Newborn Screening Laboratory
Clinical Biochemistry Department
Manchester University NHS Foundation Trust

Manchester Newborn Screening Laboratory Annual Report 2018-2019

Beverly Hird
Lesley Tetlow
Laura Hamilton
Teresa Wu
Aisha Rahman

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Acknowledgements

We are grateful to all staff in the Newborn Screening and Willink Laboratories for all their continuing hard work, and to our colleagues in the Haematology Department, Manchester Royal Infirmary and the Molecular Genetics Laboratory, St Mary's Hospital for their collaboration with regards to the Haemoglobinopathy and Sickle Cell Screening Programme and the Cystic Fibrosis Screening Programme respectively. We are also indebted to the North West Antenatal & Newborn Screening Quality Assurance Team and to the Greater Manchester and Lancashire NHS England Local Area Screening and Immunisation Teams with whom we work closely on governance and quality assurance aspects of the newborn blood spot programme and on teaching and training of health professionals involved in delivery of the programme.

1. Introduction

The report is a summary of the activities of the Newborn Screening and Willink laboratories which together are responsible for screening of all newborns within Greater Manchester, Lancashire and South Cumbria. The commissioning of these services falls under the remit of the Greater Manchester and Lancashire NHS England Local Area Teams.

Conditions Screened

Condition	**Year Screening Commenced***	**Analysis & referral**
Congenital Hypothyroidism (CHT)	1980s	Newborn Screening Lab
Phenylketonuria (PKU)	1970s	Willink Laboratory
Sickle cell disease (SCD)	2004/05	Newborn Screening Lab
Medium-chain acyl-CoA Dehydrogenase Deficiency (MCADD)	2004	Willink Laboratory
Cystic Fibrosis (CF)	2007	Newborn Screening Lab
Glutaric aciduria type 1 (GA1)	2012	Willink Laboratory
Homocystinuria (HCU)	2012	Willink Laboratory
Isovaleric acidaemia (IVA)	2012	Willink Laboratory
Maple syrup urine disease (MSUD)	2012	Willink Laboratory

*The year screening commenced is approximate. In some cases this was part way through a year and initially may have included only certain areas. It is important not to assume that individual babies have been screened for a particular condition

Newborn screening for Inborn Errors of Metabolism (IEM) covers 6 conditions i.e. PKU, MCADD, MSUD, HCU, GA1 and IVA. This service is provided by the Willink Biochemical Genetics Laboratory which is a part of the Willink clinical investigation unit for inherited metabolic disorders. Testing for CHT, CF and SCD is carried out within the Newborn Screening and Paediatric Specialist Endocrine Laboratory which is a section of the Clinical Biochemistry Department within the Directorate of Laboratory Medicine (Clinical and Scientific Services Division).

Initial clinical investigation, follow-up and treatment for PKU and MCADD and the additional metabolic conditions is carried out within the Willink Unit and initial clinical investigation of CHT screen positives is usually carried out by the Paediatric Endocrinology Department of the children's hospital. However, for babies who are still in hospital at the time of the

positive CHT result the initial diagnostic assessment is carried out within the corresponding hospital. Clinical follow up of SCD positive patients is carried out by the Consultant Paediatric Haematologists at Royal Manchester Children's Hospital (RMCH). Clinical follow up of positive CF cases is usually undertaken by the regional CF team at RMCH , however, there are a few hospitals within the region that carry out their own clinical follow up in collaboration with the regional CF centre (shared care centres).

Staffing

There is a single Director of Newborn Screening (Consultant Clinical Biochemist) but below that separate staffing structures for the two laboratories. The Consultant Clinical Scientist/Head of the Willink Laboratory has delegated responsibility for the Willink aspects of the newborn screening programme and all staff within the Willink laboratory are managerially responsible to them.

The Newborn Screening team is made up of Clinical Scientists. Biomedical Scientists, an Information Analyst, Medical Laboratory Assistants, and clerical staff.

Workload

A total of **56265** samples were received in the laboratory which included **52643** first samples, **2246** repeat samples and **1377** pre-transfusion 'day 0' samples.

The laboratory was notified of 211 declines for screening on a first sample, all of which were declined for all tests.

2. Services Provided

Newborn Screening/ Specialist Endocrine Laboratory

Newborn Screening

- Newborn Screening for CHT, CF and sickle cell and haemoglobinopathy disorders for all babies born within Greater Manchester, Lancashire and South Cumbria.
- Reporting of newborn screening results for CHT, CF, SCD, PKU, MCADD, MSUD, IVA, GA1, HCU, including follow up of repeat tests, queries and missing information.
- Clinical referral of screen positive CHT babies to RMCH department of Paediatric Endocrinology and performance of subsequent laboratory investigations included as part of diagnostic assessment.
- Clinical referral of babies who are screen positive for sickle cell and haemoglobinopathy disorders to the department of haematology, RMCH and referral of babies with carrier status for counselling or any further investigation.
- Clinical referral of babies with a positive CF test to the regional CF centre at Royal Manchester Children's Hospital.
- Long term storage of blood spot samples. Cards received within the last 5 years are stored on site within the Newborn Screening Laboratory and older cards are shipped out to CELLNASS for archiving.

Specialist Endocrinology

- Provision of a regional laboratory service for 17-α-hydroxyprogesterone in serum and in blood spot samples for investigation and monitoring of Congenital Adrenal Hyperplasia.
- Provision of a specialist endocrine laboratory service to the Trust.
- Provision of an analytical and interpretative service for insulin and C-peptide – for other hospitals within the region and as part of NORCHI, the North West component of the two-centre national service for babies and infants with congenital hyperinsulinaemia.

Willink Biochemical Genetics Laboratory

The Willink laboratory is located on the 6th floor of St Mary's Hospital, together with the Newborn Screening Laboratory but managerially resides within the Genetics Directorate (St Mary's Division) and is organisationally part of the Genomic Diagnostics Laboratory. The laboratory is responsible for performing the analytical service for a panel of 6 metabolic conditions: PKU, MCADD, MSUD, HCU, IVA, GA1 using tandem mass spectrometry technology. Willink staff also undertake the referral of screen positive babies with these conditions to the metabolic paediatricians and provide the service for diagnostic follow-up testing and monitoring. In addition the laboratory provides a comprehensive metabolic biochemistry service for patients with inherited metabolic disorders and their families within Greater Manchester, the North West and beyond.

All results produced by the Willink Laboratory are transferred electronically from the analysers into the dedicated screening IT system (Specimen Gate) which is shared by both laboratories. The results are subsequently reported to Child Health departments by senior staff within the Newborn Screening Laboratory.

Analysis and Reporting

Tests and technology

Condition	Analyte	Method	2nd line test
Congenital Hypothyroidism (CHT)	Thyroid stimulating hormone (TSH)	Immunoassay (AutoDELFIA®)	Not applicable
Phenylketonuria (PKU)	Phenylalanine (Phe)	Tandem Mass Spectrometry (MS/MS)	Tyrosine
Sickle cell disease (SCD)	Separation and identification of haemoglobin fractions	HPLC (ion exchange) using BIORAD Variant NBS	Isoelectric Focusing (IEF)
Medium-chain acyl-CoA Dehydrogenase Deficiency (MCADD)	Octanoylcarnitine (C8)	Tandem Mass Spectrometry (MS/MS)	Not applicable
Cystic Fibrosis (CF)	Immunoreactive trypsinogen (IRT)	Immunoassay (AutoDELFIA®)	Mutation analysis
Isovaleric acidaemia (IVA)	Isovalerylcarnitine (C5)	Tandem Mass Spectrometry (MS/MS)	Not applicable
Maple syrup urine disease (MSUD)	Leucine/isoleucine/alloisoleucine	Tandem Mass Spectrometry (MS/MS)	Not applicable
Glutaric aciduria type 1 (GA1)	Glutarylcarnitine (C5-DC)	Tandem Mass Spectrometry (MS/MS)	Not applicable
Homocystinuria (pyridoxine unresponsive; HCU)	Methionine	Tandem Mass Spectrometry (MS/MS)	Total homocysteine

The processing and reporting of results for all screening programs is carried out using a dedicated IT system (Specimen Gate Laboratory IT system, Perkin Elmer). A summary "district report" is generated and e-mailed on each working day to the individual Child

Health Records Departments (CHRD). Individual reports are generated for incorporation in the babies' personal record (red book) and are sent by first class post. Results are also reported electronically to Manchester, Bolton, Salford, Stockport and Tameside Child Health Departments.

3. Clinical Governance

Accreditation

The Newborn Screening Laboratory is accredited as part of Clinical Biochemistry and the Willink Laboratory as part of the Genomic Diagnostics Laboratory (along with molecular genetics and cytogenetics). The service is assessed by UKAS (United Kingdom Accreditation Service) against ISO 15189 standards (Medical Laboratory Accreditation).

External Quality Assessment

Both laboratories participate in the combined UK NEQAS scheme for Newborn Screening for TSH, IRT, phenylalanine, tyrosine, leucine, methionine, C5, C5DC, C8, C10. The Newborn Screening Laboratory also takes part in the UK NEQAS Newborn Sickle Screening scheme. Both laboratories also participate in the CDC EQA scheme for newborn screening.

Governance Arrangements

The CMFT Antenatal and Newborn Screening Board meets quarterly. Membership comprises the programme leads for all of the antenatal and newborn programmes, commissioners and representatives from all healthcare professional groups involved in delivery of the programmes. The Director of Newborn Screening reports to the board on behalf of the Newborn Blood Spot Programme. In addition, programme specific Operational and Quality Groups for Cystic Fibrosis and Sickle screening which include all stakeholders meet on a 6-monthly basis. A bi-monthly operational NBS meeting is held which is attended by lab managers and senior clinical scientists from both the Willink and NBS laboratories. Specific IMD NBS issues are also discussed at the monthly Heads of Department meeting for genetics and the metabolic MDT meeting (attended by the metabolic physicians). Any IMD screening issues raised are fed back for discussion and resolution at the joint operational meeting. Matters in relation to Congenital Hypothyroid Screening are discussed as part of weekly MDT meeting with paediatric endocrinology.

The Newborn Screening Laboratory also reports to the Greater Manchester and Lancashire NHS England Antenatal and Newborn Screening Board meetings.

National, Regional and Local Audit

- Data is submitted annually to the NHS Newborn Blood Spot Screening Programme regarding performance of the regional newborn blood spot programme in relation to key process and clinical referral standards.

- Performance data is also collated quarterly, and reports are presented to the Greater Manchester and Lancashire NHS England Antenatal and Newborn Screening Board meetings. Other local audits are performed on an on-going basis to assess specific aspects of the programme (both generic and programme specific).

Training and Education

The laboratory continues to have a commitment to teaching and training both laboratory scientists and other groups of health professionals involved in delivery of the newborn blood spot screening programme.

STP Clinical Scientist trainees rotate through the department, spending 4 weeks within the newborn screening laboratory and 4 weeks in the Willink laboratory.
Clinical Scientists from the Newborn Screening and Willink Laboratories together deliver the teaching elements of newborn screening for the MSc in Clinical Science (Blood Science) (University of Manchester). The Directors of Newborn Screening and the Willink Laboratory are joint module leaders for the Pregnancy and Paediatric module which includes newborn screening, paediatric and metabolic biochemistry.

The Newborn Screening Laboratory Leads contribute to regional screening training and update days organised by the North West Regional Antenatal and Newborn Screening QA Team and the Sickle Cell and Thalassaemia Centre for screening link health visitors, child health staff and staff within NICU units throughout the region, as well as providing the opportunity for midwives, health visitors and CHRD staff to visit the laboratory. The aim of these visits is to improve understanding of laboratory processes and issues around sample quality. In addition to these regular sessions, Clinical Scientists from the Willink and Newborn screening laboratories also deliver an annual teaching session over 1-2 days for trainee midwives from Salford University.

4. Summary of Programme Performance

The laboratory is required to submit screening data to the NHS Newborn Blood Spot Screening Programme each year at the end of July, for the previous 12 months of screening. A new version of the standards for newborn blood spot screening was published by the NHS Newborn Blood Spot Screening Programme in 2017 and can be found at https://www.gov.uk/government/publications/standards-for-nhs-newborn-blood-spot-screening.

There are 12 standards for newborn screening and the laboratory reported results against standards 3 (barcoded NHS number label is included on the blood spot card), 4 (timely sample collection), 5 (timely receipt of sample in the newborn screening laboratory), 6 (quality of blood spot sample) and 9 (timely processing of all PKU, CHT and MCADD screen positive samples). The data submitted by this laboratory, in addition to other data collected as part of our continuous audit (insufficient rates etc.) is summarised and discussed below and covers the time period from April 2018 through to March 2019.
Data was collected and analysed by Trust. The data for Manchester University NHS Foundation Trust (MFT) is divided into by location into St.Mary's and Wythenshawe, but counted as one maternity unit in the text.
The NHS Newborn Blood Spot Screening Programme standards are as follows:

Standard 3 – Barcoded NHS number label is included on the blood spot card:

Acceptable: ≥ 90.0% of blood spot cards are received by the laboratory with the baby's NHS number on a barcoded label.
Achievable: ≥ 95.0% of blood spot cards are received by the laboratory with the baby's NHS

The data for this standard is shown graphically in figure 1 and tabulated in table 1. This standard is applied to all samples (including repeats). In total, 87% of blood spot cards received by the laboratory had the baby's NHS number on a barcoded label
Of 11 Maternity Units, 3 met the acceptable threshold and 2 met the achievable. The percentage of samples that included an NHS number barcoded label varied throughout the region and ranged from 71% to 97%. Overall the usage of barcoded labels has increased from 83% in 2017/18 to 87% this year, but still remains below the threshold for the standard.

Trust	Number of all samples (including repeats)	Number of blood spot cards with the baby's NHS number on a barcoded label	Percentage of all blood spot cards with the baby's NHS number on a barcoded label
Blackpool Teaching Hospitals NHS FT	3008	2842	94.5%
Bolton NHS FT	6180	5008	81.0%
East Lancashire Hospitals NHS Trust	6554	6270	95.7%
Health Visitor	462	19	4.1%
Lancashire Teaching Hospitals NHS FT	4192	4050	96.6%
Manchester University NHS FT - SMH & RMCH	5746	5329	92.7%
Manchester University NHS FT - Wythenshawe	4328	4127	95.4%
Not Stated	2136	1763	82.5%
Pennine Acute Hospitals NHS Trust	10379	7998	77.1%
Southport & Ormskirk Hospital NHS Trust	844	598	70.9%
Stockport NHS FT	3284	3032	92.3%
Tameside And Glossop Integrated Care NHS FT	2934	2537	86.5%
University Hospitals of Morecambe Bay NHS FT	2967	2637	88.9%
Wrightington, Wigan and Leigh NHS FT	3251	2736	84.2%
Grand Total	**56265**	**48946**	**87.0%**

Table 1: Data for standard 3 showing number of cards with the baby's NHS number on a barcoded label.

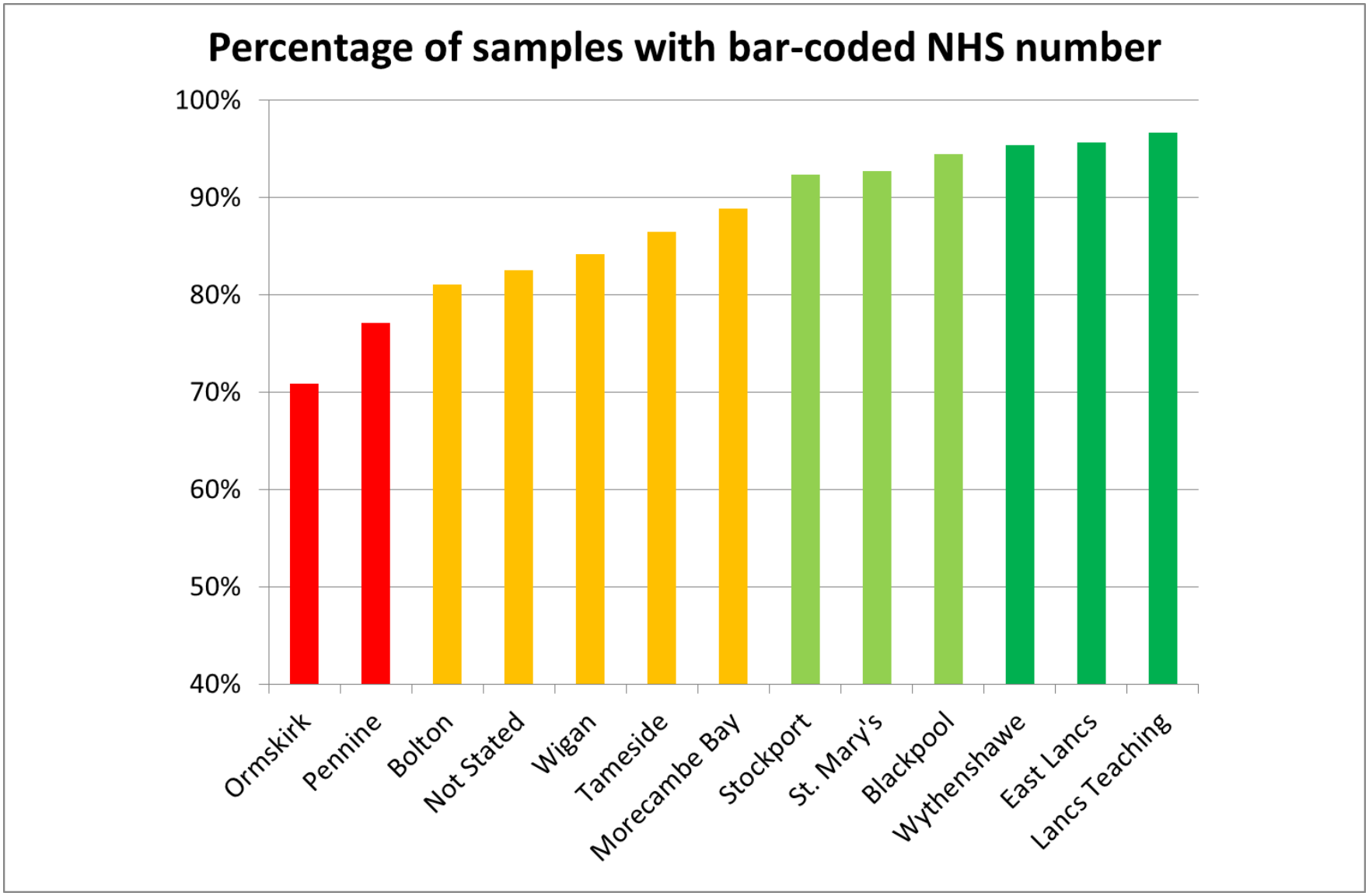


Figure 1: Graph to show percentage of cards with the baby's NHS number on a barcoded label for period April 2018–March 2019

Standard 4: Timely sample collection - The proportion of first blood spot samples taken on day 5

Acceptable: ≥ 90.0% of first blood spot samples are taken on day 5.
Achievable: ≥ 95.0% of first blood spot samples are taken on day 5.

The data corresponding to this standard is shown in figure 2 and tabulated in table 2. Six Maternity Units met the acceptable threshold (≥90.0%). Overall 89.6% of first samples were collected on day 5. None of the Maternity Units met the achievable threshold. The percentage collected on day 5 varied throughout the region ranging from 83% for Blackpool to almost 95% for Tameside. This has improved from last year when only 50% of initial samples in Blackpool were collected on day 5 and 86% of initial samples throughout the region as a whole.

Trust	Number of first samples taken						Percentage of first samples taken					
	on or before day 4	on day 5	on day 6	on day 7	on day 8	on or after day 9	on or before day 4	on day 5	on day 6	on day 7	on day 8	on or after day 9
Blackpool	2	2425	388	82	13	11	0.1%	83.0%	13.3%	2.8%	0.4%	0.4%
Bolton	3	4909	500	88	29	39	0.1%	88.2%	9.0%	1.6%	0.5%	0.7%
East Lancashire	28	5390	425	69	17	27	0.5%	90.5%	7.1%	1.2%	0.3%	0.5%
HV	0	1	0	0	0	382	0.0%	0.3%	0.0%	0.0%	0.0%	99.7%
Lancashire	17	3675	212	26	15	20	0.4%	92.7%	5.3%	0.7%	0.4%	0.5%
St. Mary's (& RMCH)	15	4600	189	32	18	23	0.3%	94.3%	3.9%	0.7%	0.4%	0.5%
Wythenshawe	2	3956	189	21	7	11	0.0%	94.5%	4.5%	0.5%	0.2%	0.3%
Not Stated	1	1734	162	27	10	30	0.1%	88.3%	8.2%	1.4%	0.5%	1.5%
Pennine	8	8602	1022	155	36	84	0.1%	86.8%	10.3%	1.6%	0.4%	0.8%
Southport & Ormskirk	6	701	52	7	2	13	0.8%	89.8%	6.7%	0.9%	0.3%	1.7%
Stockport	9	2756	285	37	7	19	0.3%	88.5%	9.2%	1.2%	0.2%	0.6%
Tameside	0	2661	105	17	6	17	0.0%	94.8%	3.7%	0.6%	0.2%	0.6%
Morecambe Bay	8	2644	143	27	5	24	0.3%	92.7%	5.0%	0.9%	0.2%	0.8%
Wigan	4	2879	189	28	5	14	0.1%	92.3%	6.1%	0.9%	0.2%	0.4%
Total	**103**	**46933**	**3861**	**616**	**170**	**714**	**0.2%**	**89.6%**	**7.4%**	**1.2%**	**0.3%**	**1.4%**

Table 2: Data for Standard 4 showing the number of cards taken in a timely manner (excluding samples with missing dates)

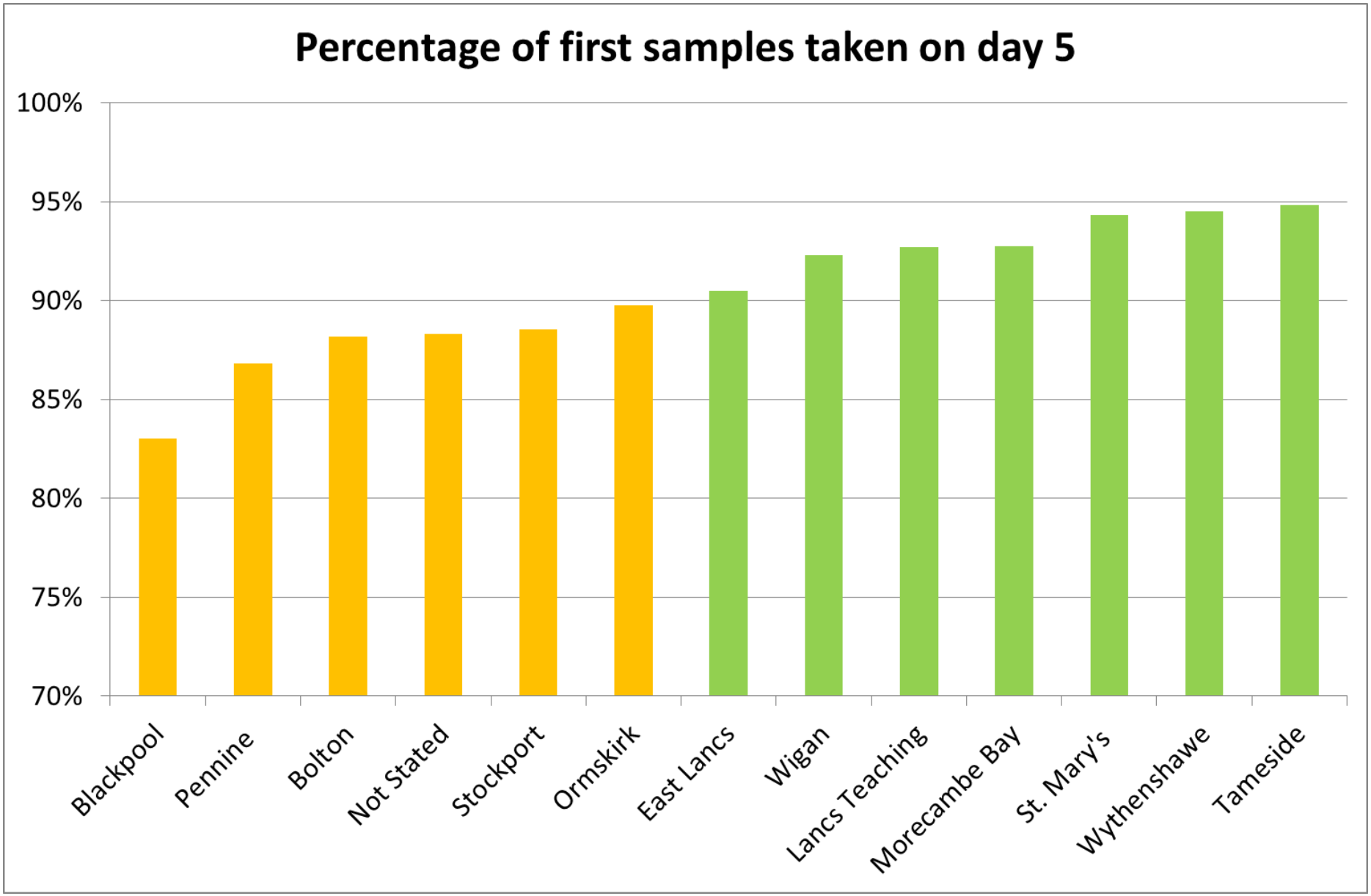


Figure 2: Graph to show percentage of samples taken on day 5

Standard 5: Timely receipt of samples in NBS laboratory

Acceptable: ≥ 95.0% of all samples received less than or equal to 3 working days of sample collection.
Achievable: ≥ 99.0% of all samples received less than or equal to 3 working days of sample collection.
The data corresponding to this standard is shown in figure 3 and tabulated in table 3. Overall 98.2% were received within 3 working days (range 80.5% to 99.9%), a slight improvement on last year (97.4%).

Trust	Number of samples received in 3 or fewer working days of sample being taken	Total number of samples received	Percentage of samples received in 3 or fewer working days of sample being taken
Blackpool Teaching Hospitals NHS FT	2983	3000	99.4%
Bolton NHS FT	5770	5855	98.5%
East Lancashire Hospitals NHS Trust	6185	6211	99.6%
Health Visitor	384	412	93.2%
Lancashire Teaching Hospitals NHS FT	4139	4143	99.9%
Manchester University NHS FT - SMH & RMCH	5143	5160	99.7%
Manchester University NHS FT - Wythenshawe	4301	4315	99.7%
Not Stated	1967	2044	96.2%
Pennine Acute Hospitals NHS Trust	9951	10292	96.7%
Southport & Ormskirk Hospital NHS Trust	674	837	80.5%
Stockport NHS FT	3242	3275	99.0%
Tameside And Glossop Integrated Care NHS FT	2888	2909	99.3%
University Hospitals of Morecambe Bay NHS FT	2827	2949	95.9%
Wrightington, Wigan and Leigh NHS FT	3197	3230	99.0%
Grand Total	**53651**	**54632**	**98.2%**

Table 3: Data for standard 5 showing the number of samples dispatched in a timely manner (excluding pre-transfusion 'day 0' samples and samples with missing dates)

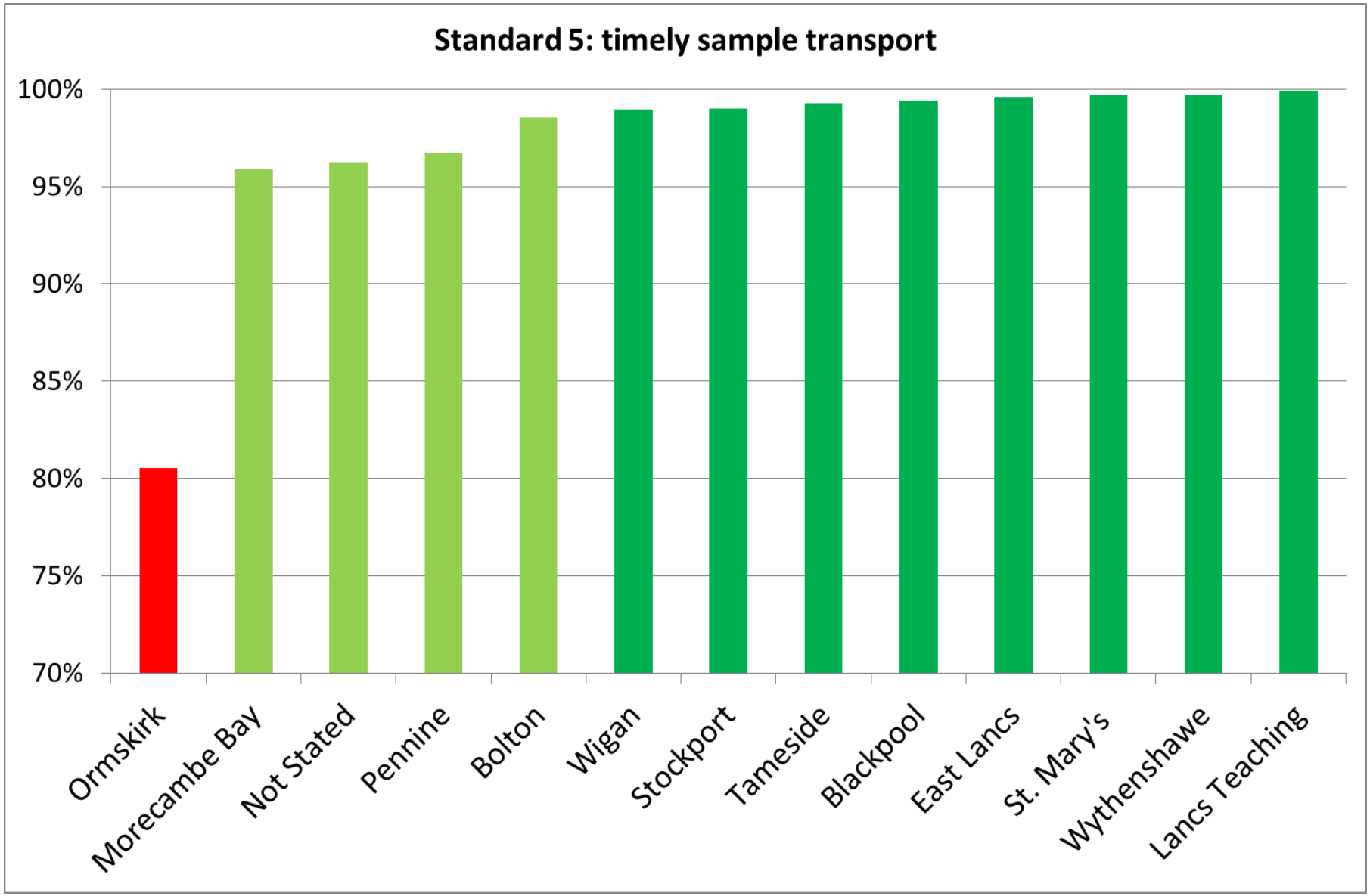


Figure 3: Graph to show percentage of samples received within 3 working days of being taken

Standard 6: Quality of blood spot sample

Acceptable: Avoidable repeat rate is ≤ 2.0%
Achievable: Avoidable repeat rate is ≤ 1%

An avoidable repeat can be classified as follows:

- Sample taken too soon (<5 days)
- Expired card
- Insufficient blood: too small or not soaked through
- Incorrect blood application (multi-spotting)
- Compressed/ damaged/ contaminated
- Contamination (discrepant IRT)
- No valid NHS number
- Missing date of sample/ date of birth
- Sample >14 days in transit
- Damaged in transit

Insufficient blood (spots too small or not soaked through) and incorrect blood application (multi-spotting) accounts for the majority of rejected samples, followed by missing date of sample. Figure 4 shows the avoidable repeat rate per Trust and also shows how each cause of sample rejection contributes to the overall avoidable repeat rate. This data is also tabulated in table 4. Four out of 12 maternity units achieved the standard. The overall avoidable repeat rate was 2.2% (ranging from 1.4 to 7.9%) which, overall, is an improvement in performance compared with last year (2.5%; ranging from 1.6 to 5.7%).

The avoidable repeat rate for samples collected from in-patients (6.2%) was over three times higher than the rate for those collected in the community (1.7%). Table 5 shows the avoidable repeat rate for each hospital in the region. This data is also displayed graphically in figure 5.

Status code and description of avoidable repeat	Blackpool Teaching Hospitals NHS FT	Bolton NHS FT	East Lancashire Hospitals NHS Trust	Health Visitor	Lancashire Teaching Hospitals NHS FT	Manchester FT - St. Mary's Hospital (& RMCH)	Manchester FT - Wythenshawe Hospital	Not Stated	Pennine Acute Hospitals NHS Trust	Southport & Ormskirk Hospital NHS Trust	Stockport NHS FT	Tameside And Glossop Integrated Care NHS FT	University Hospitals of Morecambe Bay NHS FT	Wrightington, Wigan and Leigh NHS FT	Grand Total
0301: too young for reliable screening (≤ 4 days)	2	3	24	0	17	12	3	0	9	6	8	0	8	4	96
0302: too soon after transfusion (<72 hours)	0	12	22	0	4	31	3	0	22	0	2	0	1	1	98
0303: insufficent sample	14	68	64	11	30	21	3	1	35	16	44	13	14	30	364
0304: unsuitable sample (blood quality): incorrect blood application	12	40	18	2	10	40	41	1	42	26	54	28	20	16	350
0305: unsuitable sample (blood quality): compressed/damaged	0	2	4	0	2	4	1	0	11	1	4	2	1	2	34
0306: Unsuitable sample: day 0 and day 5 on same card	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0307: unsuitable sample for CF: possible faecal contamination	4	12	4	0	3	12	7	1	10	1	5	2	2	4	67
0308: unsuitable sample: NHS number missing/not accurately recorded	2	2	4	5	3	4	1	1	31	2	2	1	11	9	78
0309: unsuitable sample: date of sample missing/not accurately recorded	5	2	22	2	22	15	8	0	38	9	3	3	10	16	155
0310: unsuitable sample: date of birth not accurately matched	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0311: unsuitable sample: expired card used	2	3	5	0	1	1	0	0	2	0	3	4	2	1	24
0312: unsuitable sample: >14 days in transit, too old for analysis	0	0	1	3	0	0	0	0	0	1	2	0	0	0	7
0313: unsuitable sample: damaged in transit	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Number of Avoidable Repeat Requests	**41**	**132**	**146**	**23**	**88**	**109**	**64**	**4**	**178**	**62**	**125**	**53**	**68**	**82**	**1175**
Number of first samples received/ babies tested	**2926**	**5570**	**5975**	**433**	**3989**	**4887**	**4192**	**2017**	**9940**	**788**	**3117**	**2809**	**2864**	**3136**	**52643**
Avoidable Repeat Requests Rate	**1.4%**	**2.4%**	**2.4%**	**5.3%**	**2.2%**	**2.2%**	**1.5%**	**0.2%**	**1.8%**	**7.9%**	**4.0%**	**1.9%**	**2.4%**	**2.6%**	**2.2%**

Table 4: Data for Standard 6 showing avoidable repeat rate

Status code 0302 (too soon after transfusion): not included in calculation of avoidable repeat rate as per the standard definition

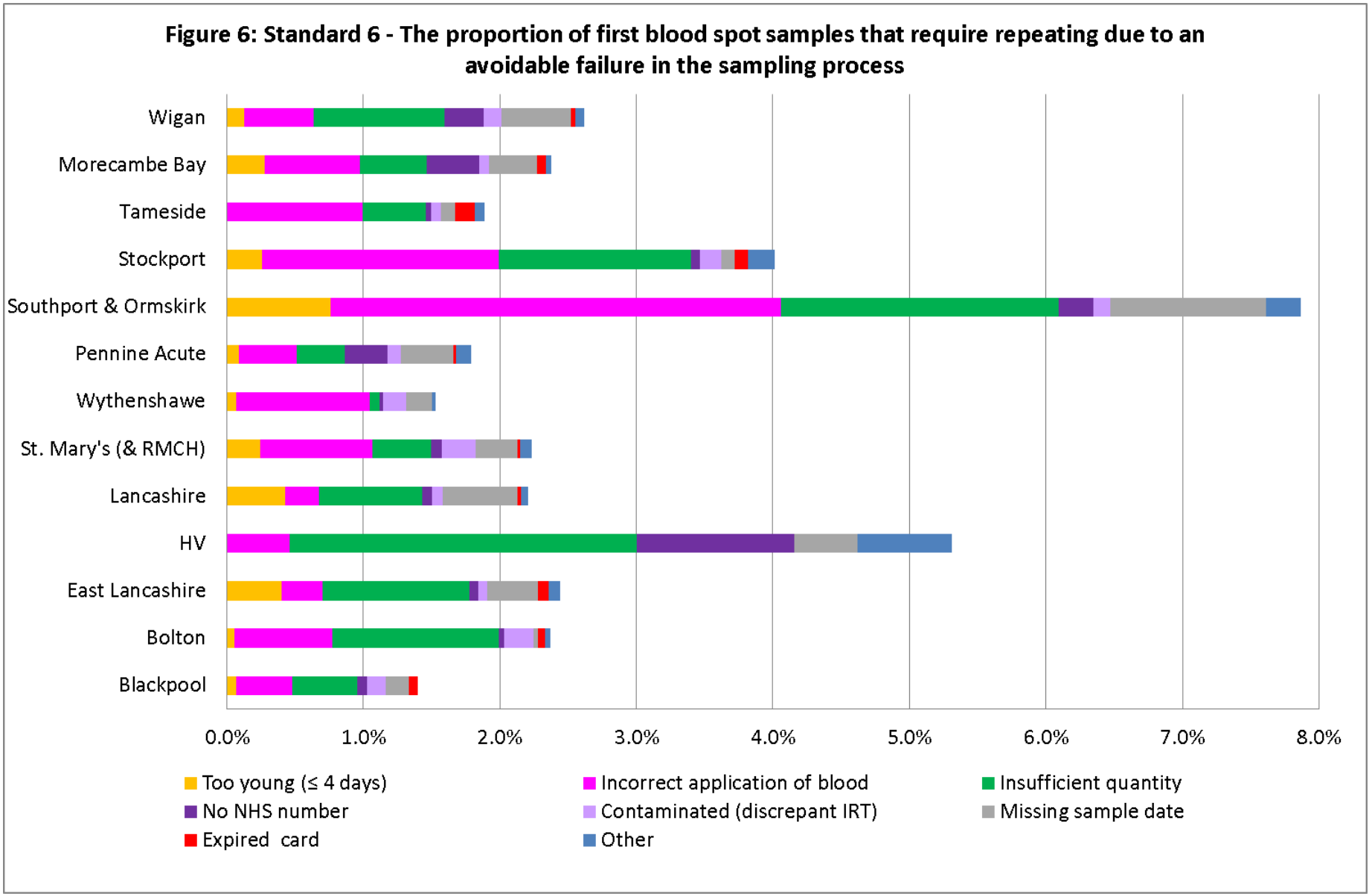


Figure 4: Graph to show avoidable repeat rate by Trust

Status code and description of avoidable repeat	Blackpool Victoria Hospital	Burnley General Hospital	Furness General Hospital	North Manchester General Hospital	Not in hospital	Ormskirk & District General	Royal Albert Edward Infirmary	Royal Blackburn Hospital	Royal Bolton Hospital	Royal Lancaster Infirmary	Royal Manchester Childrens Hospital	Royal Oldham Hospital	Royal Preston Hospital	St Mary's Hospital, Manchester	Stepping Hill Hospital	Tameside General Hospital	UK Out of Region	Wythenshawe Hospital	Grand Total
0301: too young for reliable screening (≤ 4 days)	2	13	0	1	54	6	3	1	2	0	0	1	0	9	4	0	0	0	96
0302: too soon after transfusion (<72 hours)	0	22	0	1	3	0	1	0	12	1	0	20	4	30	2	0	0	2	98
0303: insufficent sample	2	23	0	5	262	7	12	0	20	2	3	2	6	9	9	1	0	1	364
0304: unsuitable sample (blood quality): incorrect blood application	6	8	2	5	203	6	6	0	28	1	0	11	4	30	15	4	0	21	350
0305: unsuitable sample (blood quality): compressed/damaged	0	4	0	2	18	1	0	0	0	1	1	3	0	3	0	0	0	1	34
0306: Unsuitable sample: day 0 and day 5 on same card	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0307: unsuitable sample for CF: possible faecal contamination	2	3	0	1	44	0	1	0	6	0	1	2	0	5	1	0	0	1	67
0308: unsuitable sample: NHS number missing/not accurately recorded	1	2	1	1	58	1	5	0	0	1	1	5	0	2	0	0	0	0	78
0309: unsuitable sample: date of sample missing/not accurately recorded	0	4	2	0	132	0	6	0	1	1	0	2	1	4	0	1	0	1	155
0310: unsuitable sample: date of birth not accurately matched	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0311: unsuitable sample: expired card used	1	1	0	0	18	0	1	1	1	0	0	0	0	0	1	0	0	0	24
0312: unsuitable sample: >14 days in transit, too old for analysis	0	1	0	0	6	0	0	0	0	0	0	0	0	0	0	0	0	0	7
0313: unsuitable sample: damaged in transit	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Number of Avoidable Repeat Requests	**14**	**59**	**5**	**15**	**795**	**21**	**34**	**2**	**58**	**6**	**6**	**26**	**11**	**62**	**30**	**6**	**0**	**25**	**1175**
Number of first samples received/ babies tested	**314**	**699**	**67**	**347**	**46535**	**118**	**294**	**7**	**582**	**190**	**20**	**716**	**449**	**1243**	**334**	**224**	**1**	**503**	**52643**
Avoidable Repeat Requests Rate	**4.5%**	**8.4%**	**7.5%**	**4.3%**	**1.7%**	**17.8%**	**11.6%**	**28.6%**	**10.0%**	**3.2%**	**30.0%**	**3.6%**	**2.4%**	**5.0%**	**9.0%**	**2.7%**	**0.0%**	**5.0%**	**2.2%**

Table 5: The proportion of avoidable repeat samples collected from babies in hospital compared with samples collected in the community

Status code 0302 (too soon after transfusion): not included in calculation of avoidable repeat rate as per the standard definition

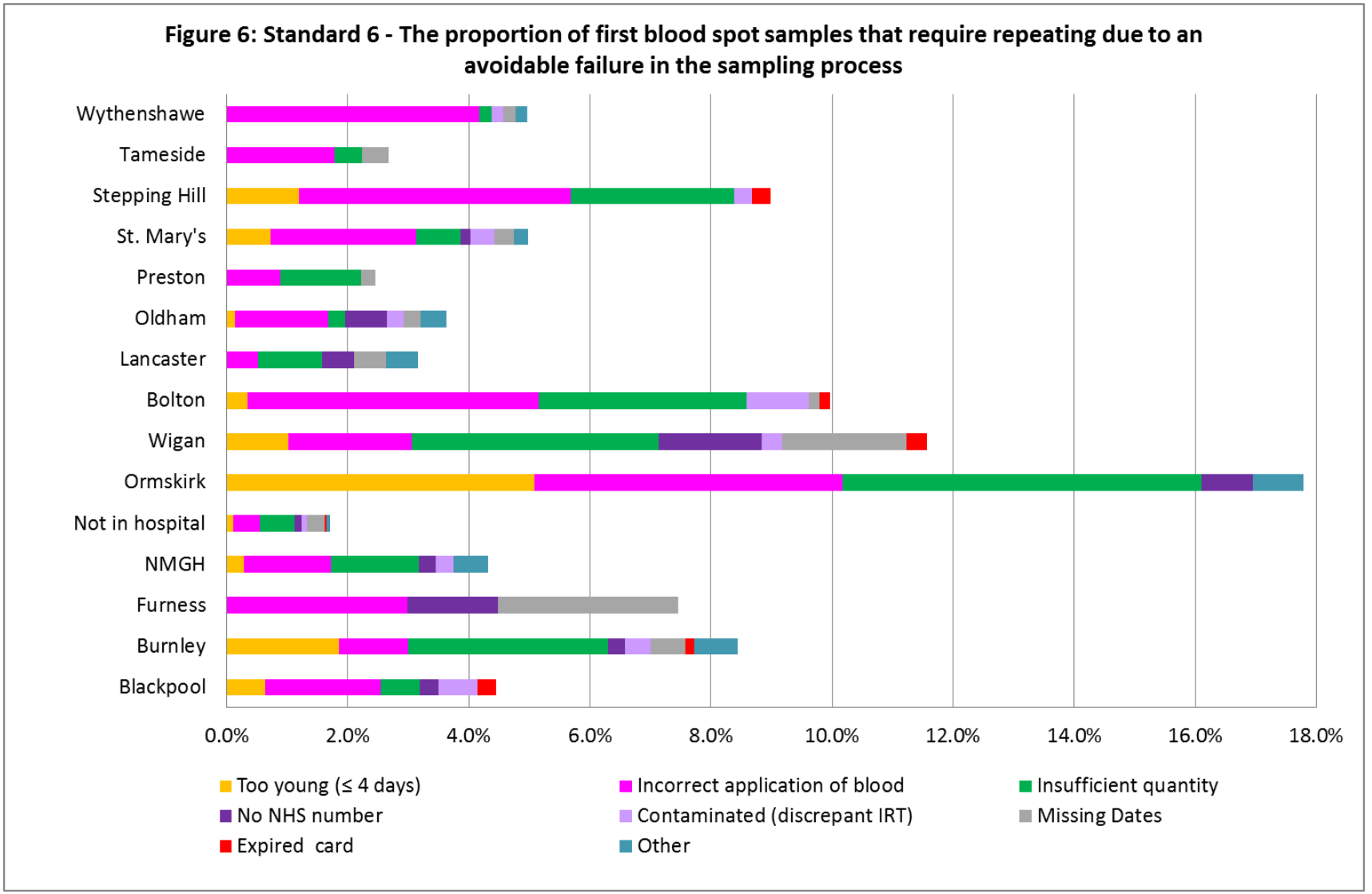


Figure 5: Graph to show avoidable repeat samples collected from babies in hospital compared with samples collected in the community. Royal Blackburn (avoidable repeat rate 28.6%; 2/7 samples) and Royal Manchester Children's Hospital (avoidable repeat rate 30%; 6/20 samples) not included on chart.

5. Clinical Referral Data

A comparison of the number of cases referred for each condition since 2007 is shown in Figure 6.

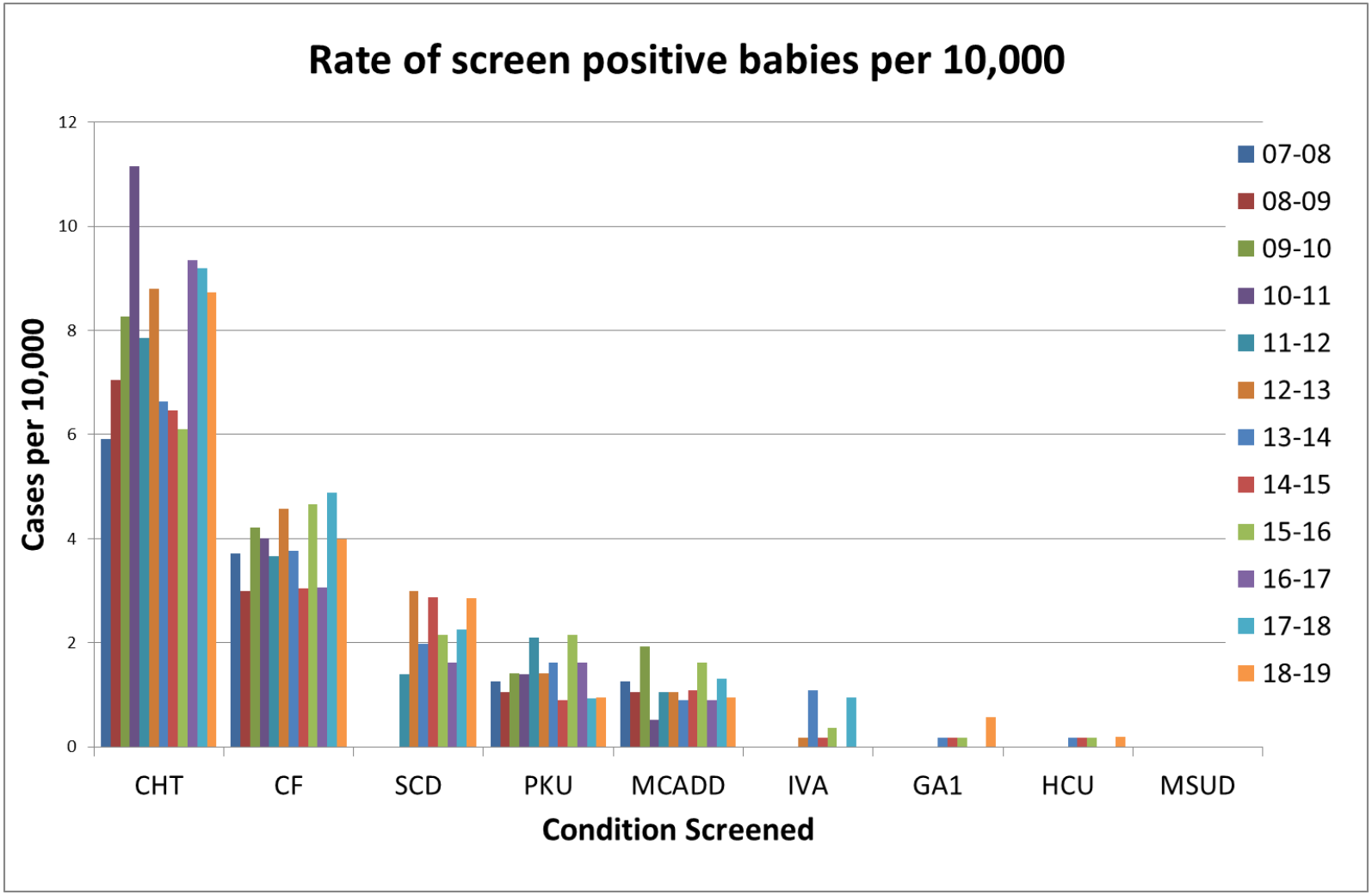


Figure 6: Rate of screen positive babies (per 10000) from 2007 onwards

Positive Cases 2018-2019

PKU Screening

Five cases of raised phenylalanine were followed up clinically by medical staff at the Willink Unit. There were 2 confirmed PKU cases, giving an estimated incidence of 1: 26322 (birth rate assumed to equal number of first samples received). Two babies required monitoring only and one further baby had galactosaemia.

The achievable threshold for standard 9 was met - timely processing of screen positive samples. 100% of positive screening results were referred within 3 working days of sample receipt. The age at referral ranged from 9-11 days, excluding one baby who had an early sample collected (due to having an affected sibling) and was seen in clinic on day 5. The acceptable threshold was met for standard 11 – timely receipt into clinical care. All PKU screen positive babies attended their first clinic appointment by day 14 (range 9-11 days).

MCADD Screening

There were 5 screen positives for MCADD and all 5 were confirmed as MCADD cases, giving an estimated incidence of 1 in 10529. One MCADD case with an affected sibling was seen on day 2 following an early screening sample. The other 4 screen positives were referred within 3 working days. The age at referral ranged from 7-12 days and all babies had their first clinic appointment by day 12 (range 7-12 days).

Screening for Other Metabolic Conditions (IVA, MSUD, GA1, HCU)

There was one screen positive for HCU, which was a confirmed case of HCU on diagnostic testing (estimated incidence of 1 in 52643). Standard 11 was met (clinic appointment by 28 days of age) as the baby was seen by the specialist on day 16. There 3 screen positive results for GA1 of which 2 were confirmed giving an estimated incidence of 1 in 26322. The babies were referred within 3 working days of sample receipt and the age at referral ranged from 7-11 days. Standard 11 was met in all 3 cases (clinic appointment by 14 days of age). The age at appointment ranged from 7-12 days. There were no screen positive babies for IVA or MSUD.

CHT Screening

All raised TSH levels (≥6.0 mU/L) were checked in duplicate on the original sample and the average result was taken. Samples with confirmed levels ≥20.0 mU/L were treated as positive and urgent follow up was arranged at RMCH, unless the baby was still in a local hospital in which case follow up was initiated by the corresponding medical team. There were 24 such cases and the blood spot TSH ranged from 20 mU/L to >299 mU/L. One further baby (a triplet with a gestational age of 34 weeks) had a normal TSH result (2.0 mU/L) on the initial sample but a repeat was required due to poor sample quality (multi-spotted). The repeat TSH on day 13 was 33 mU/L.

Confirmed TSH levels between 8.0 and 19.9 mU/L were treated as borderline and a repeat sample was requested, to be taken no sooner than one week later to allow for normalisation of transient increases. If the borderline result was persistent or had moved into the positive range (≥20.0 mU/L) clinical follow up was initiated at RMCH. Of the 138 initial borderline results, 18 (13%) were treated as positive following repeat sampling with a TSH ranging from 8 to 57 mU/L on repeat.

There were two cases of screen positive results on premature babies, detected on the day 28 preterm repeat sample (TSH 31 mU/L and 157 mU/L). A further baby had a borderline TSH on the pre-term repeat sample, which remained borderline on repeat (TSH 9.1 mU/L).

The number of positive cases (identified on the first sample) per trust is shown in Table 6. Standard 11 (timely entry into clinical care) states that for babies identified as CHT positive on the initial screening sample 100% should attend the first clinic appointment by 14 days of age. Age at first appointment for positive CHT babies, identified on the first sample are shown in figure 7 and table 6. The median age at first appointment was 12 days (range 9-16 days). The first clinic appointment was attended by day 14 in 83% (20/24) of cases, which does not meet the achievable standard. Of the cases not meeting the standard, 3 were seen on day 15 and one on day 16. The delay tended to be due to sample transport falling over a bank holiday (4-6 calendar days in transit) or a combination of being collected on day 6 rather than day 5, transport incorporating a weekend and/or referral on a Friday with the appointment not until the Monday.

Standard 11 (timely entry into clinical care) requires that for babies identified as CHT on a repeat blood spot sample that follows a borderline TSH, 100% should be on treatment by 21

days of age. Age at first appointment for positive CHT babies, identified following a repeat sample are shown in table 7 and in figure 7. The median age at the first clinic appointment was 19 days (range 16-25). The first clinic appointment was attended by day 21 in 13 cases (72%; in-patients evaluated on the day of referral). Five babies exceeded 21 days – age at first appointment ranged from 22-25 days. There were small delays in either repeat sample collection or transport: age at receipt of repeat sample ranged from 19-21 days.

The communication guidelines for CHT suspected results state that parents should be offered an appointment the same day or the day after they are informed about their baby's positive screening result. Babies referred by our screening laboratory are usually given an appointment within 1 day of the parents being informed of the result. In February 2019 there were some issues with staffing in the department which provides the thyroid scintigraphy scan (now resolved). This led to two families being given an appointment 1 day later than usual, in order to ensure that a scan was possible on the same day as the clinical assessment and confirmatory blood tests.

Standard 9 requires that for 100% of cases clinical referral is initiated within 3 working days of sample receipt. For 2018/19, 98% (45/46) of positive CHT cases were referred within 3 working days. For the case which did not meet the standard, the positive result was available on Christmas Eve but the decision was taken to delay referral until 27th December.

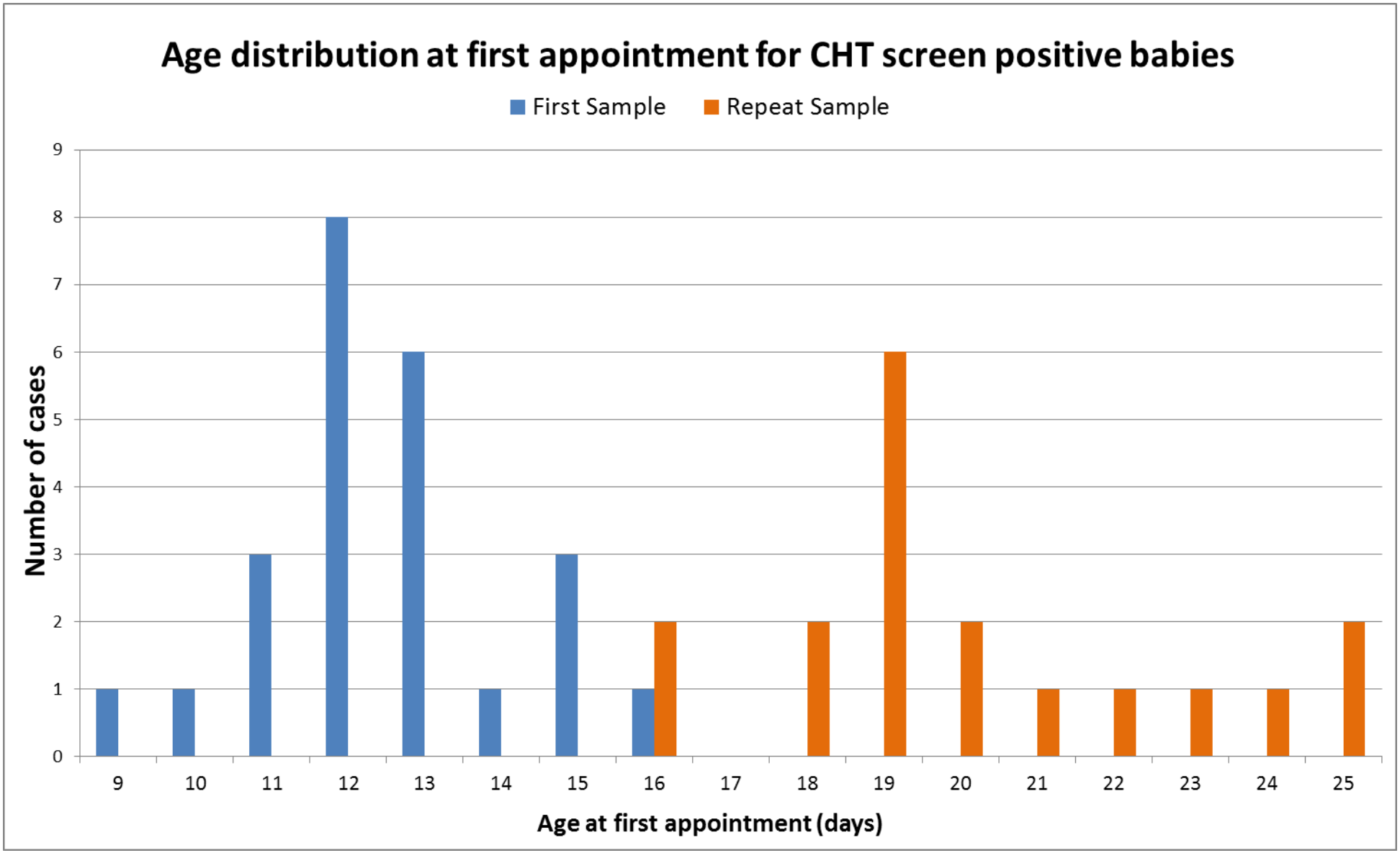


Figure 7: Graph to show age at first appointment for each positive CHT case (in days)

First sample: babies referred on first sample (TSH >20 mU/L); Repeat sample: detected on repeat sample.

Trust	Number of cases	Age at first clinic appointment (days)
Bolton NHS Foundation Trust	2	13,15
Manchester University NHS FT - SMH	2	11, 12
Manchester University NHS FT - Wythenshawe	2	12,13
East Lancashire Hospitals NHS Trust	3	12, 12, 13
Lancashire Teaching Hospitals NHS Foundation Trust	1	9
Pennine Acute Hospitals NHS Trust	8	11-16
Southport and Ormskirk Hospital NHS Trust	1	13
Stockport NHS Foundation Trust	1	12
Tameside	1	12
Wrightington, Wigan And Leigh NHS Foundation Trust	3	10, 12, 13

Table 6: Positive CHT babies identified on the first sample – age at first clinic appointment (for in-patients: age at referral is used instead of age at appointment)

Trust	Number of cases	Age at first clinic appointment (days)
Blackpool Teaching NHS FT	1	20
Bolton NHS Foundation Trust	3	19, 22, 23
East Lancashire Hospitals NHS Trust	2	16, 19
Manchester University NHS FT - SMH	3	18, 18, 19
Manchester University NHS FT - Wythenshawe	2	16, 19
Pennine Acute Hospitals NHS Trust	6	19-25
Tameside And Glossop Integrated Care NHS Foundation Trust	1	19

Table 7: Positive CHT babies identified on a repeat sample - age at first clinic appointment. (for in-patients: age at referral is used instead of age at appointment)

CF Screening

CF screening process is carried out according to the national algorithm as detailed on the NHS Newborn Blood Spot Screening website (https://www.gov.uk/government/publications/health-professional-handbook-newborn-blood-spot-screening/7-conditions#cystic-fibrosis) and involves the analysis of IRT on the initial blood spot sample taken at day 5 followed by DNA mutational analysis if the initial IRT is raised. If no mutations are identified yet the initial IRT is greatly elevated (>120 ng/mL) a second IRT sample is requested to be taken on day 21. If this is raised the baby is reported as 'CF suspected'. Referrals are carried out by liaison with the CF centre at Royal Manchester Children's Hospital. The CF screening algorithm displaying the numbers detected in each category for Manchester Newborn Screening Lab in 2018/19 is shown in figure 8. There are some discrepancies in the data for example due to babies who died prior to completing the screening pathway. Summary data since the programme was implemented in 2007 in shown in table 8.

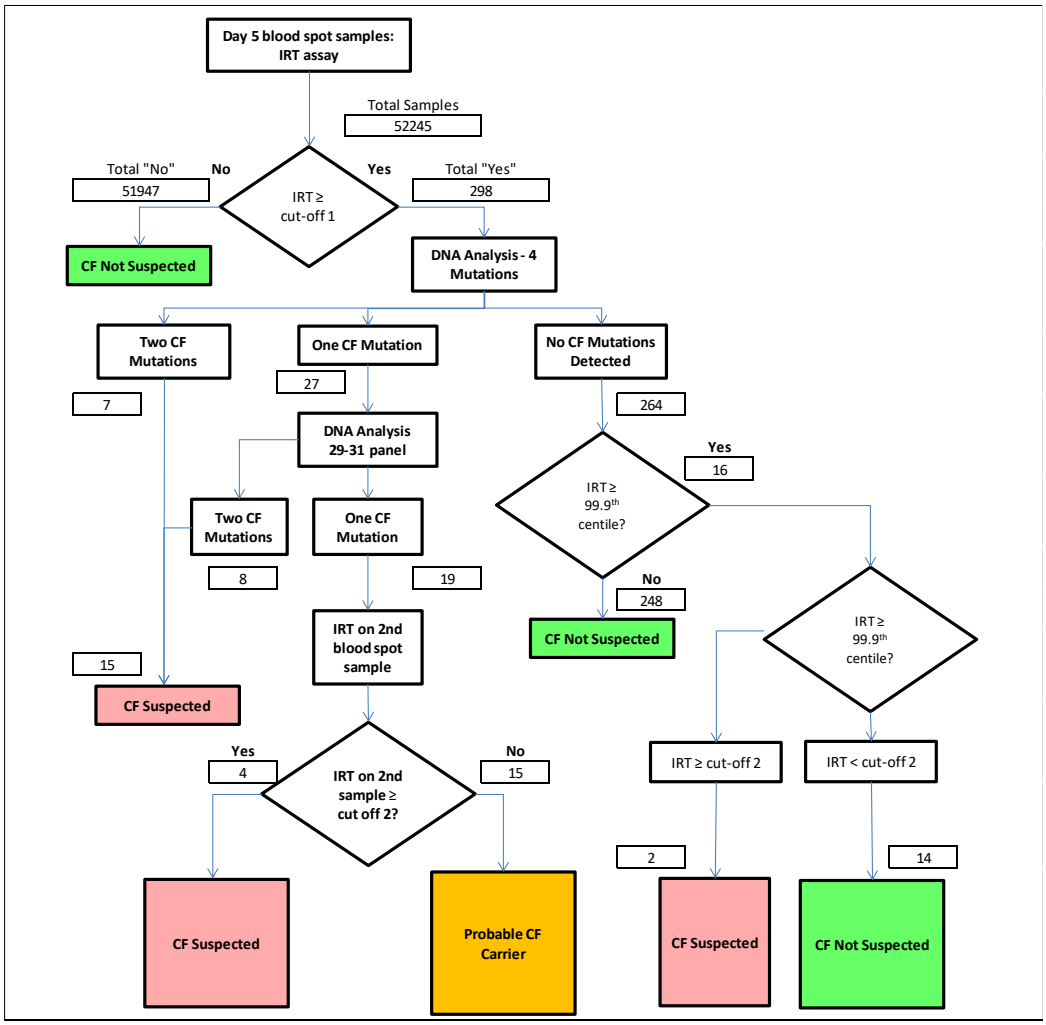


Figure 8: CF screening algorithm displaying the numbers detected in each category for Manchester Newborn Screening Lab in 2018/19

Year	Predicted number (national algorithm)	08/09	09/10	10/11	11/12	12/13	13/14	14/15	15/16	16/17	17/18	18/19
Babies Screened	-	55627	56720	57281	57142	56585	55603	55469	55407	55361	52992	52245
Samples referred for DNA	0.5%	232 (0.42%)	263 (0.46%)	307 (0.54%)	257 (0.45%)	226 (0.40%)	272 (0.49%)	274 (0.49%)	306 (0.55%)	319 (0.58%)	305 (0.58%)	298 (0.57%)
CF Suspected	23	17	24	23	21	26	21	17	26	15	25	21
2 mutations on 4 mutation panel	17	12	11	14	16	16	8	12	12	7	12	7
2 mutations on extended panel	3	1	5	4	1	6	10	4	5	3	3	8
1 mutation + 2nd IRT >cut-off 2	3	3	2	1	1	2	1	0	4	2	3	4
No mutation + 2nd IRT>cut-off 2	1	1	6	4	3	2	2	1	4	3	5	2
CF probable carriers	28	13	16	22	12	6	17	13	21	22	11	15

Table 8: CF Outcome Data since 2008

The percentage of samples referred for DNA testing was 0.57%, which is slightly above the target of 0.5%. Cut-offs are adjusted in response to lot changes. As large numbers of data points (approximately 13,000) are required to accurately determine the 99.5th centile, we collaborate with other screening labs by pooling data from new kit lots to try and improve the accuracy of cut-offs.

According to the clinical referral guidelines for cystic fibrosis, CF referrals for cases identified as positive on the first sample (i.e. two mutations) should have their first clinic appointment by the age of 28 days and those identified as positive from the second IRT sample should be seen by 35 days. Table 9 and figure 9 detail the age of each baby at the first clinic appointment. The cases that were referred following analysis of a second IRT are shown to the right of the chart, in orange. The median age for referral for the double mutation cases was 17 days (range 12–21 days). 100% of double mutation cases had their first clinic appointment before day 28, meeting standard 11. The median age at first clinic appointment for this group was 20 days (range 5-26 days, including a baby detected clinically and seen prior to the screening referral).

Of the CF positives identified following a second raised IRT 83% (5/6) had a clinic appointment by day 35. The median age for referral for this group was 27 days (range 25–30 days). The median age at first clinic appointment was 32 days (range 30-37 days). The repeat sample on the baby who was seen until day 37 was not collected until day 25.

Of the 15 double mutation cases, CF was confirmed in 12 cases and labelled as CF positive inconclusive diagnosis (CFSPID) in 3 cases. In those babies with positive results following a repeat IRT, CF was excluded in 4 cases following negative sweat tests. One case was confirmed as CF (1 mutation on the screening panel and a further mutation found by next generation sequencing, positive sweat test) and another baby was designated as CFSPID (1 mutation on the screening panel and a further mutation found by next generation sequencing, equivocal sweat test).

In 2018/19, blood spot samples were collected from 298 babies who were too old for CF screening. All 298 were born outside of the UK. It would be important to establish whether these babies arrived in the UK too late to be screened for CF or whether there was a delay in the collection of their screening samples. In one case the first sample was collected on day 55 but required a repeat sample. For the rest of the cases the initial sample was collected at >8 weeks.

Trust	Number of cases	Age at first appointment
Blackpool Teaching Hospitals NHS	4	5, 20, 21, **26**
Bolton NHS Foundation Trust	1	19
East Lancashire Hospitals NHS Trust	2	21,**30**
Lancashire Teaching Hospitals NHS	2	17, 21
Manchester University NHS FT - SMH	4	14, 20, 30**, 37**
Manchester University NHS FT - Wythenshawe	1	16
Pennine Acute	1	19
Stockport NHS FT	1	**34**
Tameside And Glossop Integrated	3	15, 30, **35**
University Hospitals of Morecambe Bay NHS FT	1	26
Wrightington, Wigan And Leigh NHS Foundation Trust	1	20

Table 9: Location of CF cases identified by screening and age at first appointment

The ages shown in bold represent the cases that were identified following receipt of a second sample for IRT analysis.

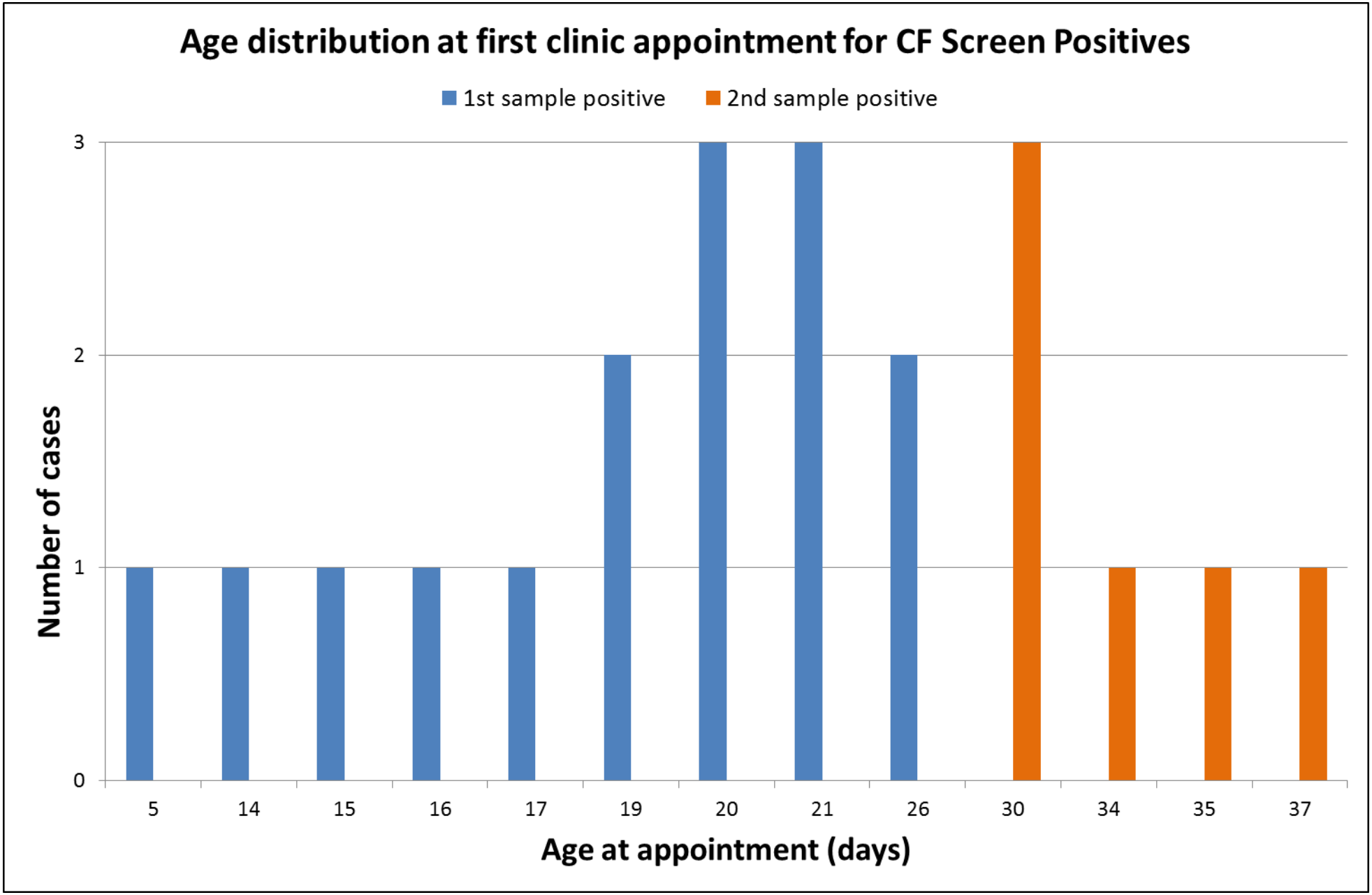


Figure 9: Graph to show the age at first clinic appointment for CF Suspected cases.

Screening for Sickle Cell disease and other Haemoglobinopathies

Screening for sickle cell and other haemoglobinopathies is carried out within the laboratory using high performance liquid chromatography (HPLC) as a first line test and any variants that have been identified are confirmed by second line isoelectric focussing which is carried out within the haematology department of Manchester Royal Infirmary. The laboratory sent 652 samples for confirmatory testing, 64 of which were subsequently reported as not suspected for Sickle Cell Disease. The 64 which were subsequently reported as not suspected include unidentified haemoglobin variants which are no longer reported, in line with national policy. A summary of all diseases (both clinically and not clinically significant) and carriers identified following confirmatory testing is provided in table 10. There were 15 babies identified as having sickle cell disease (12 FS and 3 FSC), 3 babies identified with thalassaemia (HbF) and 1 baby with an FE pattern.

Data on the ethnic origin of babies identified with sickle cell disease or other clinically significant haemoglobinopathies is shown in table 11 and age at referral for those babies in table 12. Standard 8 for this programme states that at least 90% of positive screening results for sickle cell disease should be communicated to parents by 28 days of age (NHS Sickle Cell and Thalassaemia Screening Programme Standards: https://www.gov.uk/government/publications/sickle-cell-and-thalassaemia-screening-programme-standards/sickle-cell-and-thalassaemia-screening-standards-valid-for-data-collected-from-1-april-2019).

Between April 2018 and March 2019, all babies with clinically significant disorders were referred to he Sickle Cell Centre by day 19 (median 14 days; range 12-19 days), excluding one pre-term baby (28 weeks) who had a very low proportion of haemoglobin A (<2%) at day 5. As a result the day 28 pre-term repeat sample was tested for the sickle cell screen and reported as HbF on day 43. The date the results were given to parents was unavailable for the FE case. Excluding the pre-term case and the FE case, the results for all remaining positive cases were communicated to parents by day 28 (median 21 days; range 16-28 days). Standard 11 requires that ≥ 90.0% babies with clinically significant results attend their first clinic appointment by ≤90 days of age. 18/19 (95%) babies were ≤90 days of age at their first visit to the paediatrician (median 60 days; range 45-92 days), which meets standard 11. The baby exceeding 90 days was the preterm baby discussed above (appointment on day 92).

Trust	Significant Diseases					Non-significant diseases			Carriers				
	FS	FSC	FSA	FE	F only	FC	FD	Others	FAS	FAC	FAD	FAE	Other
Blackpool Teaching Hospitals NHS FT									6				
Bolton NHS FT	2		1			1			30	3	8	2	
East Lancashire Hospitals NHS Trust				1					9	1	9	8	
Health Visitor			1						7	2		1	
Lancashire Teaching Hospitals NHS FT	2								10	1	1	1	
Manchester University NHS FT	2	2			1			2	119	21	12	15	
Not Stated	2								22	4	2	1	
Pennine Acute Hospitals NHS Trust	2	1	2		1				135	12	18	26	
Southport & Ormskirk Hospital NHS Trust									1		2		
Stockport NHS FT							1		13	3	1		
Tameside And Glossop Integrated Care NHS FT	1				1	1			17	2	7	7	
University Hospitals of Morecambe Bay NHS FT									6	1	2	1	
Wrightington, Wigan and Leigh NHS FT	1								10				
Total	**12**	**3**	**4**	**1**	**3**	**2**	**1**	**2**	**385**	**50**	**62**	**62**	**0**

Table 10: Results obtained for sickle cell and haemoglobinopathy screening

FS = sickle cell disease FAS = sickle cell carrier FE = HbE disease FAE = HbE carrier F only = β thalassaemia major

FSC = SC type sickle cell disease FAC = HbC carrier FSA = possible heterozygote for sickle cell/β thalassaemia FAD = HbD carrier

Ethnic origin	Significant diseases					Non-significant diseases			Carriers				
	FS	FSC	FS-Other	FE	F Only	FC	FD	Others	FAS	FAC	FAD	FAE	Other
A - British					1				24	4	14	2	
B - Irish												1	
C - Any other White background									4				
D - White and Black Caribbean									21	9	2		
E - White and Black African									29	1			
F - White and Asian											1	7	
G - Any other Mixed background			1						20	6	3	3	
H - Indian	1						1		8		2	2	
J - Pakistani					1				3		32	5	
K - Bangladeshi				1					1		1	38	
L - Any other Asian background									4		3	2	
M - Caribbean			1						19	6			
N - African	9	3	1			1		2	212	18			
P - Any other Black background	2					1			22	3			
R - Chinese												1	
S - Any other ethnic category			1		1				7	2	2	1	
Z - Not stated									11	1	2		
Totals	**12**	**3**	**4**	**1**	**3**	**2**	**1**	**2**	**385**	**50**	**62**	**62**	**0**

Table 11: Distribution of babies with sickle cell disease and other clinically significant haemoglobinopathies by ethnic origin

Newborn screening result	Lab notified of this 'at risk' pregnancy in advance/ parent's antenatal results recorded on the blood spot card?	Age (in days) at newborn sample	Age (in days) at receipt of newborn sample in lab	Age (in days) of screen positive baby at time of initial clinical referral	Age (in days) results given to parents	Age (in days) at first visit to paediatrician
F	No	5	6	15	21	45
FSC	No	5	6	12	17	55
FE	No	5	6	13	N/A	79
FS	No	6	7	15	21	60
FS	Yes	7	9	13	17	55
FS	No	5	6	14	21	54
FS	Yes	5	6	13	20	56
FS	Yes	6	11	19	22	57
FSC	Yes	5	6	10	22	64
FS	Yes	5	9	13	19	46
FSC	Yes	5	6	13	27	75
F	Yes	5	6	19	28	69
FS	Yes	5	7	14	17	51
FS	Yes	5	6	12	16	63
FS	Yes	5	7	17	23	78
F	No	5	9	43*	51	92
FS	No	5	9	17	25	45
FS	Yes	5	10	14	17	61
FS	Yes	5	7	18	19	62

Table 12: Age at referral and details on linkage with antenatal screening, for babies with sickle cell disease and other clinically significant haemoglobinopathies, in order of sample receipt.

*One pre-term baby (28 weeks) had a very low proportion of haemoglobin A (<2%) at day 5 so the day 28 pre-term repeat sample was tested for the sickle cell screen.

6. Summary of Audit Work and Adherence to National Standards

NHS Newborn Blood Spot Screening Programme Process Standards

- Standard 3 - Barcoded NHS number label is included on the blood spot card: In 2018/19 87.0% of cards included a barcoded NHS number label (acceptable threshold 90.0%).
- Standard 4 - Timely sample collection: 89.6% of first samples were collected on day 5 (acceptable threshold 90.0%). 6/12 maternity units met the standard.
- Standard 5 - Timely sample receipt in the lab: 98.2% samples were received within 3 working days (acceptable threshold 95.0%). 11/12 maternity units met the standard.
- Standard 6 - Quality of Blood spot Sample: The avoidable repeat rate was 2.2% (acceptable ≤2.0%). 4/12 maternity units met the standard. The rate varied between units from 1.4 to 7.9%.

Clinical Referral of Positive Cases

- Standard 11 (timely entry into clinical care) states that all screen positive babies for IMDs (excluding HCU) and CHT (suspected on first sample) should attend the first clinical appointment by 14 days of age. In 100% (5/5) of PKU cases the standard was met. All 5 MCADD cases were seen in the correct timeframe. In 83% of CHT cases (20/24) the standard was met.
- HCU positives should attend their 1st clinic appointment by day 28. The HCU positive case was seen on day 16.
- CHT cases suspected on repeat following borderline TSH should be seen by 21 days. 13/18 (72%) of such cases met the standard.
- Clinical referral for PKU, MCADD and CHT screen positive babies should be initiated within 3 working days of sample receipt by the laboratory. All referrals for PKU and MCADD were initiated within 3 working days. 98% (45/46) of CHT referrals met the standard.
- Of 15 CF screen positive cases with two mutations, 100% were assessed by the CF team by 28 days (standard 11 acceptable threshold 95.0%).
- Of 6 CF suspected cases identified following a second raised IRT, 83% (5/6) had a clinic appointment by day 35 (standard 11 acceptable threshold 80.0%)
- Standard 11 (timely entry into clinical care) states that at least 90% of babies screen positive for sickle cell disease should attend the first clinical appointment by 90 days of age. 95% (18/19) of sickle cell disease screen positive cases were seen by 90 days.

Newborn Screening Incidents

A breakdown of all incidents identified by the laboratory team or notified to the laboratory team is shown by cause in Figure 10 and by location in Figure 11. It is acknowledged that other incidents may have occurred due to failures in various components of the pathway which were not communicated to the laboratory. Blood spot card labelling errors comprised 38% of the total incidents. 35% of incidents were due to collection errors. A description of each of the level 3 & 4 incidents can be found in the quarterly reports.

Lack of consistency in reporting newborn screening incidents has previously been a problem. The National Screening Committee has published guidance on Managing Safety Incidents in NHS Screening Programmes (October 2015) which clarifies the roles and responsibilities for reporting, investigating and managing screening incidents in the context of the changes to commissioning and public health from April 2013. It defines the specific responsibilities of PHE regional quality assurance team and the NHS England Local Area Teams for investigating and managing screening incidents and the communication required between providers of NHS screening programmes and the regional QA and local area team leads. We have developed specific local guidelines for reporting and investigation of incidents in newborn blood spot screening which comply with the NSC guidance and include grading criteria and pathways for communication. These provide a framework for a standardised approach, the aim of which was to improve consistency and communication flows.

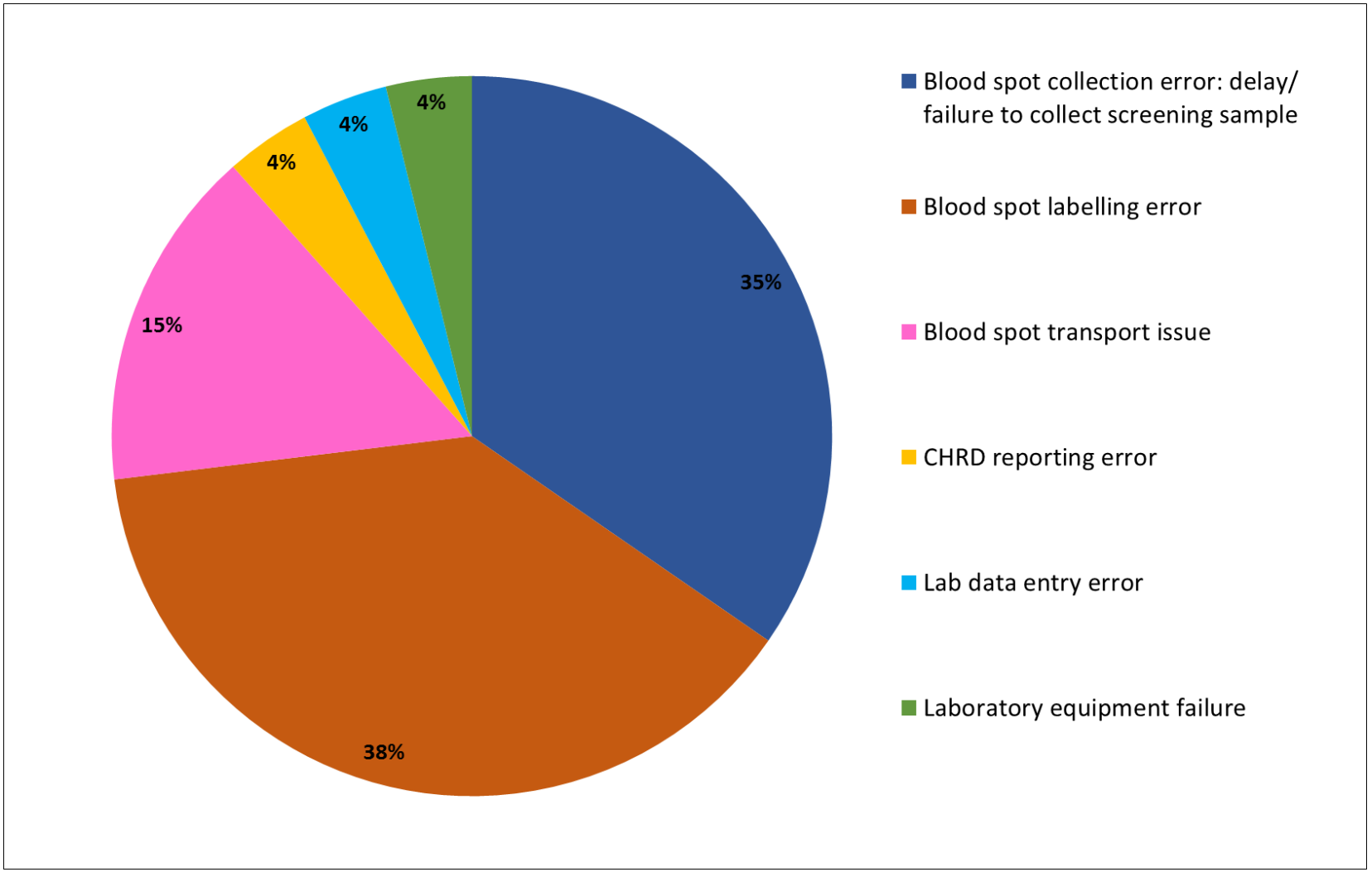
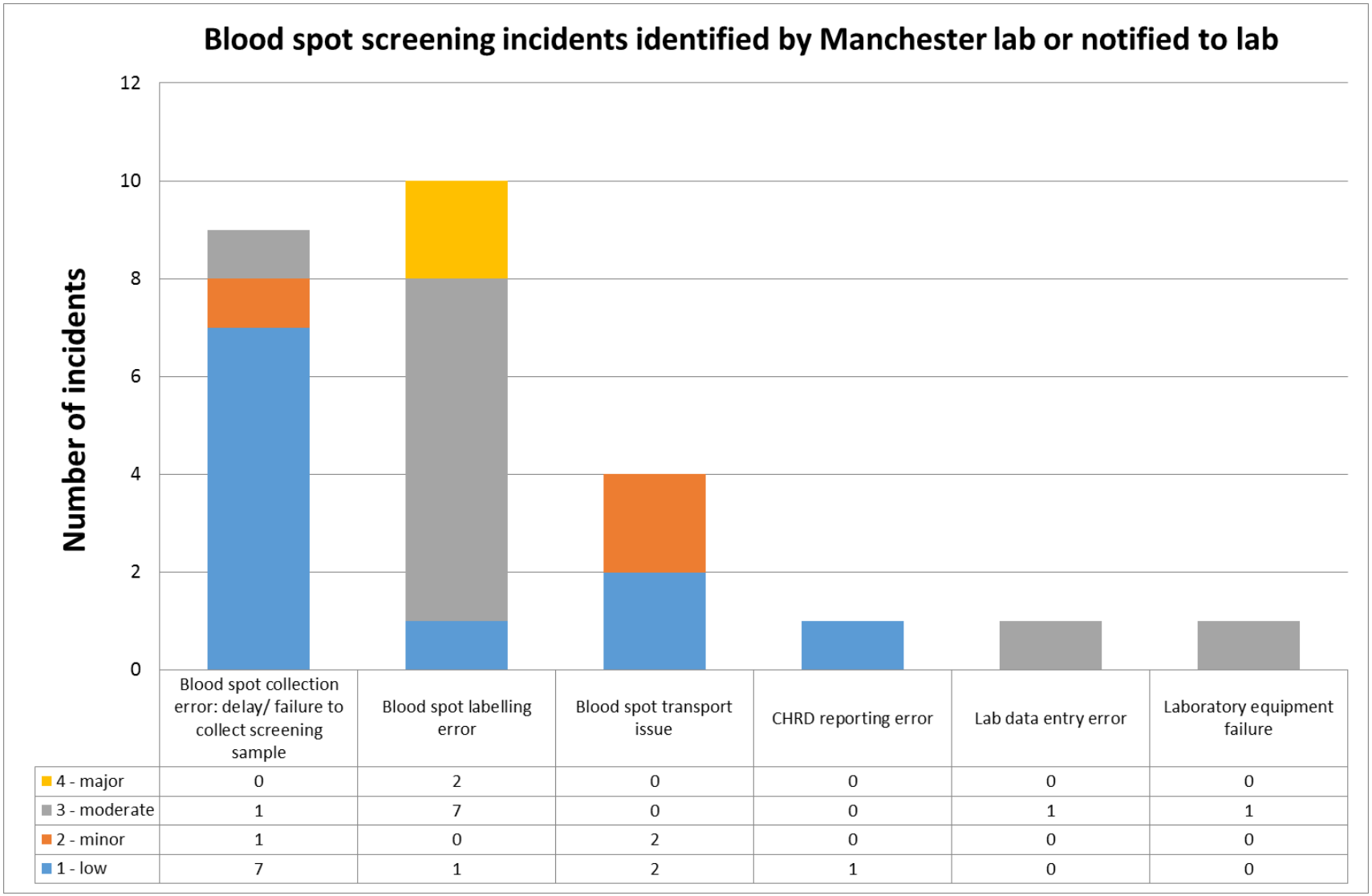


Figure 10: Newborn blood spot screening clinical incidents by cause 2018-19



	Blood spot collection error: delay/ failure to collect screening sample	Blood spot labelling error	Blood spot transport issue	CHRD reporting error	Lab data entry error	Laboratory equipment failure
4 - major	0	2	0	0	0	0
3 - moderate	1	7	0	0	1	1
2 - minor	1	0	2	0	0	0
1 - low	7	1	2	1	0	0

Figure 11: Blood Spot Screening Incidents 2018-19