Manchester University
NHS Foundation Trust

Audit of the age at which newborn screening carrier results for sickle cell disease and cystic fibrosis are given to parents

Clinical Audit Report

Dates audit undertaken: 01/03/2021-15/06/2021
Date Completed: 30/06/2022

Clinical Audit Lead/s: Claire Bradford

Person/s responsible for action plan: Beverly Hird

Person/s responsible for dissemination: Beverly Hird

Clinical Audit Facilitator: Maggie Briggs

Green	Amber	Red	Assurance Level	Risk Ref
1	4	1	Limited	

Contents

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Clinical Audit Report – Outcome Summary	
Audit Title	Audit of the age at which newborn screening carrier results for sickle cell and cystic fibrosis are given to parents in Greater Manchester, Lancashire and South Cumbria.

Standard	Compliance (%)
1. Standard one Parents should be informed of their baby's carrier status by 6 weeks (42 days) of age.	63% (304/480)
2. Standard two All carrier status audit forms should be completed and returned to the laboratory.	89% (485/542)
3. Standard three Carrier letters should be sent to the screening link health visitor by day 32.	99% (541/542)

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 2022
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?	Yes	When will the re-audit take place?	April 2023 for the period April 2022-March 2023

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 and cystic fibrosis (CF). This will help inform us of the implications of national plans to make newborn screening results available to parents via a digital Personal Child Health Record (dPCHR).

Background

There are national plans to make newborn screening results available to parents via a dPCHR, with proposals that child health records will be digitised for every birth from April 2023. Public Health England Newborn blood spot screening: programme handbook (January 2014; updated 2018) state that all parents should receive carrier results for CF and sickle cell disease screening by six weeks of birth (day 42), although no formal screening standard exists[1]. 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.[2] 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.

Parents of babies found to be a carrier of CF should be given the results face-to-face with a designated health visitor or trained professional and be given a parent information leaflet. [3] Carriers can pass on the CF gene to their children, so it is important parents tell their child later in life that they are a carrier of the CF gene. If both parents are carriers of the CF gene, all future children have a 1 in 4 chance of developing CF, therefore they can find out if they are both carriers by asking their GP for an appointment with a clinical genetics centre. On that same visit parents should also be told that occasionally there are uncommon alterations of the CF gene that are not recognised by the screening test and therefore a small chance that the child will have CF. They should contact their health visitor or GP if they have any concerns about their child's health. The healthcare professional who gives the carrier result to the family should complete and return a 'CF screening: carrier of CF gene follow-up form' to the newborn screening laboratory within 24 hours of the visit.[3]

With the planned 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 and CF to help inform us of the implications of national plans to make screening results available to parents via a dPCHR.

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.

Public Health England Newborn blood spot screening: programme handbook (January 2014; updated 2018) state that all parents should receive carrier results for CF and sickle cell disease screening by six weeks of birth (day 42).[1]

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. In terms of CF carriers, the healthcare professional who gives the carrier result to the family should complete and return a 'CF screening: carrier of CF gene follow-up form' to the newborn screening laboratory within 24 hours of the visit.[3]

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 one-year period of babies identified as sickle cell and CF carriers on newborn bloodspot screening between 1st April 2019 and 31st March 2020 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
- Age at sample collection
- Age at sample receipt in lab
- Age at repeat sample collection (in the case of CF carriers)
- Age at repeat sample receipt in lab (in the case of CF carriers)
- Age at which letter informing of carrier status was sent to the SLHV

Data was also extracted from the completed audit forms and consisted of:

- Age at which the carrier result was given to parent(s) by the SLHV

Any duplicates within the resultant extracted spreadsheet were removed. Babies born outside the UK, babies screened elsewhere, babies who moved abroad following screening, babies who moved out of area, babies tested elsewhere and babies who tested positive for FDV were also removed (as not technically a carrier status). Hard copy sickle cell and CF audit forms received by the newborn screening laboratory (see Appendix 1 and 2 for the form templates) were checked for a date when the screening result was given to parents, and this was recorded in the spreadsheet. 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 and either outstanding completed

audit forms were scanned and emailed or posted to the newborn screening laboratory. 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 and CF carrier audit forms received by the laboratory was calculated and the results were presented by child health region.

In total 542 sickle cell and 12 CF carriers were identified on newborn bloodspot screening between 1st April 2019 and 31st March 2020.

Results

Carrier Results for Sickle Cell Disease

Completed sickle cell disease carrier audit forms were received from all child health regions included in this audit, however, there was variation in how many returned all forms and/or emailed with a date that parents were informed of their baby's carrier result. 10 out of 17 child health regions successfully completed all sickle cell carrier audit forms or informed the newborn screening laboratory of the date when parents were told the screening result. Blackpool and Trafford returned 7 (88%) and 21 (95%), respectively, with 1 outstanding for both regions. Blackburn returned 19 forms (90%), Bury returned 14 forms (74%), Manchester returned 166 forms (94%) and Rochdale returned 38 forms (76%). Salford had the poorest return with 29 forms (34%), despite repeated emails to the health visiting team in Salford. However, this was reported to be due to high staff sickness at the time.

Figure 1 is a flowchart describing the number of sickle cell carriers identified on newborn screening, those excluded from data collection and the number of audit forms received by the laboratory.

Figure 2 displays the number of babies identified as sickle cell carriers on newborn screening by child health region and the proportion of sickle cell carrier audit forms received in the laboratory, by child health region.

Figure 3 shows the age of the baby when the dried blood spot sample was collected with a median age of 5 days and included 540 babies. Two samples were received from babies with the sample date missing therefore age of baby at initial collection could not be ascertained. Of these initial samples, 493/540 and 36/540 were collected on days 5 and 6, respectively with 7/540 taken between days 7 and 10. This was in keeping with the standard set by PHE that all babies should be screened at day 5 for sickle cell disease. The remaining 3/540 were collected at day 12. On further investigation, one of these babies had previously had a sample collected too early at 4 days of age, another baby had previously had a sample collected where the sample date had not been accurately recorded, both requiring a repeat sample to be sent. However, for the third baby there was no obvious reason for the delay in taking the initial sample.

Figure 4 shows the sample was received by the laboratory when the babies were aged between 5 and 18 days of age with a median age of 7 days and included 542 babies. Of these initial samples, 222/542 were received by the laboratory at age 6 days and a further 142/542 were received at 7 days of age. The remaining samples were received when babies were aged between 8 and 12 days of age. Three samples were received when babies were aged 15, 16 and 18 days, however, on further investigation these were the same babies where their initial samples were taken at day 12.

Figure 5 shows that sickle cell carrier status letters were sent to SLHV between day 12 and 35 with a median age of 18 days and included 542 babies. Of this 541/542 sickle cell carrier letters were sent to SLHV by day 32. One baby fell outside the standard devised for this audit whereby the sickle cell carrier audit letter was sent to the SLHV when the baby was aged 33 days. The initial sample for this baby was collected at 6 days, received at 7 days, measured by HPLC at 10 days but the IEF result was not entered until 32 days and subsequently the carrier letter was sent at 33 days. This suggests a delay in sending the sample to haematology for IEF or a delay in completing the IEF analysis.

Figure 6 shows that 63% (303/478) of parents were informed of their baby's sickle cell carrier status by 42 days of age, with a median age of 33 days. 37% (175/478) of parents were informed of their baby's sickle cell carrier status at greater than 42 days of age. 5 completed audit forms were excluded due to the date when the result was given to parents being either missing or not correctly entered. Of those that were informed when their baby was aged over 42 days of age, 105/175 were informed by age 51 days, 66/175 were informed between 52 days and 97 days of age. Four parents were informed when their babies were greater than 100 days of age. The timeline for these 4 cases was investigated further. One baby was 106 days of age when parents were informed. The initial sample for this baby was taken at day 6, received at day 9 with the carrier letter sent at day 23. However, the result was not given to the parents by the SLHV until day 106 with no reason indicated on the returned audit form for the delay (was pre-covid). A second baby was 118 days of age when parents were informed of their carrier status. The initial sample for this baby was collected on day 5, received on day 6 with the carrier letter sent at day 18. However, the result was not given to the parents by the SLHV until day 118 over the phone due to COVID-19, which may account for some of the delay. The third baby was 119 days of age when parents were informed of their carrier status. The initial sample was collected at day 5 and received at day 6 but the blood was incorrectly applied therefore a repeat sample was requested which was collected when baby was 11 days of age and received as 12 days of age with the carrier letter sent at day 18. However, the screening result was not given to parents by the SLHV until baby was aged 119 days, with no obvious reason stated (was also pre-covid). Lastly, one baby was 127 days of age when parents were informed of their carrier status. The initial sample for this baby was collected at day 6 and

received on day 8 with the carrier letter sent at day 19. However, the result was not given to the parents by the SLHV until day 127 with no obvious reason for delay (was pre-COVID).

Figure 7 shows a summary of the 483 babies in which either completed audit forms were received or a date at which parents were informed of their babies carrier status was given to the newborn screening laboratory, showing the overall pathway from age of baby at initial sample collection, age of baby at receipt of initial sample by the laboratory, age of baby when carrier letter sent and age of baby when parents informed of baby's carrier status.

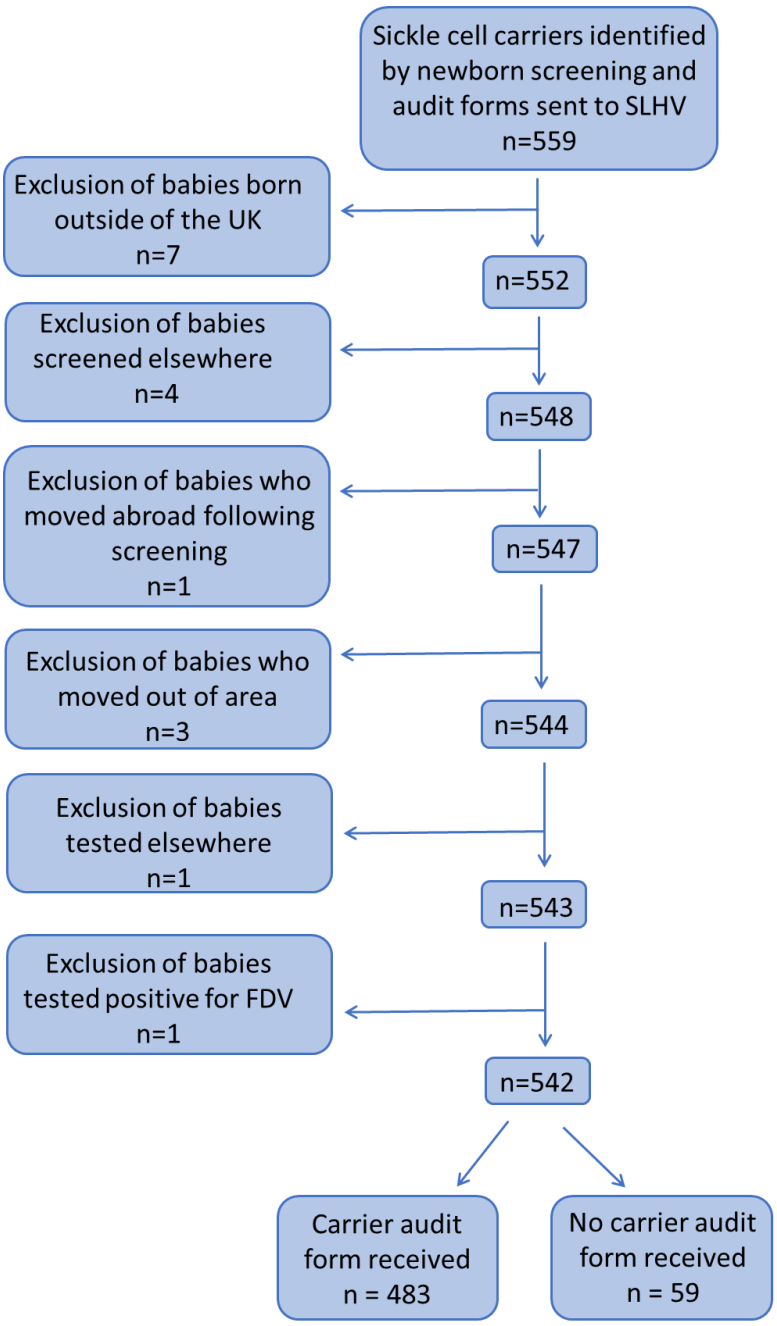
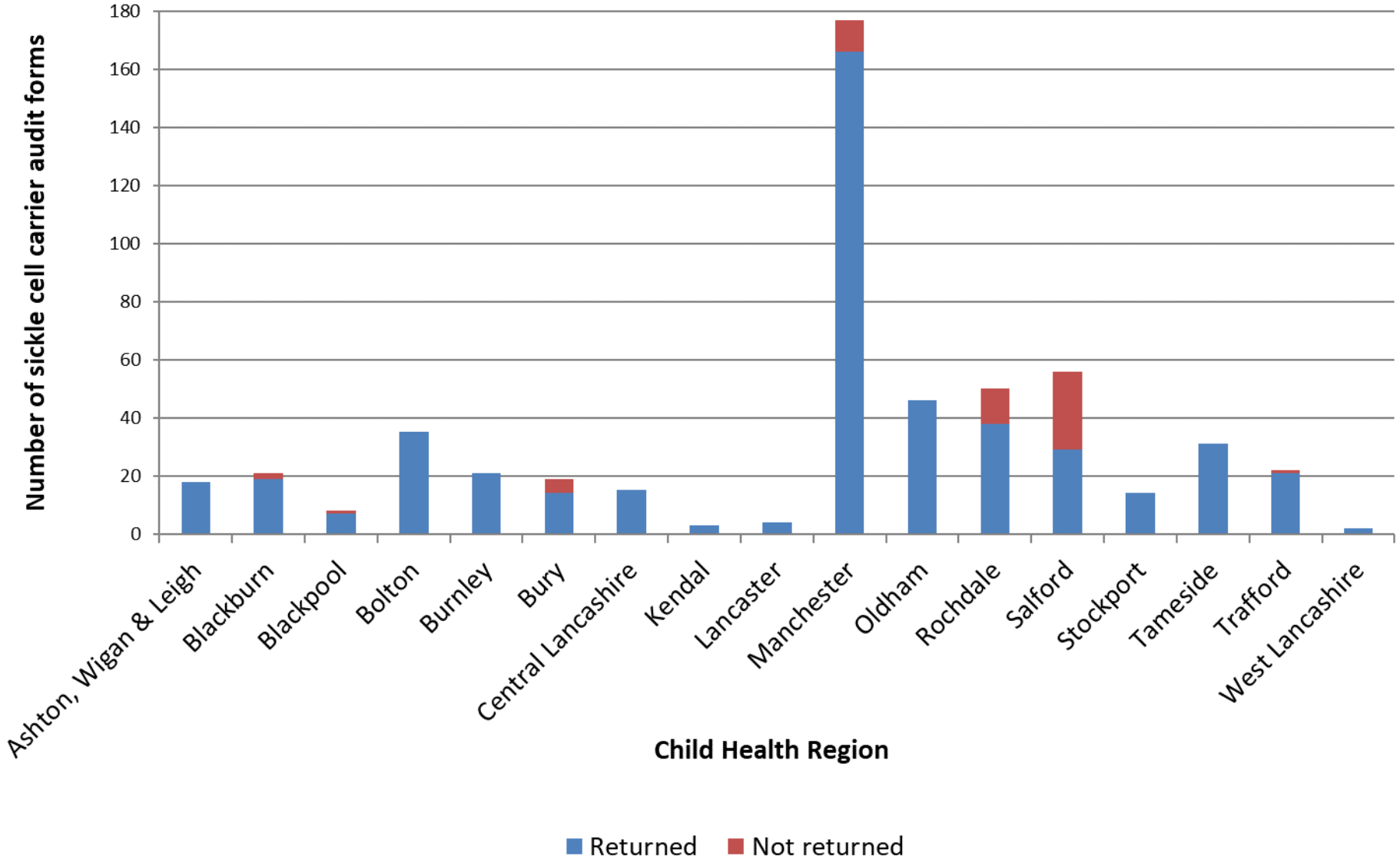


Figure 1: Flowchart describing numbers in each group.

Figure 2: Proportion of sickle cell carrier audit forms received by the laboratory between April 2019 and March 2020



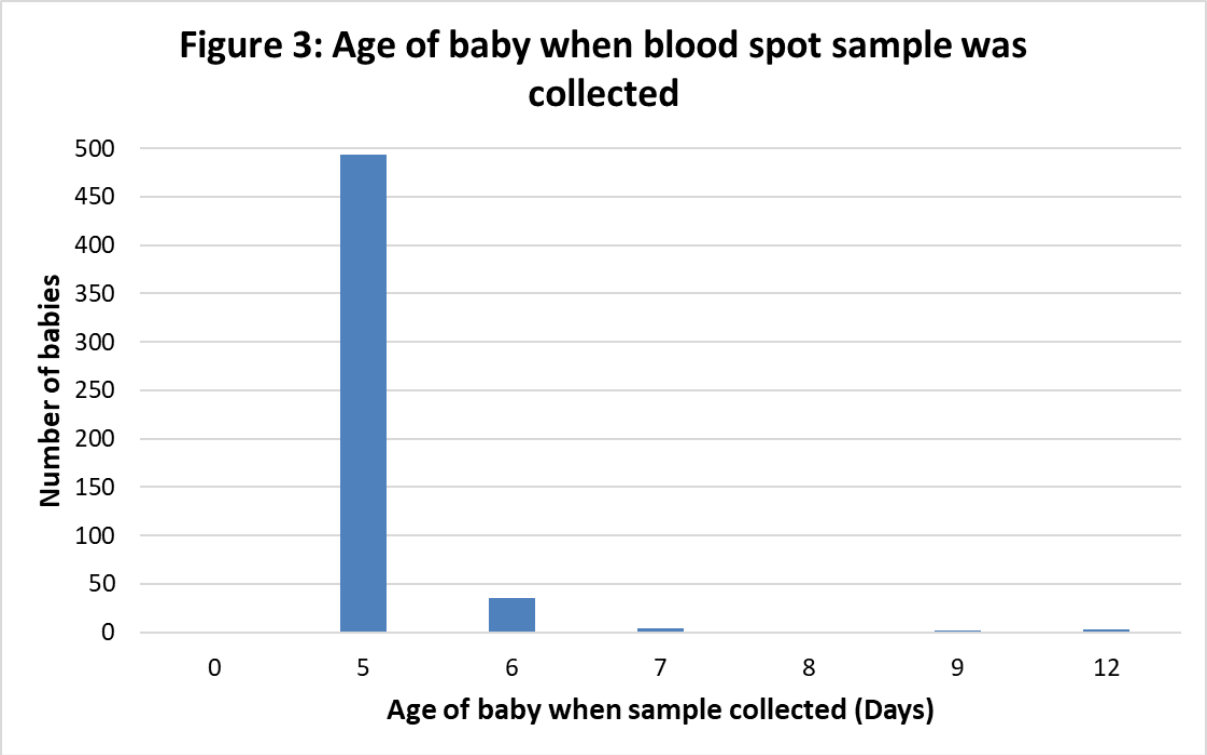


Figure 3: Age of baby when blood spot sample was collected
Number of babies
500
450
400
350
300
250
200
150
100
50
0
0
5
6
7
8
9
12
Age of baby when sample collected (Days)

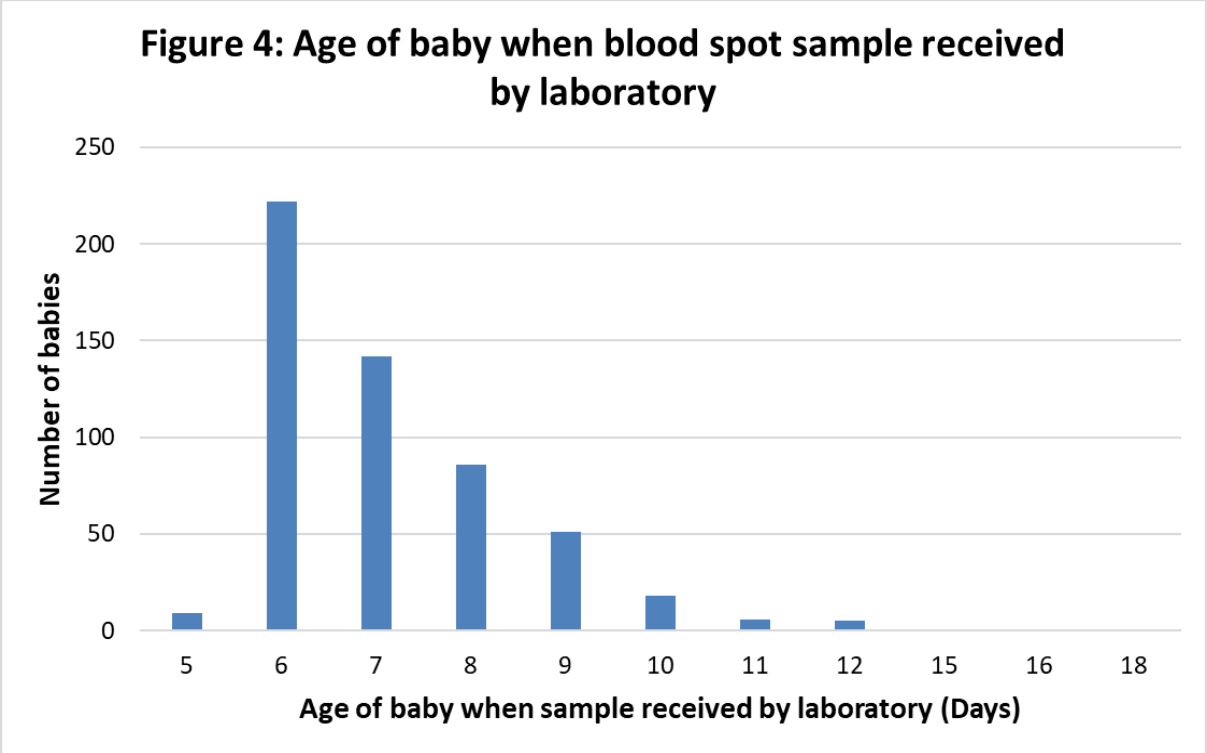


Figure 4: Age of baby when blood spot sample received by laboratory
Number of babies
250
200
150
100
50
0
5
6
7
8
9
10
11
12
15
16
18
Age of baby when sample received by laboratory (Days)

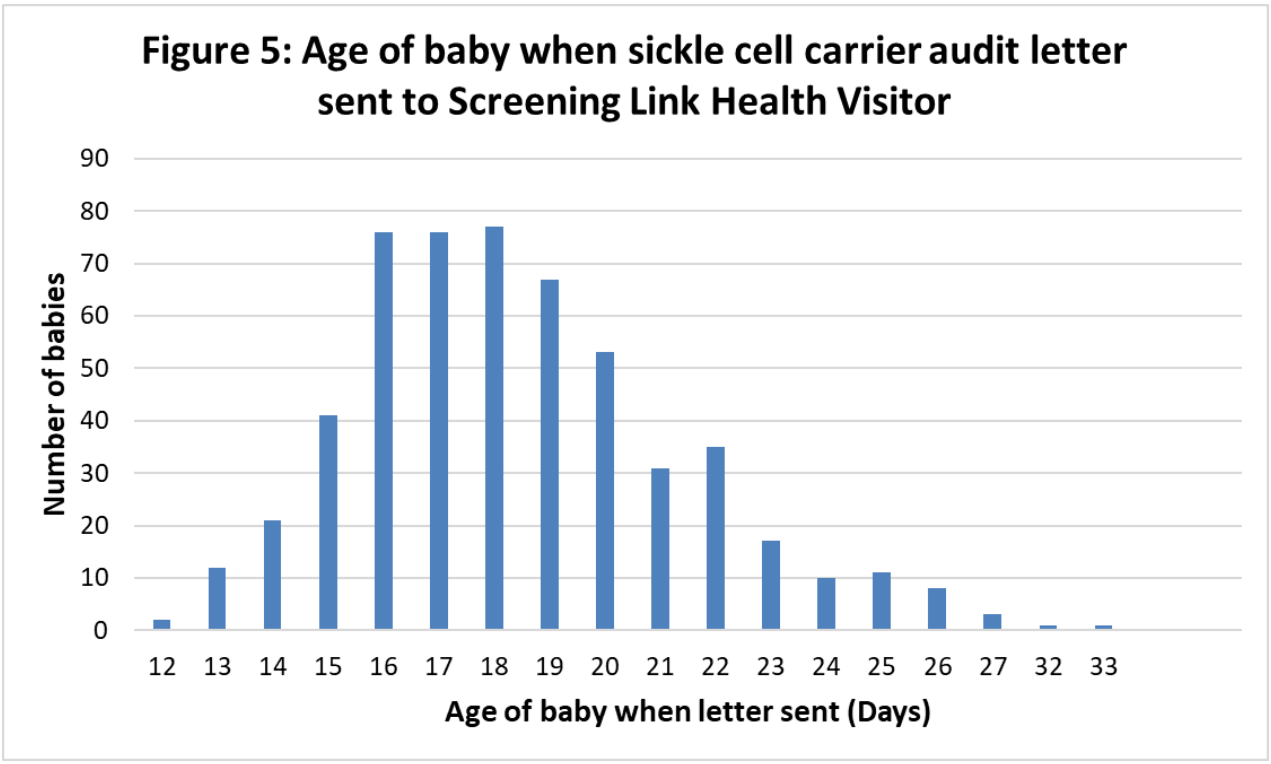


Figure 5: Age of baby when sickle cell carrier audit letter sent to Screening Link Health Visitor
Number of babies
90
80
70
60
50
40
30
20
10
0
12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 32 33
Age of baby when letter sent (Days)

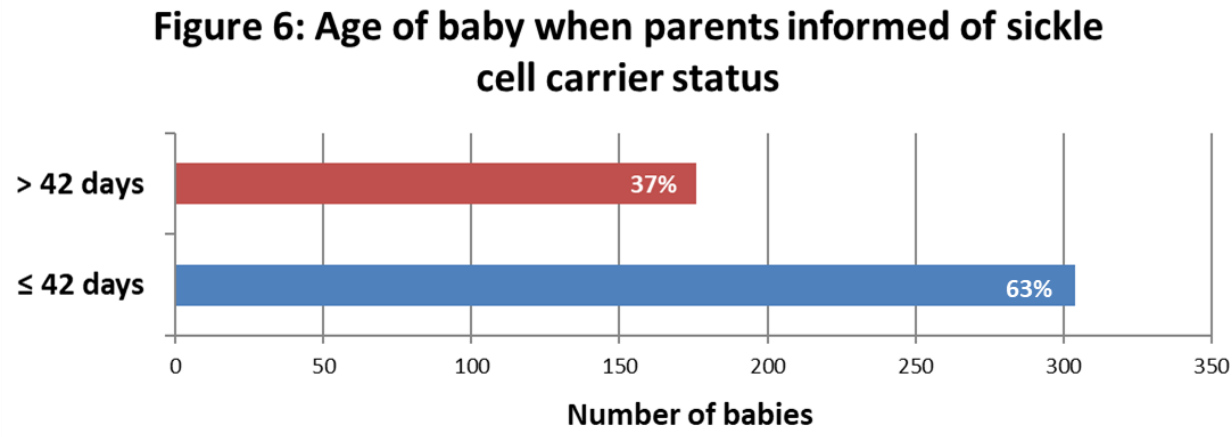
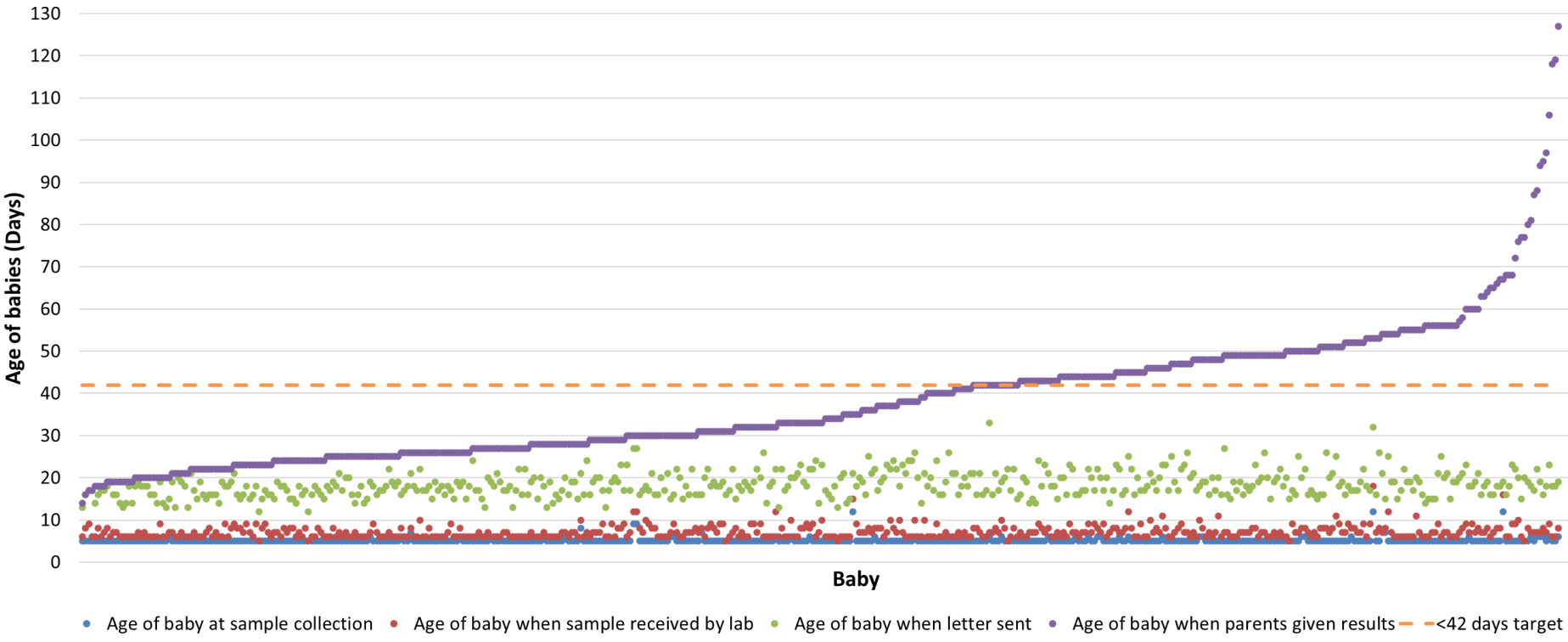


Figure 6: Age of baby when parents informed of sickle cell carrier status
> 42 days
37%
≤ 42 days
63%
0 50 100 150 200 250 300 350
Number of babies

Figure 7: Age in days of babies identified as sickle cell carriers from age at sample collection, age when sample received by laboratory, age when letter sent to screening link health visitor and age when parents given the results



Carrier Results for Sickle Cell Disease

Key:

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

Standard	Compliance (%)
1. Standard one Parents should be informed of their baby's sickle cell carrier status by 6 weeks (42 days) of age. This shows compliance with this standard is below 75% at 63%, with 303/478 parents informed of their baby's sickle cell carrier status by 6 weeks (42 days) of age. *N.B. 5 completed audit forms were excluded due to date when result given to parents either missing or not correctly entered.*	63% (303/478)
2. Standard two All sickle cell carrier status audit forms should be completed and returned to the laboratory. This shows compliance with this standard is 89%, with 483/542 carrier status audit forms returned to the laboratory.	89% (483/542)
3. Standard three Sickle cell carrier letters should be sent to the screening link health visitor by day 32. This shows compliance with this standard is 99%, with 541/542 carrier letters sent to the screening link health visitor by day 32.	99% (541/542)

Carrier Results for Cystic Fibrosis

Comparatively few CF carriers are detected by newborn screening, as the algorithm for CF screening is designed to minimise carrier detection. Figure 8 is a flowchart describing the number of CF carriers identified on newborn screening and the total number of audit forms received by the laboratory.

Figure 9 displays the number of babies identified as CF carriers on newborn screening by child health region and the proportion of CF carrier audit forms received in the laboratory, by child health region.

Figure 10 shows the age of the baby when the initial dried blood spot sample was collected varied between 5 and 6 days of age with a median age of 5 days and included 12 babies. In this audit 9/12 babies had their initial blood spot taken on day 5, with the remaining 3/12 performed on day 6. This was in keeping with the standard set by PHE that all babies should be screened at day 5 CF.

Figure 11 shows the initial sample was received by the laboratory when babies were aged between 6 and 10 days of age with a median age of 7 days and included 12 babies. Of these initial samples, 5/12 were received by the laboratory the following day after being collected and a further 5/12 were received two days after initially being collected. 2/12 were received 3 and 5 days after collection, respectively. On further investigation, these blood spot samples were collected on a Friday and a Thursday, respectively.

Figure 12 shows the age of the baby when the repeat sample was collected which varied between 21 and 42 days with a median age of 21 days and included 12 babies. This was in keeping with the standard set by PHE which states that all babies requiring a repeat blood spot for CF should have the repeat blood spot collected on day 21 and by day 24; this allows for a day 21 to fall on a weekend when a special visit is not warranted. In this audit 7/12 babies had their repeat blood spots taken on day 21 with a further 3/12 taken before day 24. Two babies had their repeat blood spots taken on day 28 and day 42, respectively. On further investigation, these babies both had their initial blood spots taken on day 5 and letters for a repeat blood spot on day 21 were sent on day 15 and 20, respectively.

Figure 13 shows the repeat sample was received by the laboratory when the babies were aged between 22 and 43 days of age with a median age of 24 days and included 12 babies. Of these repeat samples, 9/12 were received by the laboratory the following day after being collected, with 1/12 taking 3 and 2/12 taking 4 days, respectively to arrive to the laboratory after collection.

However, on further investigation these blood spots were taken either on a Thursday or a Friday and were booked into our newborn screening laboratory the following Monday.

Figure 14 shows that CF carrier status letters were sent to SLHVs between day 25 and 47 with a median age of 27 days and included 12 babies. 10/12 letters were sent before the baby was 32 days of age. However, two letters were sent at 35 days and 47 days of age, respectively. These two babies were identified as the same two babies who had their repeat blood spots taken as 28 and 42 days of age, respectively.

Figure 15 shows that of the 10/12 audit forms returned, 90% (9/10) of parents were informed of their baby's cystic fibrosis carrier status by the time their baby was 42 days of age, with a median age of 30 days. One baby did fall just outside of this with parents informed of their baby's carrier status when their baby was 44 days of age. In this instance the initial sample was collected at day 5 and the repeat was collected at day 21 and were received by the laboratory at days 7 and 22, respectively. The letter was sent to the SLHV at day 25 but parents weren't informed until baby was aged 44 days. Two babies were excluded from this dataset due to non-return of a completed audit forms.

Figure 16 shows a summary of the ten babies in which completed audit forms were received, showing the overall pathway from age of baby at initial sample collection, age of baby at receipt of initial sample by the laboratory, age of baby at repeat sample collection, age of baby at receipt of repeat sample by the laboratory, age of baby when carrier letter sent and age of baby when parents informed of baby's carrier status.

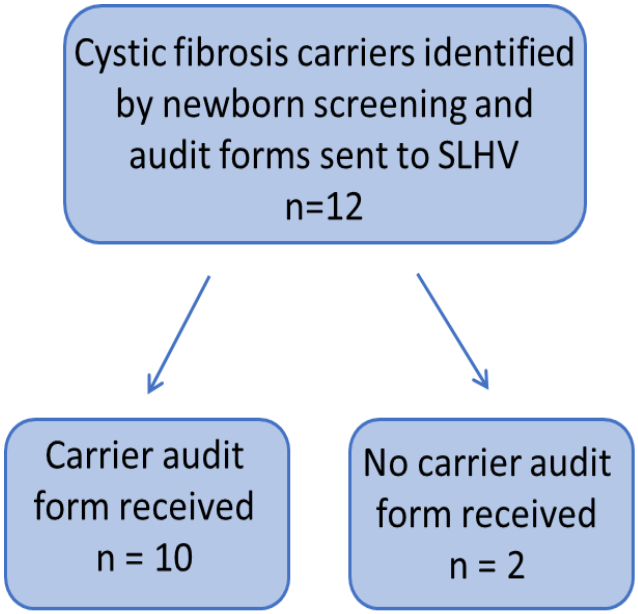
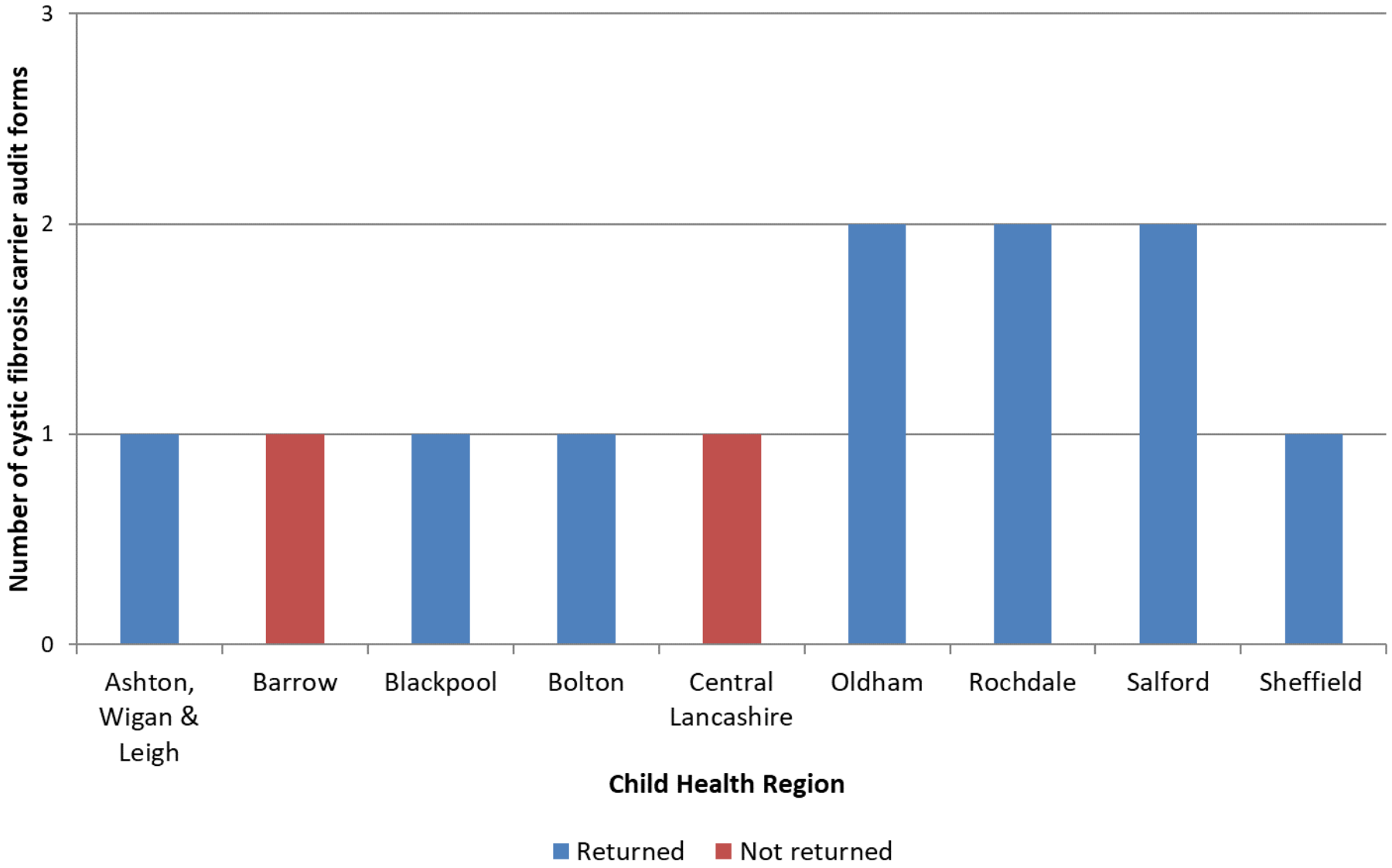


Figure 8: Flowchart describing numbers in each group.

Figure 9: Proportion of cystic fibrosis carrier audit forms received by the laboratory between April 2019 and March 2020



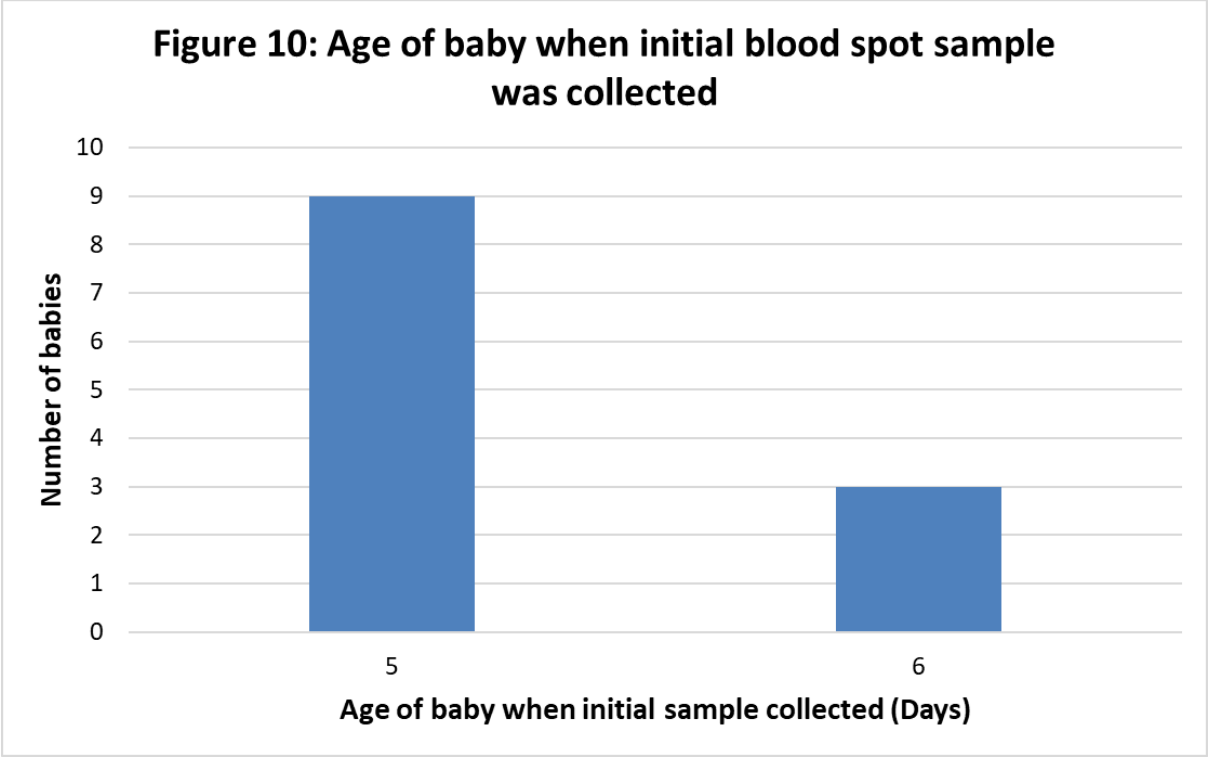


Figure 10: Age of baby when initial blood spot sample was collected
Number of babies
10
9
8
7
6
5
4
3
2
1
0
5
6
Age of baby when initial sample collected (Days)

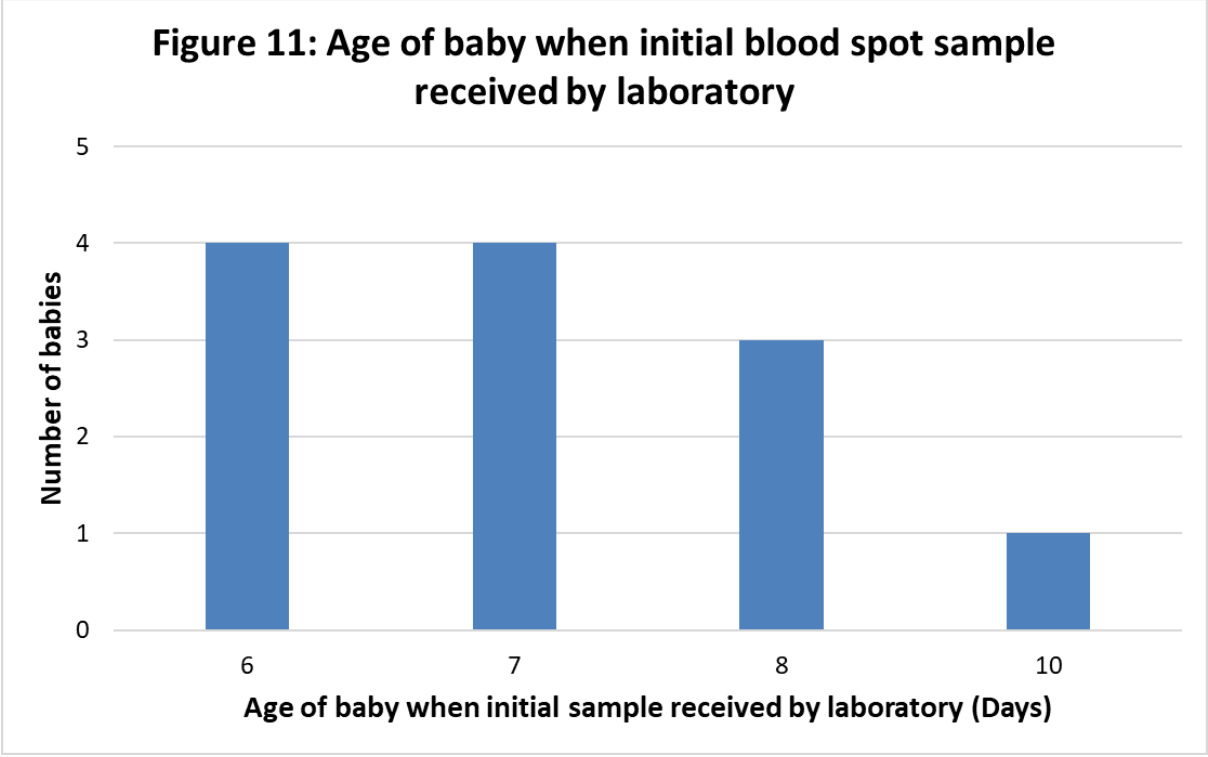


Figure 11: Age of baby when initial blood spot sample received by laboratory
Number of babies
5
4
3
2
1
0
6
7
8
10
Age of baby when initial sample received by laboratory (Days)

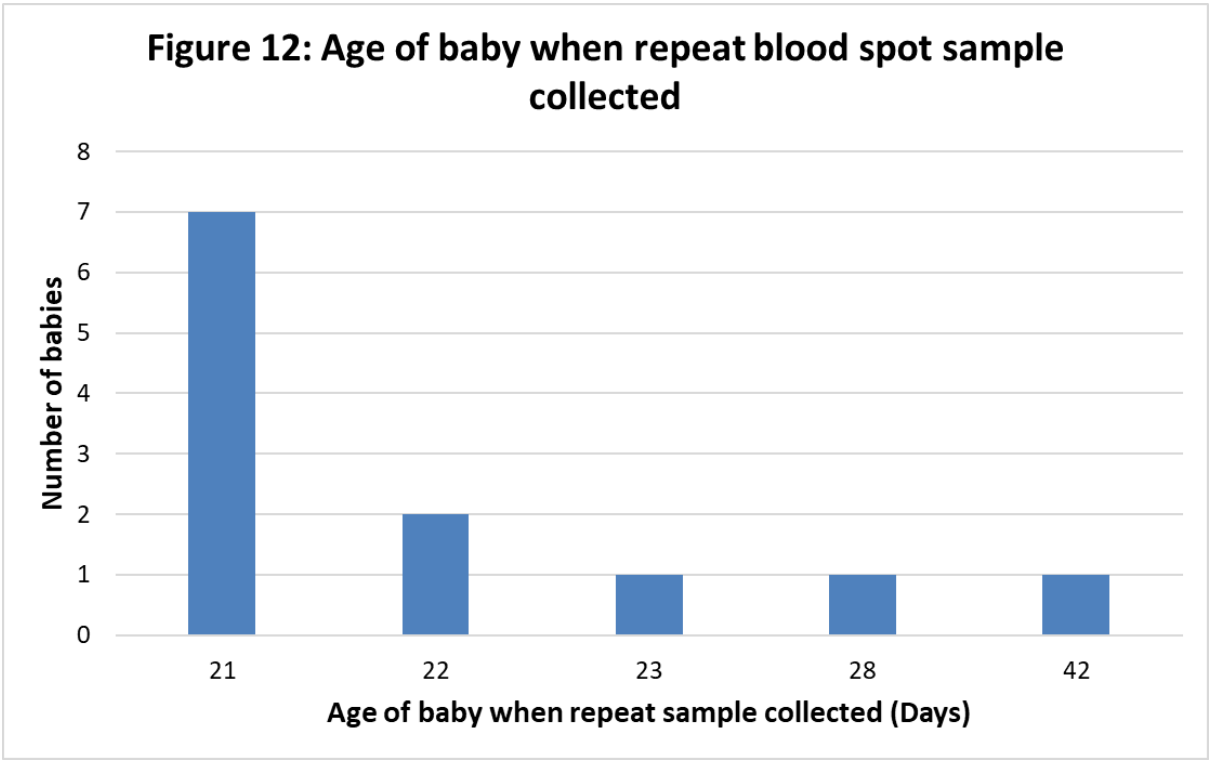


Figure 12: Age of baby when repeat blood spot sample collected
Number of babies
8
7
6
5
4
3
2
1
0
21
22
23
28
42
Age of baby when repeat sample collected (Days)

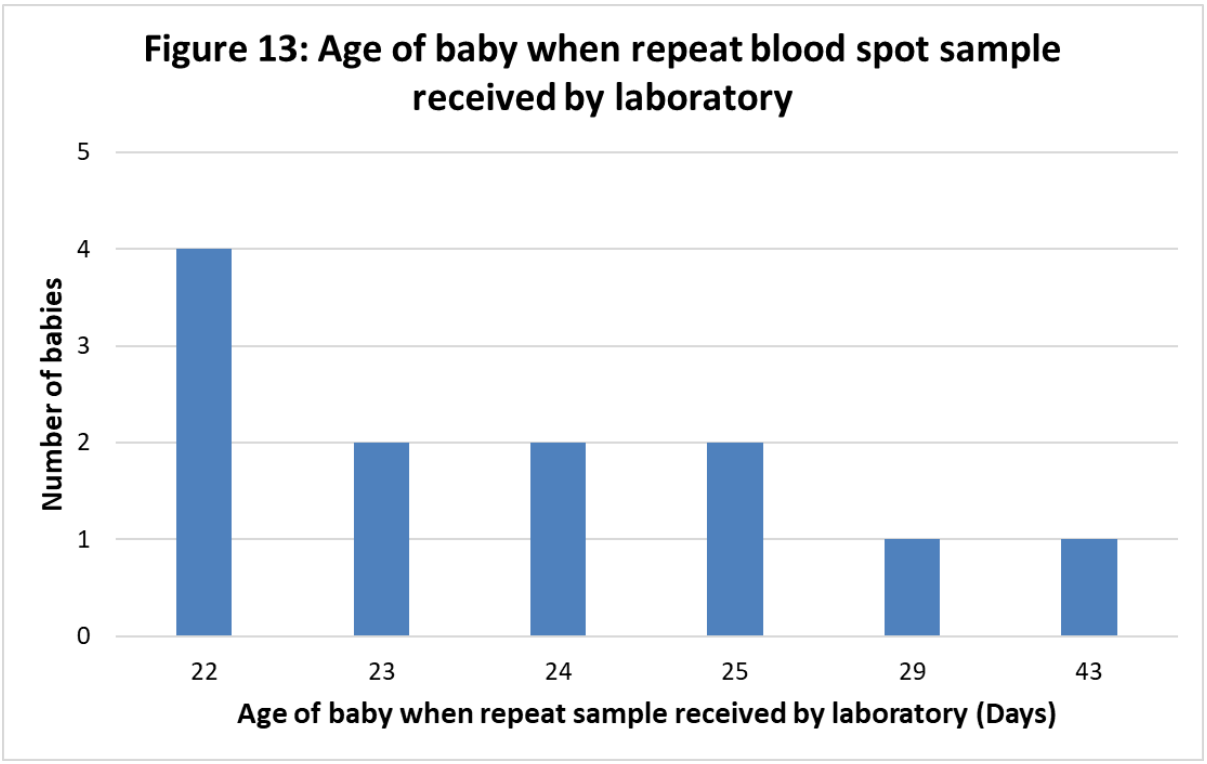


Figure 13: Age of baby when repeat blood spot sample received by laboratory
Number of babies
5
4
3
2
1
0
22
23
24
25
29
43
Age of baby when repeat sample received by laboratory (Days)

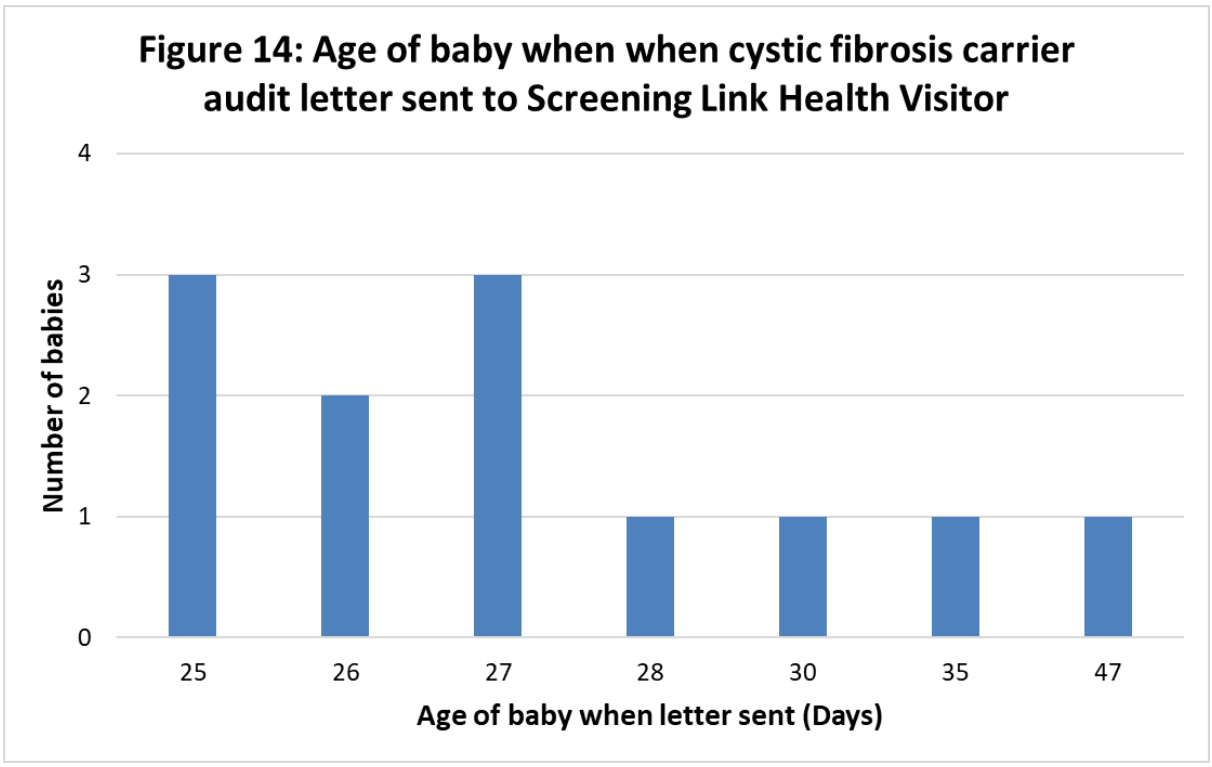


Figure 14: Age of baby when when cystic fibrosis carrier audit letter sent to Screening Link Health Visitor
Number of babies
0
1
2
3
4
25
26
27
28
30
35
47
Age of baby when letter sent (Days)

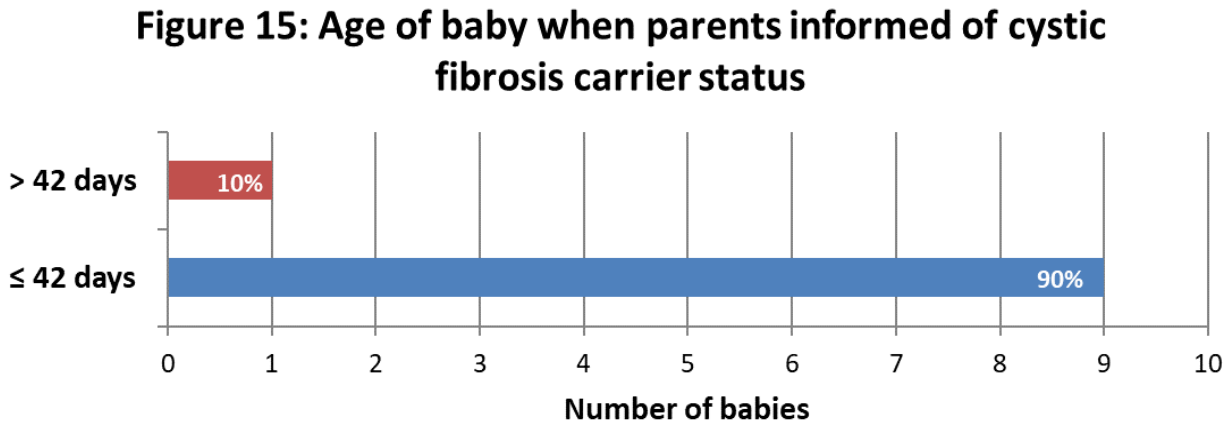
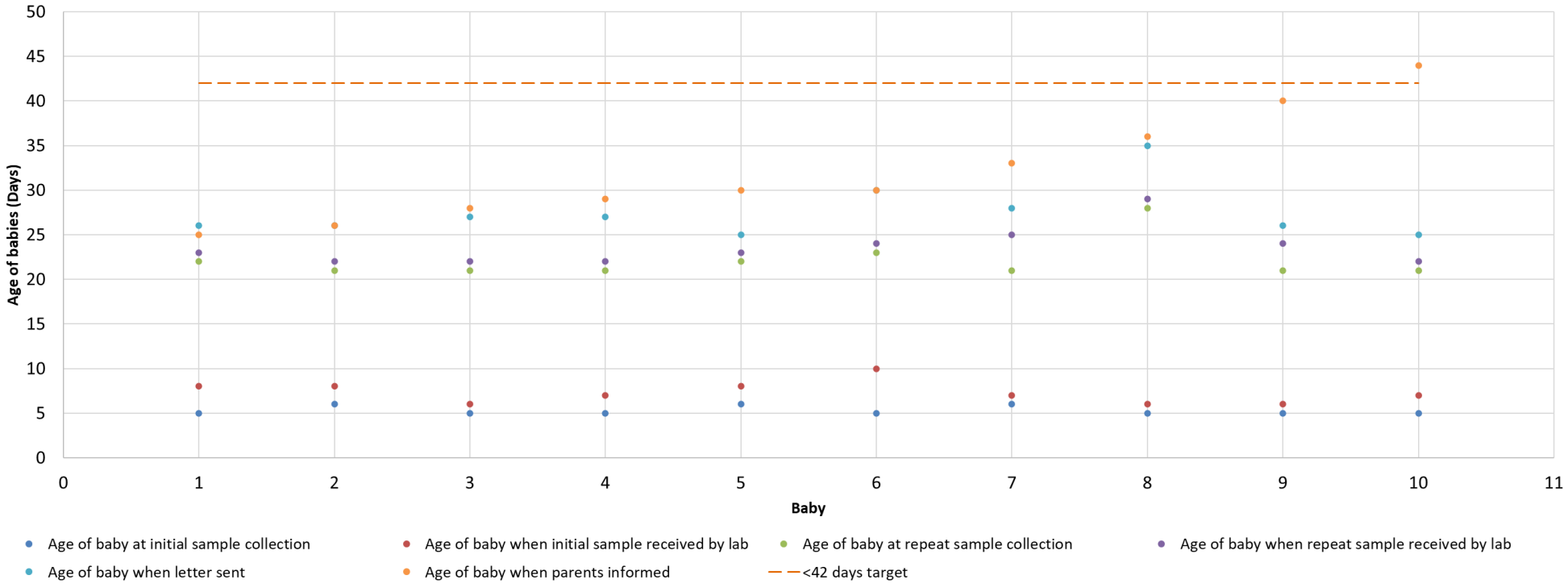


Figure 15: Age of baby when parents informed of cystic fibrosis carrier status
> 42 days
10%
≤ 42 days
90%
0
1
2
3
4
5
6
7
8
9
10
Number of babies

Figure 16: Age in days of babies identified as cystic fibrosis carriers from age at initial and repeat sample collection, age when initial and repeat sample received by laboratory, age when letter sent to screening link health visitor and age when parents



Carrier Results for Cystic Fibrosis

Key:

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

Standard	Compliance (%)
1. Standard one Parents should be informed of their baby's cystic fibrosis carrier status by 6 weeks (42 days) of age. This shows compliance with this standard is below 95% at 90%, with 9/10 parents informed of their baby's sickle cell carrier status by 6 weeks (42 days) of age.	90% (9/10)
2. Standard two All cystic fibrosis carrier status audit forms should be completed and returned to the laboratory. This shows compliance with this standard is 83%, with 10/12 carrier status audit forms returned to the laboratory.	83% (10/12)
3. Standard three Cystic fibrosis carrier letters should be sent to the screening link health visitor by day 32. This shows compliance with this standard is 92%, with 11/12 carrier letters sent to the screening link health visitor by day 32.	92% (11/12)

Conclusions

This audit has provided only limited assurance that parents are informed of newborn screening carrier results within the timescale recommended by the newborn blood spot screening programme (by day 42). On the whole, the delay in this process appears to be communication of results to parents by the SLHVs, rather than delay in the laboratory reporting results to SLHVs. It is recognised that the time period covered in this audit is over 2 years ago (due to unforeseen circumstances) and may not reflect current performance. For this reason (and because of the limited assurance findings), a re-audit is planned for the time period April 2022-March 2023.

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 2022
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What are the main benefits, to patients or Trust processes, expected as a result of this action plan?			
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Will there be a re-audit?	Yes	When will the re-audit take place?	April 2023 for the period April 2022-March 2023

References

1. Public Health 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

2. Public Health 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).

3. Public Health England Guidance Newborn blood spot: managing positive results from cystic fibrosis screening (February 2015 (updated May 2021); https://www.gov.uk/government/publications/clinical-referral-national-standard-protocol-for-cystic-fibrosis/newborn-blood-spot-managing-positive-results-from-cystic-fibrosis-screening).

Appendix 1

NHS
Manchester University
NHS Foundation Trust

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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Public Health England

NHS

NHS Newborn Blood Spot Screening Programme

Cystic fibrosis screening: carrier of CF gene follow-up form

The healthcare professional that gives the carrier result to the family must complete and return this form to the Director of the newborn screening laboratory within 24 hours of the visit.

The laboratory will anonymise and report the data to the NHS Newborn Blood Spot Screening Programme.

Full name of infant	
Date of birth	
NHS number	

Date result received from screening laboratory	
Who gave the result to the family (for example, health visitor, screening link health visitors (SLHV), GP or genetic counsellor)	
Date result given	
How the result was given to the family (for example, face-to-face or telephone)	
Whether the family received the 'Your baby carries the cystic fibrosis gene' leaflet (delete as appropriate)	Yes / No

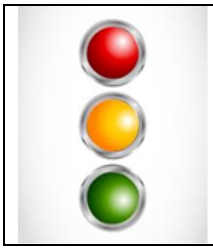
Your name	
Your contact details (including telephone and email address)	
Date	

The 'your baby carries the cystic fibrosis gene' leaflet is available online – just search for 'gov.uk cystic fibrosis carrier'.

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	Re-audit Requirement
To be used when each essential standard has achieved a score of 95% or above and is rated Green	Full	Not required (re-audit where topic is important and assurance needs to be maintained)
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)	Significant	Not usually required (re-audit where topic is important and assurance needs to be maintained)
To be used when there is a small ratio of Red and Amber to Green rated findings	Limited	Re-audit against amber or red standards within 2 years unless agreed that audit topic no longer relevant
To be used when the ratio of Red rated findings are greater than the Amber and Green	Very Limited	Re-audit within 1 year unless agreed topic no longer relevant.

- The appropriate level of assurance will be decided following a discussion between the clinical audit lead/s, sponsor and the clinical audit team.
- 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 Hospital/MCS Clinical Audit Leads
- All Hospital/MCS Clinical Effectiveness Leads
- Head of Nursing
- Clinical Audit team (via Facilitator for Hospital/MCS)
- Clinical Audit Supervisor
- Members of the clinical audit project team (if any)

For all Hospital/MCS audits copies of the completed report must be sent to the following:

- Clinical Head of Hospital/MCS
- All Directorate/CSU Managers
- Lead Nurse for Hospital/MCS
- The Hospital/MCS Clinical Audit Lead
- The Hospital/MCS Clinical Effectiveness Lead
- Clinical Audit team (via Facilitator for Hospital/MCS)
- 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 Hospital/MCS Clinical Audit Lead
- The Hospital/MCS Clinical Effectiveness Lead
- Clinical Audit team (via Facilitator for Hospital/MCS)
- Clinical Audit Supervisor
- Members of the clinical audit project team (if any)
- Any Staff who may be affected by the audit report