make newborn screening results available to parents digitally.

For simplicity, in this audit the term sickle cell carrier is used to describe all carriers detected by sickle cell newborn screening, which includes the following haemoglobin variants: S, C, D, E and O^{Arab}.

Background

One of the aims of NHS England's Digital Child Health Programme is to produce digital personal child health records (DPCHR) to supplement or replace paper red books, making it easier for families to hold online records for their children and access them via smartphones, laptops and tablets[1].

NHS England's Newborn blood spot screening: programme handbook (January 2014; updated 2018) states that all parents should receive carrier results for sickle cell disease screening by six weeks of birth (day 42), although no formal screening standard exists.[2] Current best practice is for a trained healthcare professional to communicate the carrier results to parents. Parents of babies found to be a carrier of a haemoglobin variant must be given the opportunity for a face-to-face discussion with a suitably trained professional to enable the significance of the carrier status to be explained.[3] It is important for the parents to understand that their child could pass on the gene for the unusual haemoglobin to future generations when they have their own baby. There is also a parent information leaflet to support the information given by the healthcare professional. The healthcare professional who gives the carrier results to the family should complete and return a 'newborn screening sickle cell and thalassemia carrier audit form' produced locally by our newborn screening laboratory.

With the introduction of DPCHR there are concerns that parents may receive the results electronically before being contacted by a trained healthcare professional. Therefore, the purpose of this audit was to determine the age at which parents are informed of their baby's newborn screening carrier results for sickle cell to help inform us of the implications of national plans to make screening results available to parents via a DPCHR. This audit was carried out previously for the period 1st April 2019 and 31st March 2020, for both sickle cell disease carrier and cystic fibrosis carrier results (by Claire Bradford, Clinical Biochemist). The assurance level was limited for sickle cell carrier results, so the decision was made to re-audit, following dissemination of the findings of the first audit throughout the region.

Standards

Standard 1: 95% of parents should be informed of their baby's carrier status by 6 weeks (42 days) of age.

Criteria: Proportion of parents informed of their baby's carrier status by six weeks of age.

Numerator: Number of parents informed of their baby's carrier status by six weeks of age.

Denominator: Number of babies with a carrier result on newborn screening

Threshold: 95% selected arbitrarily for this initial audit.

Data source for numerator: Screening Link Health Visitor (SLHV).

Data source for denominator: Newborn Screening Laboratory.

NHS England's Newborn blood spot screening: programme handbook (January 2014; updated 2018) states that all parents should receive carrier results for sickle cell disease screening by six weeks of birth (day 42).[2]

Standard 2: 100% of all carrier status audit forms should be completed and returned to the laboratory.

Criteria: Proportion of completed carrier status audit forms completed and returned to the Newborn Screening Laboratory.

Numerator: Number of completed carrier status audit forms received by the Newborn Screening Laboratory.

Denominator: Number of carrier audit forms sent to SLHVs for completion.

Threshold: 100% selected arbitrarily for this initial audit.

Data source for numerator: Newborn Screening Laboratory.

Data source for denominator: Newborn Screening Laboratory.

In terms of sickle cell carriers, this is a local standard developed for this audit with carrier audit forms in operation for at least 10 years.

Standard 3: 95% of carrier letters should be sent to the screening link health visitor by day 32.

Criteria: Proportion of carrier letters sent to the SLHV by day 32.

Numerator: Number of carrier letters sent to the SLHV by day 32.

Denominator: Number of carrier letters produced by the Newborn Screening Laboratory

Threshold: 95% selected arbitrarily for this initial audit.

Data source for numerator: Newborn Screening Laboratory.

Data source for denominator: SLHV.

This is a local standard developed for this audit based on allowing a reasonable time period (10 days) for the SLHV to communicate the result by day 42.

Method

This was a retrospective audit, covering a 6 month period, of babies identified as carriers on sickle cell disease newborn blood spot screening between 1st April 2023 and 30th September 2023 in Greater Manchester, Lancashire and South Cumbria (the area covered by Manchester Newborn Screening Laboratory).

Data was extracted from the screening IT systems and included the following:

- Child Health Region
- Date of sample collection
- Date of receipt of sample in lab
- Date at which letter informing of carrier status was sent to the SLHV

Hard copy sickle cell audit forms received by the newborn screening laboratory (see Appendix 1 for form template) were checked for a date when the screening result was given to parents, and this was recorded in the spreadsheet.

Age of the baby on the above dates was calculated in Excel. Any duplicates within the extracted spreadsheet were removed as well as cancelled results, babies tested elsewhere, resident out of area babies or older babies who had moved into the country.

The presence or absence of a form was also recorded within the spreadsheet. Any missing audit forms were then followed up with the relevant child health team by email. If it was not possible to receive completed audit forms, then emails with the date parents were given the results was also accepted. The proportion of sickle cell carrier audit forms received by the laboratory was calculated and the results were presented by child health region.

Results

The tables below illustrate the results of the audit. See results section below for all the data collected for this project.

Key:

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

Standard	Compliance Initial Audit	Compliance Re-audit	Change
1. Standard one Parents should be informed of their baby's carrier status by 6 weeks (42 days) of age.	63% (304/480)	64% (228/355)	↔
2. Standard two All carrier status audit forms should be completed and returned to the laboratory.* *N.B. Figures after laboratory has chased missing data.	89% (485/542)	99% (357/361)	↑
3. Standard three Carrier letters should be sent to the screening link health visitor by day 32.	99% (541/542)	99% (359/361)	↔

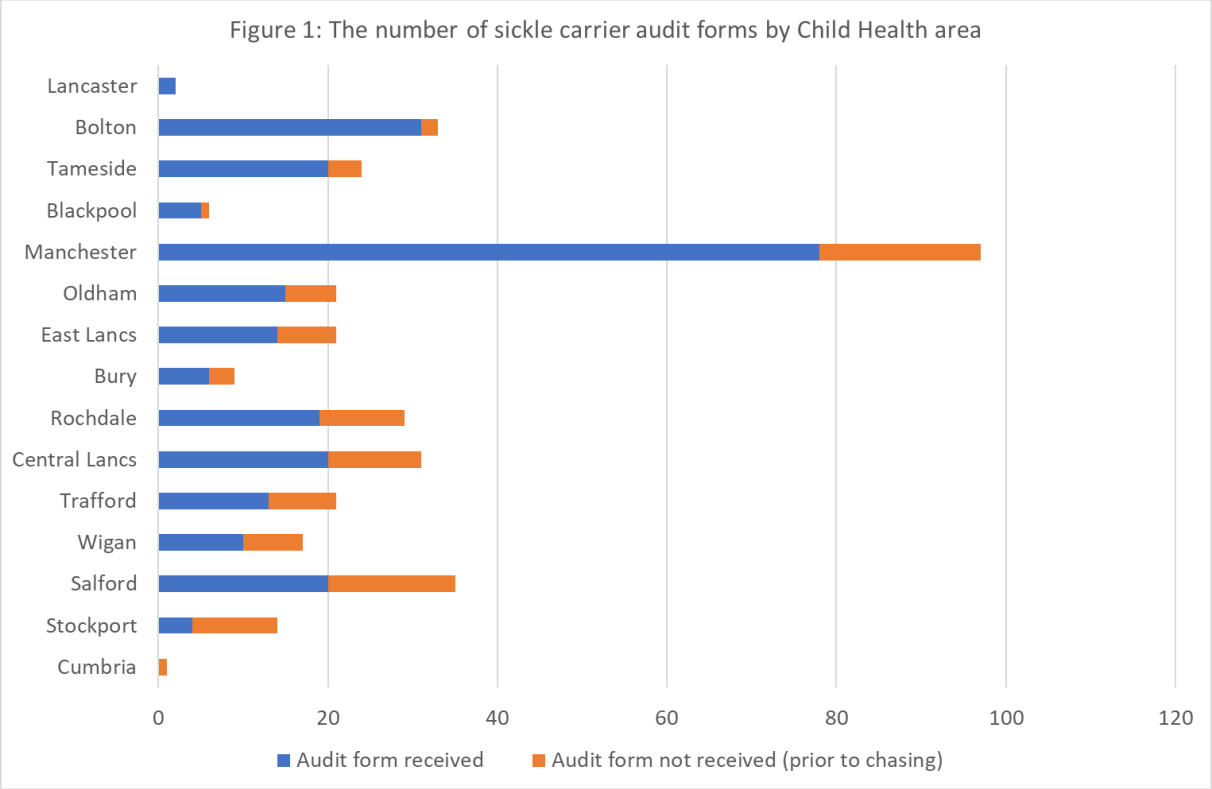
In total 361 carriers were identified from sickle cell disease newborn blood spot screening between 1st April 2023 and 30th September 2023, after removal of babies tested elsewhere (n=2), out of area babies (n=7) and older babies who had moved into the country (n=14, sample collected day 61-352).

The median age at sample collection was 5 days (range 0-16 days, including day 0 pre-transfusions samples). The median age at receipt of samples in the laboratory was 7 days (range 5-18 days).

The proportion of carrier letters sent from the laboratory to the SLHV by day 32 was 99% (359/361). Letters were sent at a median age of 20 days (range 13-49 days). Two letters sent after 32 days were delayed due to a delay in obtaining a sickle cell screening 2nd line testing result from the Haematology Laboratory. In the first case, a blood spot from the sample was sent to Haematology for 2nd line testing on day 8 but due to an IT issue the sample didn't appear on the assay worklist and as a result it was disposed of in error. The error was detected when the newborn screening laboratory chased up the missing result. Fortunately, there was sufficient blood on the original sample card, so a further blood spot was sent to the Haematology Laboratory and the result was reported on day 48 and the letter sent on day 49. In the second case, there was difficulty in obtaining a valid 2nd line testing result due to the extreme prematurity of the baby. A result was

obtained after repeating the testing with 3 times the usual amount of sample applied. The result was reported on day 39 and the letter was sent on day 40.

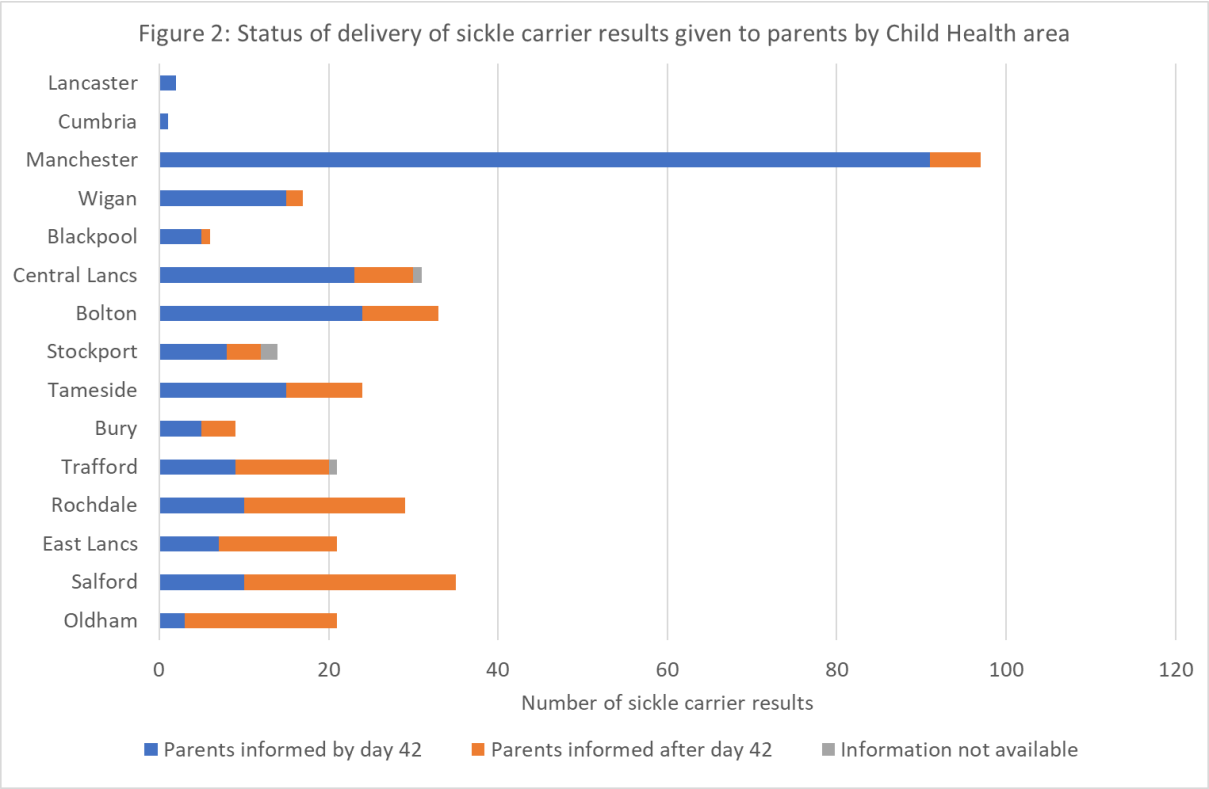
The date at which the sickle cell carrier result was given to parents was available for 71% of babies (257/361) from Sickle carrier audit forms received in the laboratory. This was assessed 4 months after the end of the audit period. After contact from the newborn screening laboratory to request the missing data, this number rose to 357 (99%). Figure 1 displays the number of audit forms received in the laboratory by Child Health area.



A date was unavailable for 4 babies:

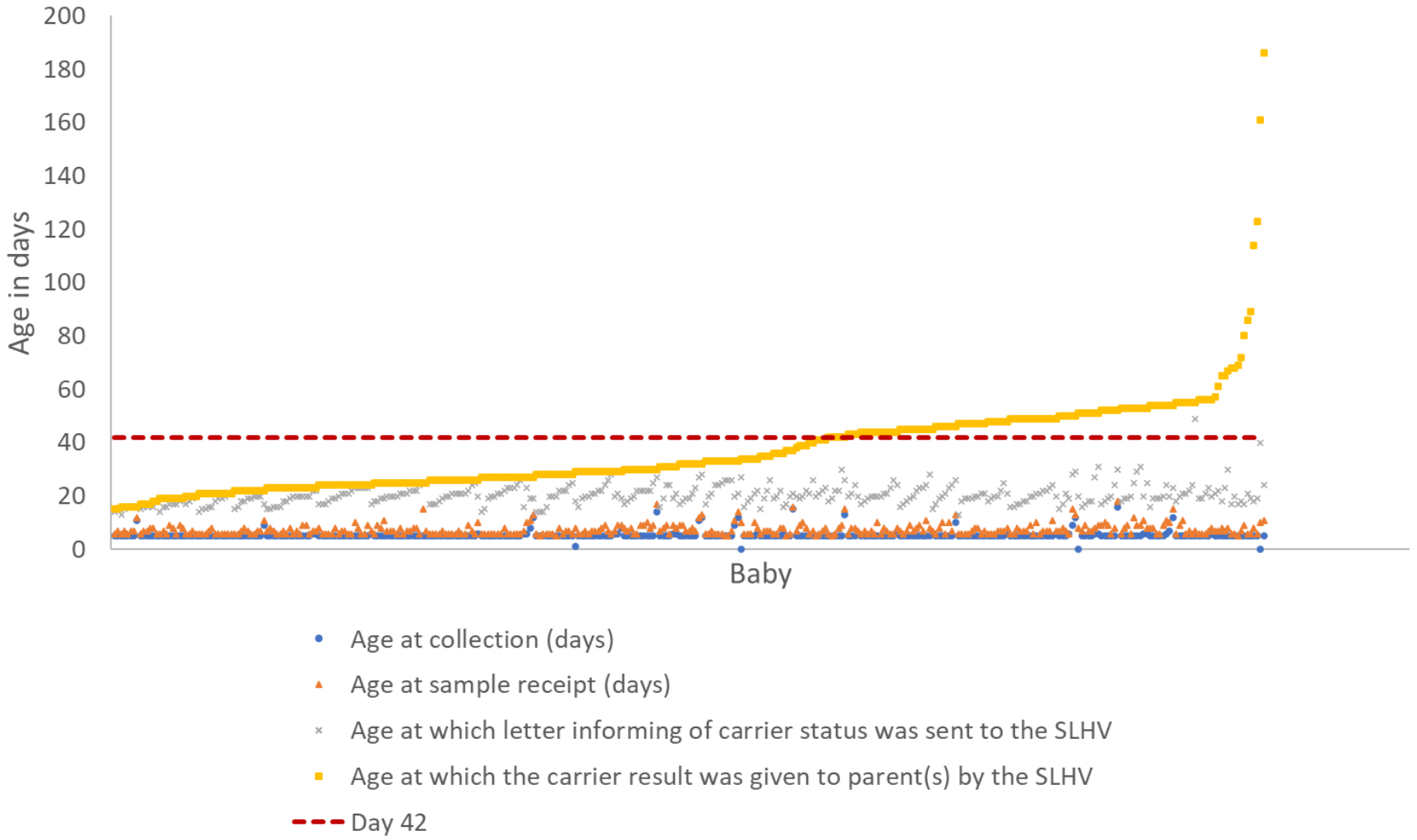
- Parents aware of carrier result but date not known (n=1)
- Baby in Interim Care Order and Social Care will talk to parents (n=1)
- Family moved out of area before result available (n=1)
- No information (n=1)

The proportion of parents informed of their baby's carrier result by day 42 was 64% (228/355; median age 32 days, range 12-186 days). Two babies were excluded as the date given for when parents were informed was before the results were reported by the laboratory, indicating an error. Figure 2 displays the status of delivery of sickle cell carrier results by Child Health area.



In Figure 3 the ages at sample collection, receipt, sending of the letter and informing parents of results are displayed for each baby, with babies in the order of age parents were informed. With the exception of 2 babies where the letters were delayed (discussed above), letters were sent to SLHVs in a timely manner. This indicates that delays in informing parents of carrier results was likely to be due to issues with processes or capacity within Health Visiting services.

Figure 3: For each baby with a carrier result, the ages at sample collection, receipt, sending of letter and informing parents of results, are displayed, with babies in order of age parents were informed



Conclusions

Performance against the 3 standards was very similar to the previous audit. The primary outcome was the age at which parents are given carrier results and the standard for this was not met, therefore the assurance level for this audit it limited. As there was high compliance with standard 3, which is mainly under the control of the laboratory (processing of the sample once received and sending the letter), a re-audit is not planned.

Action Plan

Clinical Audit Action Plan			
Key Action		Action Co-ordinator	Target Date
Share the report with the Greater Manchester and Lancashire and South Cumbria NHS England Screening and Immunisation teams and ask for feedback if any actions are proposed as a result of this work.		Beverly Hird	July 2024
What were the main concerns that this audit identified?			
More than one third of sickle carrier results from newborn screening were communicated to parents beyond the recommended timeframe.			
What are the main benefits, to patients or Trust processes, expected as a result of this action plan?			
Confirmation that newborn screening carrier results have been communicated to parents, by a suitably trained professional, in a timely manner.			
Will there be a re-audit?	No	When will the re-audit take place?	N/A

References

1. https://digital.nhs.uk/services/digital-child-health (Accessed 05.06.24)
2. NHS England Newborn blood spot screening: programme handbook Guidance 3. Results and Records (January 2014 (updated August 2018) https://www.gov.uk/government/publications/health-professional-handbook-newborn-blood-spot-screening/3-results-and-records
3. NHS England Sickle cell and thalassaemia: screening handbook Guidance Newborn screening (January 2012 (updated July 2018); https://www.gov.uk/government/publications/handbook-for-sickle-cell-and-thalassaemia-screening/newborn-screening

Appendix 1

NHS
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Newborn Screening for Sickle Cell and Thalassemia ***Carrier Audit***

Please return to the laboratory following your visit to the family.

Laboratory Number:
NHS number:

To be completed by SLHV and posted to:
Newborn Screening Lab
6th Floor, Genetic Medicine
St. Mary's Hospital
Oxford Road
Manchester
M13 9WL

Or fax to: 0161 7012264

1. Family given SCT screening result by: _____

   Date: ____ / ____ /____ Time: _____ : _____hrs

2. Was this visit prearranged ☐ or spontaneous? ☐

3. Who was present mother ☐ father ☐ other _____

4. Was the "*Information for mums and dads: your baby carries a gene for sickle cell/unusual haemoglobin*" leaflet discussed and left with parent? YES ☐ NO ☐

5. Were you asked any questions not covered by the leaflet? YES ☐ NO ☐
   If you answered YES please record the questions in the space below

6. Did you put a copy of the results in the "Red Book"? YES ☐ NO ☐

Thank you for completing this form, the information will help to maintain the quality of the sickle cell and thalassaemia screening service.

www.mft.nhs.uk

Incorporating:
Altrincham Hospital • Manchester Royal Eye Hospital • Manchester Royal Infirmary • Royal Manchester Children's Hospital • Saint Mary's Hospital • Trafford General Hospital • University Dental Hospital of Manchester • Wythenshawe Hospital • Withington Community Hospital • Community Services

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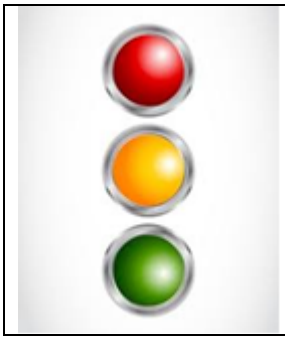
Appendix 2 – Assurance levels for Clinical Audit

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
Every 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 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 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