Newborn Screening Laboratory
Clinical Biochemistry Department
Manchester University NHS Foundation Trust

Manchester Newborn Screening Laboratory Annual Report 2016-2017

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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 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).

2. Laboratory Staffing – April 2016

MFT Director of Newborn Screening

Lesley Tetlow BSc MSc DipCB FRCPath, Consultant Paediatric Biochemist

Newborn Screening/ Specialist Endocrine Laboratory

Clinical Scientists

- Beverly Hird BSc MSc FRCPath, Principal Clinical Scientist & Clinical Lead for Newborn Screening (0.85 WTE)
- Claire Manfredonia BSc MSc PhD Senior Clinical Scientist (rotational post) (0.8 WTE)*
- Laura Green BSc MSc PhD Senior Clinical Scientist (rotational post) (1.0 WTE)*
- Anna Robson BSc MSc MRes PhD Senior Clinical Scientist (rotational post) (1.0 WTE)*
- Chris Chaloner BSc PhD FRCPath Consultant Clinical Scientist (0.1 WTE)

* Period of rotation - 12 months.

Laura Green left in September 2016. Anna Robson was appointed in March 2016.

Biomedical Scientists

- Laura Hamilton BSc MSc FIBMS CSci Chief Biomedical Scientist (Job share post) (0.5 WTE)
- Helen Sumner BSc FIBMS CSci Chief Biomedical Scientist (Job share post) (0.5 WTE)
- Anne Walsh BSc FIBMS Senior Biomedical Scientist (1.0 WTE)
- Emma Shore MChem BSc LIBMS (0.93 WTE)

Information Analyst

- Aisha Rahman BSc MSc (0.67 WTE)

Medical Laboratory Assistants

- Gayle Mobey (0.8 WTE)
- Dawn Mechan (0.8 WTE)
- Steve Gregson BSc (1.0 WTE)

Secretarial/Clerical

- Neera Jones Screening Administrator (0.85 WTE)
- Patricia Richards Clerical assistant/data entry clerk (0.69 WTE)
- Turan Hall Clerical assistant/data entry clerk (0.8 WTE)

Willink Biochemical Genetics Laboratory

Clinical Scientists

- *Mick Henderson PhD FRCPath FRCPCH, Consultant Clinical Scientist, Director of Willink Biochemical Genetics Laboratory (0.4 WTE)
- Teresa Hoi-Yee Wu MSc FRCPath, Principal Clinical Scientist, Deputy Director of Willink Biochemical Genetics Laboratory, Head of Newborn Screening and Metabolites section (1.0 WTE)
- Alistair Horman BSc MSc PhD FRCPath, Principal Clinical Scientist, Deputy Head of Metabolites and Newborn Screening section (1.0 WTE)
- Oliver Parkes BSc MSc, Clinical Scientist (0.5 WTE)
- Pam Grundy BSc MSc PhD, Clinical Scientist (0.3 WTE)Jackie Till BSc, Senior Clinical Scientist (0.3 WTE)

Technical Staff in Metabolites and Newborn screening section with rotational duties in screening

- Robert Gibson BSc MSc MIBMS, Chief Biomedical Scientist (1.0 WTE)
- James Cooper BSc MChem, Senior Medical Technical Officer (1.0 WTE)
- Graeme Smith BSc MSc, Senior Medical Technical Officer (1.0 WTE)
- Liz Smith, Senior MLA (0.8 WTE)
- Stephen Dent BSc BSc, Associate Genetic Technologist (1.0 WTE)
- Anita Lau BSc, Assistant Genetic Technologist (1.0 WTE)
- Dale Taylor BSc, Assistant Genetic Technologist (0.3 WTE)

*Mick Henderson is Director of Willink Biochemical Genetics Laboratory in Manchester (0.4WTE) and also of the Newborn Screening and Biochemical Genetics Laboratories in Leeds Teaching Hospitals (0.6 WTE)

The staffing complement and structure of the screening laboratories at the end of the financial year (March 2017) is depicted in the following organisational chart.

Newborn Screening Staffing Structure

MFT DIRECTOR OF NEWBORN SCREENING
Lesley Tetlow

NEWBORN SCREENING/ SPECIALIST ENDOCRINE LABORATORY*

CHT, Sickle Cell and CF Screening

PRINCIPAL CLINICAL SCIENTIST (0.85)
Beverly Hird

CHIEF BIOMEDICAL SCIENTIST (1.0)
Laura Hamilton/Helen Sumner

SENIOR CLINICAL SCIENTIST (ROTATIONAL, 1.0)
Claire Manfredonia/ Laura Green/ Anna Robson

SENIOR BIOMEDICAL SCIENTIST (1.0)
Anne Walsh

SPECIALIST BIOMEDICAL SCIENTIST (0.93)
Emma Shore

PATHOLOGY SUPPORT WORKER (2.6)
Gayle Mobey
Dawn Mechan
Steve Gregson

INFORMATION ANALYST (0.67)
Aisha Rahman

SCREENING ADMINISTRATOR (0.85)
Neera Jones

CLERICAL ASSISTANTS (1.3)
Patricia Richards
Turan Hall

*All scientific staff cover both newborn screening and specialist endocrine services. The duties of pathology support workers and clerical staff are predominantly screening related.

WILLINK LABORATORY**

IMD Screening

CONSULTANT CLINICAL SCIENTIST (0.4)
Mick Henderson

PRINCIPAL CLINICAL SCIENTIST (1.0)
Teresa Wu

PRINCIPAL CLINICAL SCIENTIST (1.0)
Alistair Horman

SENIOR CLINICAL SCIENTIST (0.9)
Oliver Parkes/ Pam Grundy/ Jackie Till

CHIEF BIOMEDICAL SCIENTIST (1.0)
Robert Gibson

SENIOR MEDICAL TECHNOLOGISTS (2.0)
James Cooper / Graeme Smith

SENIOR MLA/ASSOCIATE GENETIC TECHNOLOGIST (1.8)
Liz Smith/ Stephen Dent

ASSISTANT GENETIC TECHNOLOGIST (1.3)
Anita Lau / Dale Taylor

**All Willink staff have other functions in addition to NBS within the Willink laboratory (diagnostic + screening) as a whole. Collectively screening activities account for ~20% of the WTE of this group of staff.

Equipment

- 2 x AutoDELFIA immunoassay analysers (Perkin Elmer) used for the analysis of TSH and IRT in blood spots for the purposes of newborn screening and also for blood spot 17-hydroxyprogesterone analysis for monitoring patients with CAH.
- 2 x BioRad Variant NBS HPLC system for SCD screening
- Semi-automated DELFIA system (Perkin Elmer) used for non-screening assays (plasma/serum LH/FSH and 17-α-hydroxyprogesterone).
- Microtitre plate washer and reader for manual ELISA assays for Insulin and C-peptide
- IDS iSYS used for specialised paediatric/adult endocrine tests (Growth Hormone, IGF-I, PINP, renin, aldosterone).
- Perkin Elmer Panthera for punching dried blood spot samples prior to analysis.
- Specimen Gate laboratory screening IT system (Perkin Elmer™)
- 2 x Waters MS/MS instruments (collectively used to provide both screening and diagnostic services by Willink laboratory).

Workload

A total of 59541 samples were received in the laboratory which included 55661 first samples, 2437 repeat samples and 1442 pre-transfusion 'day 0' samples.

This includes 525 samples (386 first samples, 86 pre-transfusion 'day 0' samples and 53 repeats) taken on babies that were resident in other areas of the country but were in-patients in hospitals within our catchment area.

The laboratory was notified of 181 declines for screening on a first sample, all of which were declined for all tests.

Services Provided

Newborn Screening/ Specialist Endocrine Laboratory

Newborn Screening

- Newborn Screening for congenital hypothyroidism (CHT), cystic fibrosis (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, Stockport and Tameside CHRDs.

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 Newborn Screening Laboratory was assessed by UKAS (United Kingdom Accreditation Service) against ISO 15189 standards in February 2017. Accreditation was granted subject to the clearance of a small number of findings. Evidence has been submitted to clear the findings and a response from UKAS is awaited. The Willink Laboratory has full CPA accreditation status, a UKAS assessment is planned for October 2017. Work to map the NHS Newborn Blood Spot Screening Programme standards to ISO 15189 is almost complete and assessment of screening laboratories with respect to these standards will be piloted (as part of the scheduled UKAS inspections) in the near future.

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, and achieved satisfactory results. The Newborn Screening Laboratory also takes part in the UK NEQAS Newborn Sickle Screening scheme and reported results that agreed with the consensus for all samples. Both laboratories also participate in the CDC EQA scheme for newborn screening and have received satisfactory reports all year.

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.
- Additionally data regarding blood spot quality and total "avoidable repeats" is reported monthly to the NHS Newborn Blood Spot Screening Programme.
- 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).

Research and Development

The laboratory is committed to on-going research and development both independently and in collaboration with clinical colleagues, other screening laboratories within the UK Newborn Screening Laboratory Network (UKNSLN) and NHS Newborn Bloodspot Screening Programme and National Sickle Cell and Thalassaemia Programme.
Details of oral presentations, posters and publications in 2016/17 are provided in Appendix 1.

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. The standards for newborn blood spot screening were revised by the NHS Newborn Blood Spot Screening Programme in August 2013 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 (Baby's NHS number (or UK equivalent) 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 2016 through to March 2017.
Data was collected and analysed both by CCG and maternity unit. For the sake of brevity only the analysis by CCG is included within the body of the document but tables and charts relating to analysis by maternity unit can be found in Appendix 2.

The NHS Newborn Blood Spot Screening Programme standards are as follows:

Standard 3: Baby's NHS number is included on the blood spot card

Acceptable standard: 100% of blood spot cards include the babies' NHS number

This standard states that 100% of samples should include babies' NHS number. 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, 99.7% of samples met the standard, which is the same as last year. Figure 1 also shows the number of samples that included a bar-coded label detailing the NHS number (the achievable standard states that 95% samples should include a NHS bar-coded label). The percentage of samples that included an NHS number bar-coded label varied dramatically throughout the region and ranged from 32% to 95%. Overall the usage of bar-coded labels has increased from 73% in 2015/16 to 80% this year, but still remains below the threshold for the standard.

CCG	Number of all samples (including repeats)	Number of blood spot cards including babies' NHS number	Percentage with NHS number	Percentage with bar-coded NHS number
Blackburn	3854	3848	**99.8%**	**89.8%**
Blackpool	1701	1697	**99.8%**	**82.9%**
Bolton	4182	4175	**99.8%**	**64.8%**
Bury	2509	2497	**99.5%**	**74.5%**
C Manc	3750	3742	**99.8%**	**89.3%**
Chorley	1920	1920	**100.0%**	**92.1%**
S Cumbria	1639	1630	**99.5%**	**79.3%**
E Lancs	3257	3253	**99.9%**	**91.5%**
Fylde & Wyre	1515	1511	**99.7%**	**82.6%**
Grt Preston	2725	2722	**99.9%**	**94.5%**
HMR	3252	3241	**99.7%**	**65.4%**
N Lancs	1683	1676	**99.6%**	**79.6%**
N Manc	2759	2741	**99.3%**	**78.9%**
Oldham	3499	3482	**99.5%**	**66.1%**
Salford	3866	3851	**99.6%**	**80.0%**
S Manc	2204	2203	**100.0%**	**91.8%**
Stockport	3612	3605	**99.8%**	**86.7%**
Tameside	3447	3444	**99.9%**	**86.4%**
Trafford	2931	2926	**99.8%**	**91.9%**
W Lancs	869	866	**99.7%**	**31.9%**
Wigan	3842	3829	**99.7%**	**63.6%**
Out of region	525	516	**98.3%**	**59.0%**
Total	59541	59375	**99.7%**	**79.9%**

Table 1: Data for standard 3 showing number of cards that include NHS number

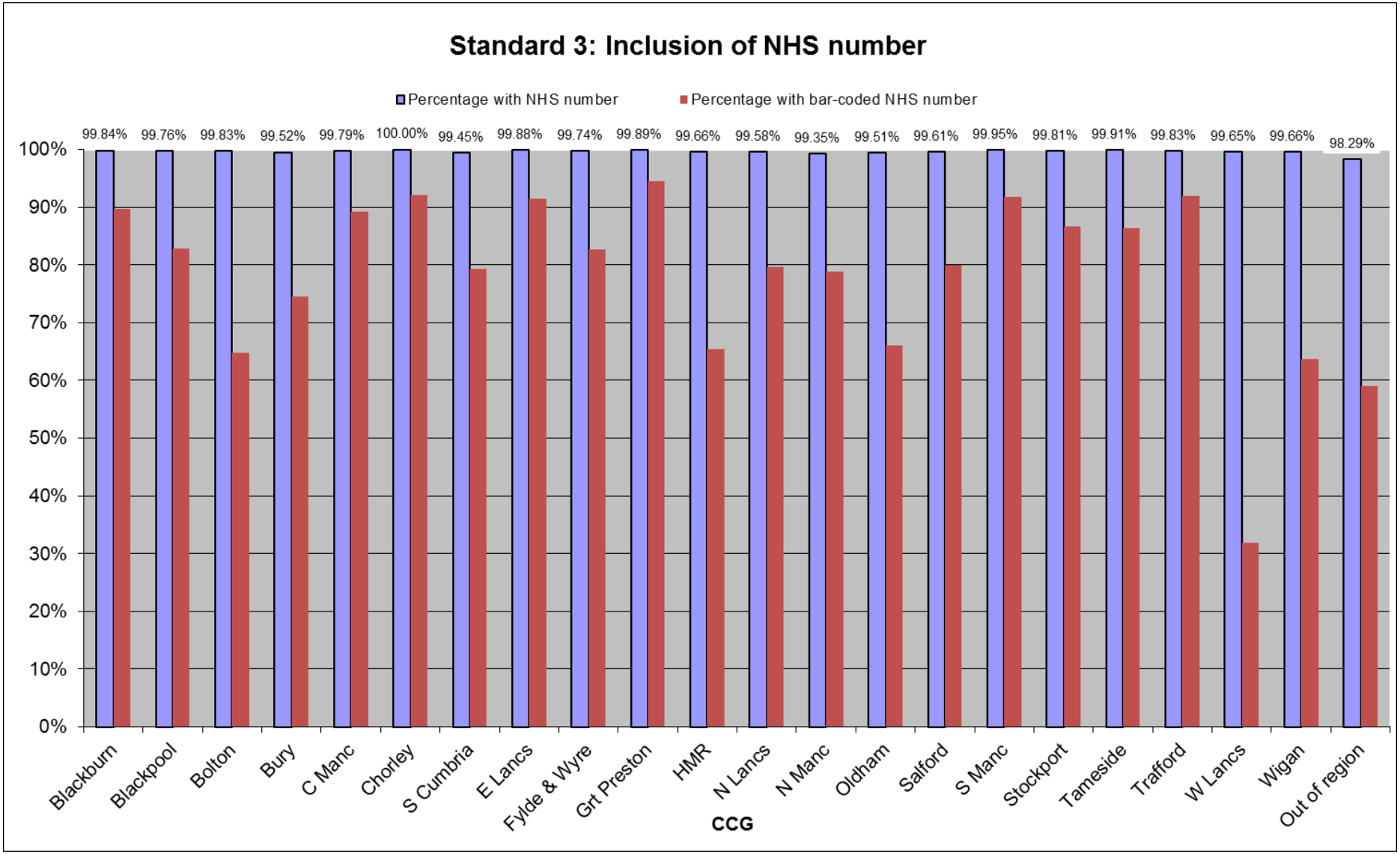

Figure 1: Graph to show percentage of cards that included NHS number for period April 2016–March 2017

Standard 4: Timely sample collection

Acceptable standard: 95% of first samples taken 5-8 days after birth

The data corresponding to this standard is shown in Figure 2. All CCGs met the acceptable threshold (95%). Overall 98.0% of first samples were collected on days 5-8, which is similar to 2015/16 (97.6%). The 'achievable' threshold of 99% was met by 9 CCGs (Bolton, Bury, C Manchester, Chorley, S Cumbria, Trafford, W Lancs and Wigan). The percentage collected on day 5 varied throughout the region ranging from 57% for Blackpool CCG to 92% for Cumbria CCG (80% overall).

CCG	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
Blackburn	11	2007	951	360	66	107	**0.3%**	**57.3%**	**27.2%**	**10.3%**	**1.9%**	**3.1%**
Blackpool	5	927	355	270	37	28	**0.3%**	**57.2%**	**21.9%**	**16.6%**	**2.3%**	**1.7%**
Bolton	5	3047	546	144	26	51	**0.1%**	**79.8%**	**14.3%**	**3.8%**	**0.7%**	**1.3%**
Bury	6	1772	424	93	10	26	**0.3%**	**76.0%**	**18.2%**	**4.0%**	**0.4%**	**1.1%**
C Manc	7	3007	205	34	13	122	**0.2%**	**88.8%**	**6.1%**	**1.0%**	**0.4%**	**3.6%**
Chorley	5	1481	288	37	6	7	**0.3%**	**81.2%**	**15.8%**	**2.0%**	**0.3%**	**0.4%**
S Cumbria	5	1414	89	11	2	13	**0.3%**	**92.2%**	**5.8%**	**0.7%**	**0.1%**	**0.8%**
E Lancs	12	1948	729	184	31	72	**0.4%**	**65.5%**	**24.5%**	**6.2%**	**1.0%**	**2.4%**
Fylde & Wyre	3	864	312	230	31	18	**0.2%**	**59.3%**	**21.4%**	**15.8%**	**2.1%**	**1.2%**
Grt Preston	7	1947	555	69	15	20	**0.3%**	**74.5%**	**21.2%**	**2.6%**	**0.6%**	**0.8%**
HMR	2	2761	238	48	14	52	**0.1%**	**88.6%**	**7.6%**	**1.5%**	**0.4%**	**1.7%**
N Lancs	3	1308	185	30	12	24	**0.2%**	**83.7%**	**11.8%**	**1.9%**	**0.8%**	**1.5%**
N Manc	5	2094	319	53	12	55	**0.2%**	**82.5%**	**12.6%**	**2.1%**	**0.5%**	**2.2%**
Oldham	6	2917	280	45	12	64	**0.2%**	**87.8%**	**8.4%**	**1.4%**	**0.4%**	**1.9%**
Salford	5	3053	311	62	17	86	**0.1%**	**86.4%**	**8.8%**	**1.8%**	**0.5%**	**2.4%**
S Manc	1	1931	112	12	2	38	**0.0%**	**92.1%**	**5.3%**	**0.6%**	**0.1%**	**1.8%**
Stockport	12	2909	339	47	12	39	**0.4%**	**86.6%**	**10.1%**	**1.4%**	**0.4%**	**1.2%**
Tameside	13	2384	623	148	28	54	**0.4%**	**73.4%**	**19.2%**	**4.6%**	**0.9%**	**1.7%**
Trafford	5	2550	167	16	6	26	**0.2%**	**92.1%**	**6.0%**	**0.6%**	**0.2%**	**0.9%**
W Lancs	4	660	110	20	5	9	**0.5%**	**81.7%**	**13.6%**	**2.5%**	**0.6%**	**1.1%**
Wigan	7	3121	345	65	8	35	**0.2%**	**87.2%**	**9.6%**	**1.8%**	**0.2%**	**1.0%**
Out of region	2	277	63	17	10	16	**0.5%**	**71.9%**	**16.4%**	**4.4%**	**2.6%**	**4.2%**
Total	131	44379	7546	1995	375	962	**0.2%**	**80.1%**	**13.6%**	**3.6%**	**0.7%**	**1.7%**

Table 2: Data for Standard 4 showing the number of cards taken in a timely manner (between days 5-8)

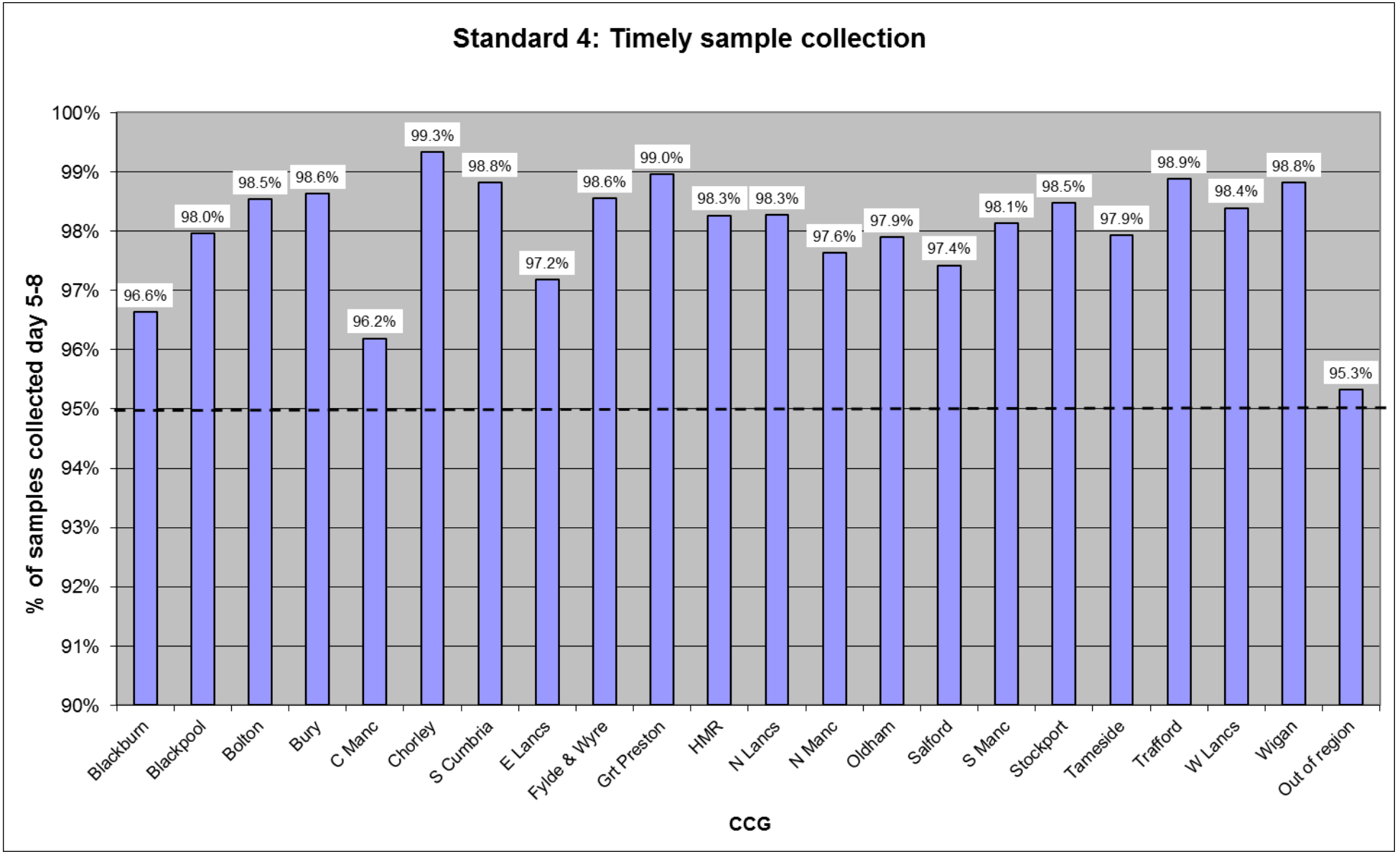

Figure 2: Graph to show percentage of samples taken 5-8 days after birth

Standard 5: Timely receipt of samples in NBS laboratory

Acceptable standard: 100% of samples to be received by laboratory within 4 working days.

The data corresponding to this standard is shown in Figure 3. Overall 99.2% were received within 4 working days (range 97-100%). The developmental target for standard 4 is that 100% of cards are received within 3 working days. The percentage of cards that were received within 3 working days ranged from 84.2% to 99.7% (overall 97.3%).

CCG	Number of samples received			Percentage of samples received		
	in 3 or fewer working days of sample being taken	in 4 or fewer working days of sample being taken	on or after 5 working days of sample being taken	In 3 or fewer working days of sample being taken	In 4 or fewer working days of sample being taken	On or after 5 working days of sample being taken
Blackburn	3656	3673	6	**99.4%**	**99.8%**	**0.2%**
Blackpool	1645	1672	9	**97.9%**	**99.5%**	**0.5%**
Bolton	3957	3976	4	**99.4%**	**99.9%**	**0.1%**
Bury	2374	2416	12	**97.8%**	**99.5%**	**0.5%**
C Manc	3508	3532	13	**99.0%**	**99.6%**	**0.4%**
Chorley	1887	1892	0	**99.7%**	**100.0%**	**0.0%**
S Cumbria	1542	1581	27	**95.9%**	**98.3%**	**1.7%**
E Lancs	3079	3101	11	**98.9%**	**99.6%**	**0.4%**
Fylde & Wyre	1451	1496	10	**96.3%**	**99.3%**	**0.7%**
Grt Preston	2690	2693	3	**99.8%**	**99.9%**	**0.1%**
HMR	3081	3186	20	**96.1%**	**99.4%**	**0.6%**
N Lancs	1482	1607	40	**90.0%**	**97.6%**	**2.4%**
N Manc	2545	2643	39	**94.9%**	**98.5%**	**1.5%**
Oldham	3332	3428	21	**96.6%**	**99.4%**	**0.6%**
Salford	3621	3675	20	**98.0%**	**99.5%**	**0.5%**
S Manc	2143	2156	6	**99.1%**	**99.7%**	**0.3%**
Stockport	3298	3442	101	**93.1%**	**97.1%**	**2.9%**
Tameside	3306	3338	35	**98.0%**	**99.0%**	**1.0%**
Trafford	2844	2863	15	**98.8%**	**99.5%**	**0.5%**
W Lancs	717	828	23	**84.3%**	**97.3%**	**2.7%**
Wigan	3677	3749	17	**97.6%**	**99.5%**	**0.5%**
Out of region	421	435	5	**95.7%**	**98.9%**	**1.1%**
Total	56256	57382	437	**97.3%**	**99.2%**	**0.8%**

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)

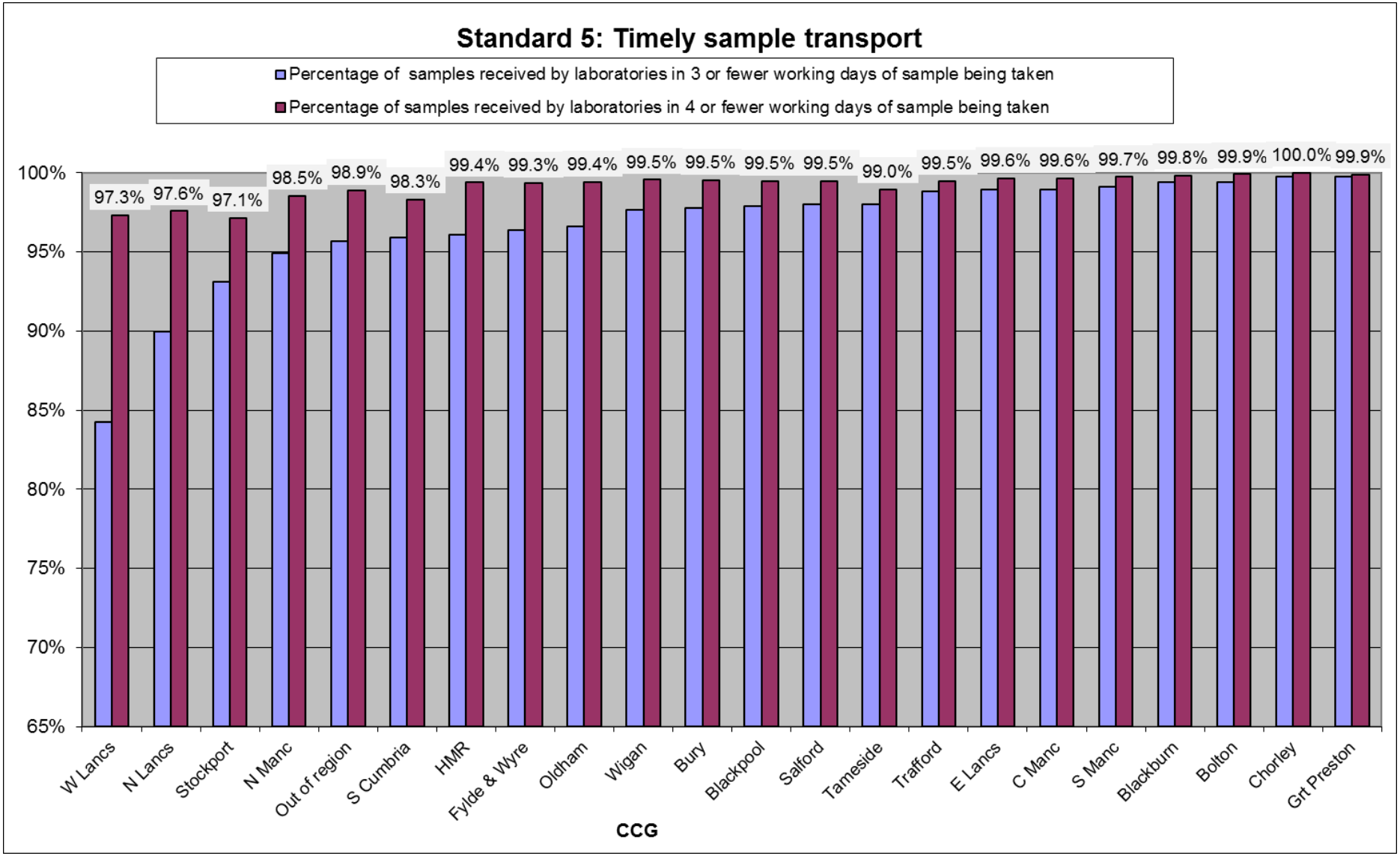

Figure 3: Graph to show percentage of samples received within 3 and 4 working days of being taken

Standard 6: Quality of blood spot sample

Acceptable standard: The avoidable repeat rate is less than or equal to 2%.

An avoidable repeat can be classified as follows:

- Sample taken too soon (< 5 days)
- Sample taking too long to reach the laboratory (> 14 days)
- Sample taken too soon after a transfusion (within 72 hrs)
- Insufficient blood: too small or not soaked through
- Unsatisfactory sample/ card: incorrect blood application such as multi-spotting, expired card, compressed/ damaged
- No valid NHS number
- Contamination (discrepant IRT)

Insufficient/ unsatisfactory samples remain the biggest contributor to the avoidable repeat rate, followed by missing/invalid NHS numbers. Figure 4 shows the avoidable repeat rate per CCG and also shows how each cause of sample rejection contributes to the overall avoidable repeat rate. This data is also tabulated in table 4. The acceptable rate for avoidable repeats is 2%. This year, 12 out of 21 CCGs achieved the standard (57% of CCGs; compared with 14% of CCGs during 2015/16).

The overall percentage avoidable repeat rate was 2.1% (ranging from 1.3 to 3.8%) which is an improvement compared with last year (3.3%; ranging from 1.4 to 5.6%).

The avoidable repeat rate for samples collected from in-patients (5.5%) was three times higher than the rate for those collected in the community (1.7%). Table 5 shows the avoidable repeat rate for each hospital within the area of coverage. This data is also displayed graphically in Figure 5.

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

CCG	Number of first samples received/ babies tested	Status code 0301: too young for reliable screening (≤ 4 days)	Status code 0302: too soon after transfusion (<72 hours)	Status code 0303: insufficent sample	Status code 0304: unsuitable sample (blood quality): incorrect blood application	Status code 0305: unsuitable sample (blood quality): compressed/ damaged	Status code 0306: unsuitable sample: day 0 and day 5 on same card	Status code 0307: unsuitable sample for CF: discrepant IRT replicates, possible faecal contamination	Status code 0308: unsuitable sample: NHS number missing/not accurately recorded	Status code 0309: unsuitable sample: date of sample missing/not accurately recorded	Status code 0310: unsuitable sample: date of birth not accurately matched	Status code 0311: unsuitable sample: expired card used	Status code 0312: unsuitable sample: >14 days in transit, too old for analysis	Status code 0313: unsuitable sample: damaged in transit	Avoidable Repeat Requests Rate
NHS Blackburn with Darwen CCG	3510	9	8	44	0	1	0	1	2	4	0	3	0	0	**1.8%**
NHS Blackpool CCG	1626	5	2	7	1	0	0	1	4	6	0	0	0	0	**1.5%**
NHS Bolton CCG	3826	4	8	41	0	4	0	6	3	2	0	3	0	0	**1.6%**
NHS Bury CCG	2341	5	1	16	1	2	0	6	10	7	1	2	0	0	**2.1%**
NHS Central Manchester CCG	3407	7	15	16	2	7	0	7	5	20	0	1	0	0	**1.9%**
NHS Chorley and South Ribble CCG	1836	5	5	14	0	1	0	4	0	12	0	2	0	0	**2.1%**
NHS Cumbria CCG	1552	5	0	6	3	3	0	0	8	18	0	3	1	0	**3.0%**
NHS East Lancashire CCG	2990	12	11	27	0	1	0	3	3	5	0	2	0	0	**1.8%**
NHS Fylde and Wyre CCG	1461	3	0	10	0	0	0	0	4	3	0	2	0	0	**1.5%**
NHS Greater Preston CCG	2620	7	5	18	1	1	0	2	1	8	0	2	0	0	**1.5%**
NHS Heywood, Middleton and Rochdale CCG	3124	2	1	11	1	6	0	3	10	5	0	1	0	0	**1.2%**
NHS Lancashire North CCG	1579	3	2	15	4	3	0	2	6	19	0	0	0	0	**3.3%**
NHS North Manchester CCG	2552	5	0	53	2	2	0	3	16	14	0	0	0	0	**3.7%**
NHS Oldham CCG	3334	5	3	10	1	1	0	3	15	5	0	2	0	0	**1.3%**
NHS Salford CCG	3556	6	4	38	1	4	0	8	11	15	1	3	0	0	**2.4%**
NHS South Manchester CCG	2102	1	0	11	4	1	0	3	1	5	0	0	1	0	**1.3%**
NHS Stockport CCG	3386	14	3	43	2	2	0	13	7	21	0	6	1	2	**3.3%**
NHS Tameside and Glossop CCG	3251	12	2	19	4	0	0	11	3	4	1	7	0	0	**1.9%**
NHS Trafford CCG	2777	6	2	16	4	2	0	8	3	6	0	2	1	0	**1.7%**
NHS West Lancashire CCG	822	3	2	6	1	1	0	3	3	14	0	0	0	0	**3.8%**
NHS Wigan Borough CCG	3606	7	3	48	2	1	0	1	13	25	0	1	1	0	**2.7%**
Out of region	403	2	18	9	0	0	0	1	6	1	0	1	0	0	**5.0%**
Grand Total	55661	128	95	478	34	43	0	89	134	219	3	43	5	2	**2.1%**

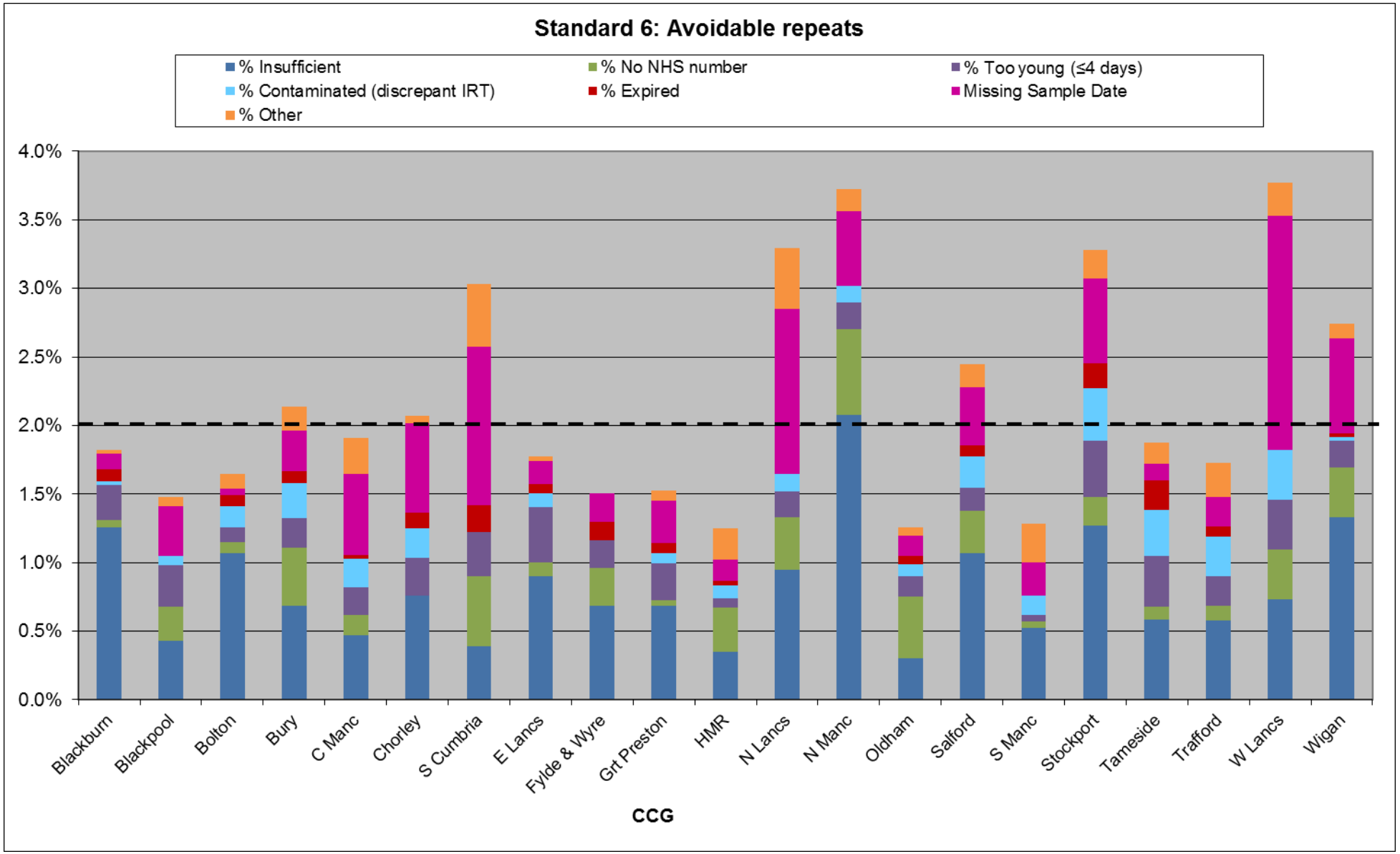

Figure 4: Graph to show avoidable repeat rate by CCG

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

Current Hospital	Number of first samples received/ babies tested	Status code 0301: too young for reliable screening (≤ 4 days)	Status code 0302: too soon after transfusion (<72 hours)	Status code 0303: insufficent sample	Status code 0304: unsuitable sample (blood quality): incorrect blood application	Status code 0305: unsuitable sample (blood quality): compressed / damaged	Status code 0306: unsuitable sample: day 0 and day 5 on same card	Status code 0307: unsuitable sample for CF: discrepant IRT replicates, possible faecal contamination	Status code 0308: unsuitable sample: NHS number missing/not accurately recorded	Status code 0309: unsuitable sample: date of sample missing/not accurately recorded	Status code 0310: unsuitable sample: date of birth not accurately matched	Status code 0311: unsuitable sample: expired card used	Status code 0312: unsuitable sample: >14 days in transit, too old for analysis	Status code 0313: unsuitable sample: damaged in transit	Avoidable Repeat Requests Rate
Burnley General Hospital	**617**	9	19	20	0	1	0	1	0	3	0	0	0	0	**5.5%**
The Royal Bolton Hospital	**494**	2	12	10	3	2	0	4	2	0	0	0	0	0	**4.7%**
Blackpool Victoria Hospital	**290**	1	0	6	1	0	0	0	1	3	0	0	0	0	**4.1%**
Furness General Hospital	**74**	0	0	2	1	1	0	0	0	2	0	0	0	0	**8.1%**
North Manchester General Hospital	**417**	4	0	24	2	3	0	2	2	1	0	0	0	0	**9.1%**
Not in hospital	**49638**	82	6	333	9	25	0	70	95	184	3	38	3	2	**1.7%**
Ormskirk & District General	**121**	0	2	2	0	1	0	0	3	1	0	0	0	0	**5.8%**
Royal Albert Edward Infirmary	**292**	5	2	18	0	0	0	1	5	6	0	0	0	0	**12.0%**
Royal Blackburn Hospital	**41**	1	0	0	1	0	0	0	0	0	0	0	0	0	**4.9%**
Royal Lancaster Infirmary	**177**	1	0	5	3	0	0	0	1	4	0	0	0	0	**7.9%**
Royal Manchester Children's Hospital	**35**	3	2	5	0	0	0	0	6	0	0	1	0	0	**42.9%**
Royal Oldham Hospital	**675**	2	5	6	0	5	0	1	9	3	0	0	0	0	**3.9%**
Royal Preston Hospital	**428**	2	10	6	1	1	0	1	0	2	0	1	0	0	**3.3%**
Stepping Hill Hospital	**307**	3	1	7	2	0	0	2	1	1	0	1	0	0	**5.5%**
St Mary's Hospital, Manchester	**1336**	9	36	16	3	4	0	3	4	8	0	0	1	0	**3.6%**
Tameside General Hospital	**263**	2	0	1	2	0	0	0	2	0	0	2	0	0	**3.4%**
University Hospital of South Manchester	**453**	2	0	17	6	0	0	4	3	1	0	0	1	0	**7.5%**
Chorley South Ribble Hospital	**1**	0	0	0	0	0	0	0	0	0	0	0	0	0	**0.0%**
United Kingdom Out of Region	**2**	0	0	0	0	0	0	0	0	0	0	0	0	0	**0.0%**
Grand Total	**55661**	128	95	478	34	43	0	89	134	219	3	43	5	2	**2.1%**

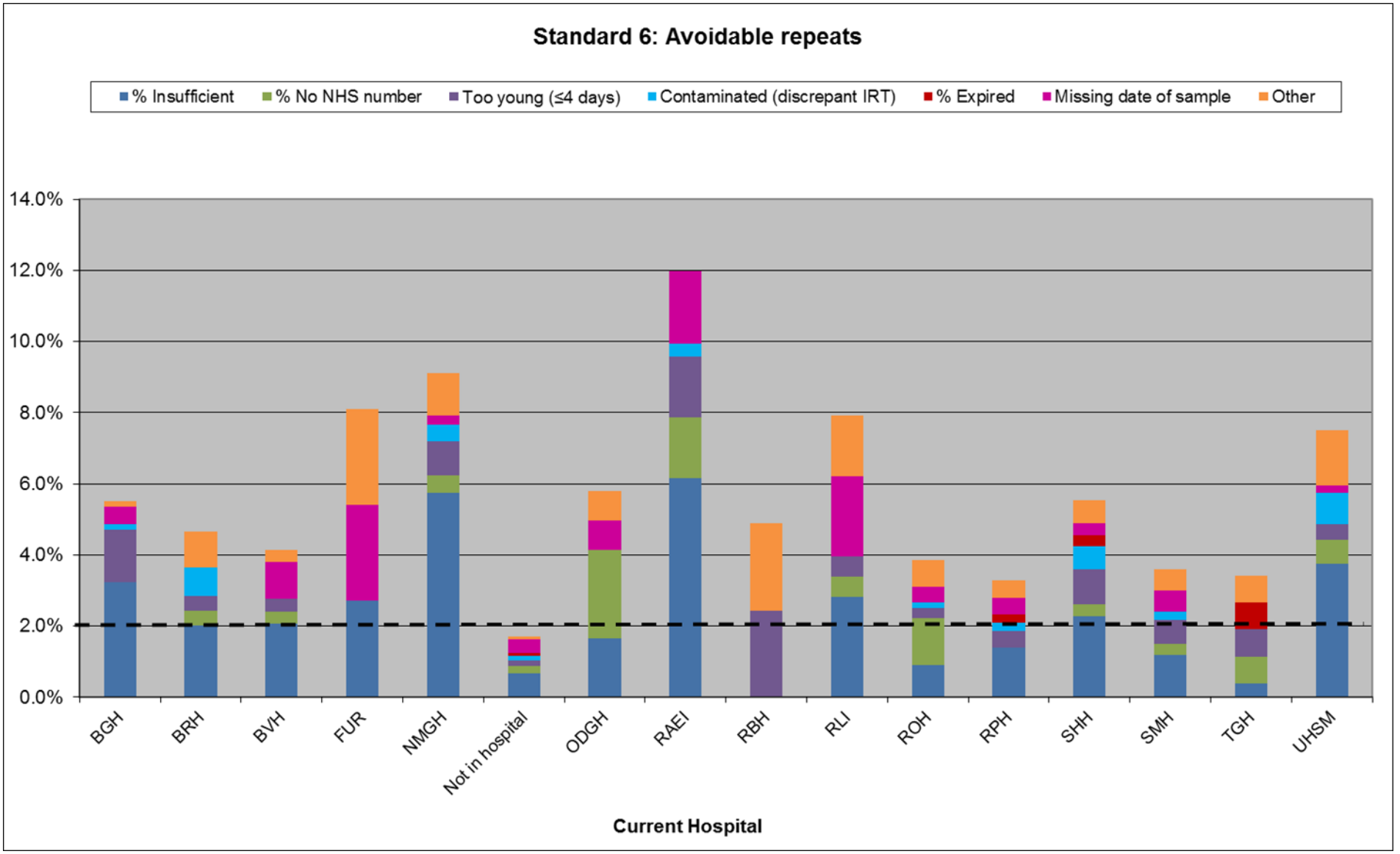

Figure 5: Graph to show avoidable repeat samples collected from babies in hospital compared with samples collected in the community

Note: Royal Manchester Children's Hospital excluded from graph (avoidable repeat rate 42%)

5. Clinical Referral Data

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

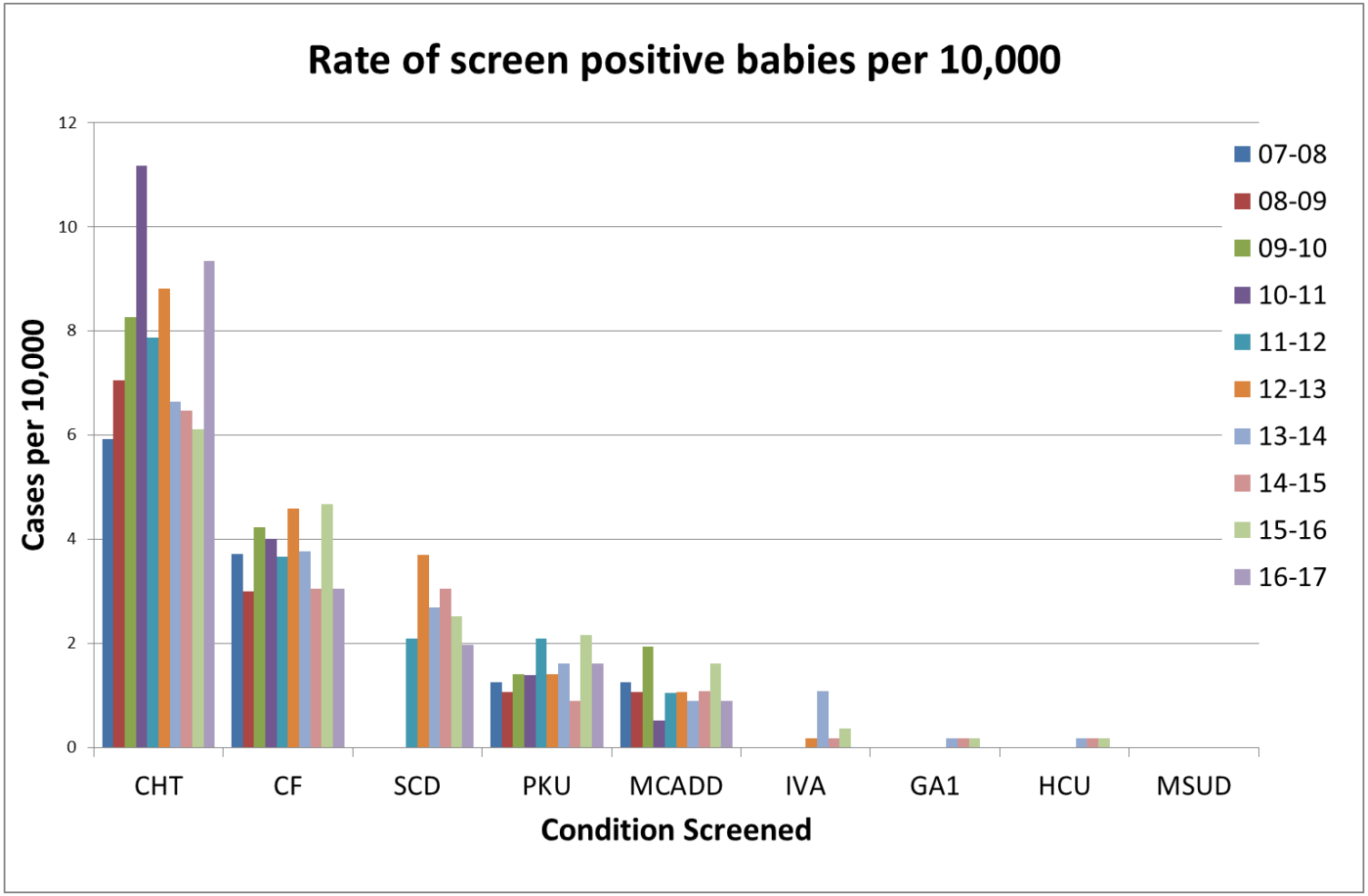

Figure 6: Rate of screen positive babies (per 10000) from 2007 onwards

Positive Cases 2017-2018

PKU Screening

Nine cases of confirmed raised phenylalanine were followed up clinically by medical staff at the Willink Unit. There were 7 confirmed PKU cases, giving an estimated incidence of 1: 7952 (birth rate assumed to equal number of first samples received). One case was a sibling of a known PKU patient who had an early sample collected on day 2 and was referred on day 5. Two screen positive babies (in-patients) were classified as false positives. One died on day 10, prior to clinical referral and the other died on day 14 (2 days after referral, liver failure).

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 5-14 days. The acceptable threshold was met for standard 11 – timely receipt into clinical care. Excluding two babies who died, 100% attended their first clinic appointment by day 17 (7/7). One baby's sample was delayed in the post and arrived 7 days after collection (referred on day 14, appointment on day 17). The remaining babies with positive results had a clinic appointment by 14 days of age (6/7, 86%, range 6-12 days).

MCADD Screening

There were 5 screen positives for MCADD and 4 were confirmed as MCADD cases, giving an estimated incidence of 1 in 13915. The other screen positive baby was diagnosed with LCHADD/MTP deficiency (affected sibling, acylcarnitines tested on day 2). One MCADD case with an affected sibling had a clinic appointment on day 3 following an early screening sample. The other 3 screen positives were referred within 3 working days. The age at referral ranged from 7-10 days. All babies had their first clinic appointment by day 12.

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

There were two screen positives for HCU, both of which were referred within 3 working days and were confirmed as false positives. Both babies died during the second week of life and

also had false positive results for PKU. There were no screen positive babies for IVA, GA2 or MSUD.

CHT Screening

All raised TSH levels (>5 mU/L) were checked in duplicate on the original sample and the average result was taken. Samples with confirmed levels >20 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 32 such cases and the blood spot TSH ranged from 20 mU/L to >255 mU/L.

Confirmed TSH levels between 8 and 20 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 mU/L) clinical follow up was initiated at RMCH. Of the 139 initial borderline results (using a local cut off of 8 mU/L as opposed to the national cut off of 10 mU/L), 18 (13%) were treated as positive following repeat sampling with a TSH ranging from 8 to 101 mU/L on repeat.

There were two cases of screen positive results on premature babies following two borderline results. In both cases the initial day 5 sample was normal and two subsequent repeats were in the borderline range, requiring referral. Both babies were in-patients and one baby was on thyroxine at the time of referral.

The number of positive cases (identified on the first sample) per trust is shown in Table 6. The clinical referral guidelines state that for babies identified as CHT positive on the initial screening sample 100% should be on treatment by 17 days of age (acceptable standard). 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 8-14 days). The first clinic appointment was attended by day 14 in all cases, which met the achievable standard. Two babies detected clinically were already on treatment at the time of referral.

The clinical referral guidelines state that, for babies identified as CHT on a repeat blood spot sample that follows a borderline TSH, 100% should be on treatment by 24 days of age (acceptable standard). 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 20 days (range 16-53), excluding 3 babies on treatment prior to referral. The first clinic appointment was attended by day 24 in 13 cases (76%; in-patients evaluated on the day of referral). Four babies exceeded 24 days, including a premature baby with multiple samples (referred on day 53).

The national guidelines for clinical referral of CHT babies state that parents should be offered an appointment within three days of being informed about their baby's positive screening result. All babies referred by our screening laboratory are given an appointment within 1 day of the parents being informed of the result. The guidelines also state that clinical referral should be initiated within four working days of sample receipt by the laboratory for 100% of cases. All positive CHT cases were referred within 3 working days.

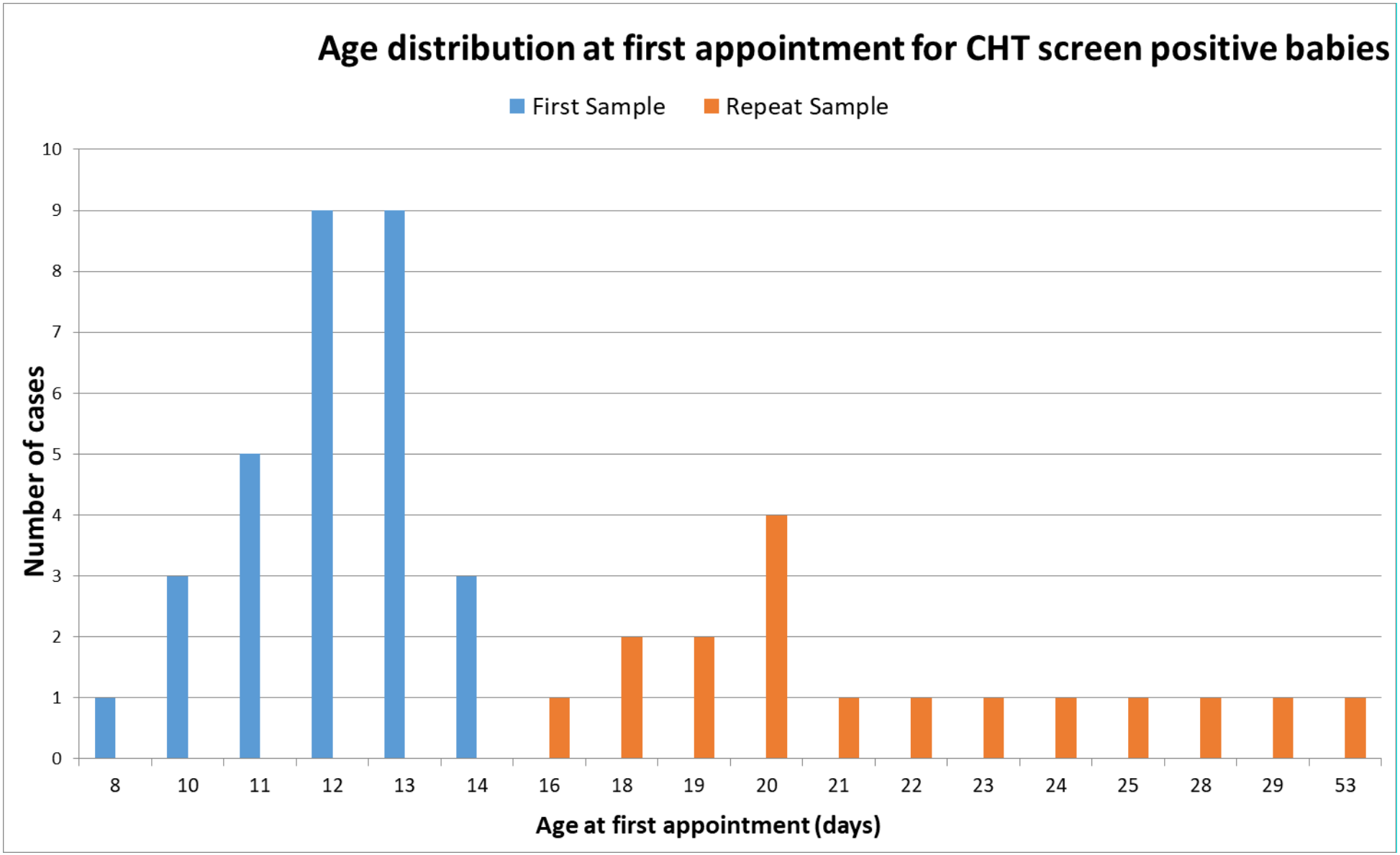

Figure 7: Graph to show age at first appointment for each positive CHT case (in days)

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)
Blackpool Teaching Hospitals NHS Foundation Trust	1	13
Bolton NHS Foundation Trust	2	10,13
Central Manchester University Hospitals NHS Foundation Trust	6	8-14
East Lancashire Hospitals NHS Trust	3	11,12,13
Lancashire Teaching Hospitals NHS Foundation Trust	1	13
Pennine Acute Hospitals NHS Trust	11	10-14,
Stockport NHS Foundation Trust	2	13,14
University Hospital Of South Manchester NHS Foundation Trust	4	11-12
Wrightington, Wigan And Leigh NHS Foundation Trust	2	11,13

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, two babies detected prior to referral: CMFT & Pennine)

Trust	Number of cases	Age at first clinic appointment (days)
Central Manchester University Hospitals NHS Foundation Trust	4	16,18,28
East Lancashire Hospitals NHS Trust	3	20,20,29
Lancashire Teaching Hospitals NHS Foundation Trust	1	19
Pennine Acute Hospitals NHS Trust	4	18,20,24
Wrightington, Wigan And Leigh NHS Foundation Trust	1	23
Bolton NHS Foundation Trust	2	19,53
Stockport NHS Foundation Trust	2	22,25
Tameside And Glossop Integrated Care NHS Foundation Trust	1	20
University Hospital Of South Manchester NHS Foundation Trust	2	21

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, 3 babies detected prior to referral: CMFT, Pennine, UHSM)

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/collections/newborn-blood-spot-screening-programme-supporting-publications) and involves the analysis of IRT on the initial blood spot sample taken at day 5-8 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 2016/17 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.

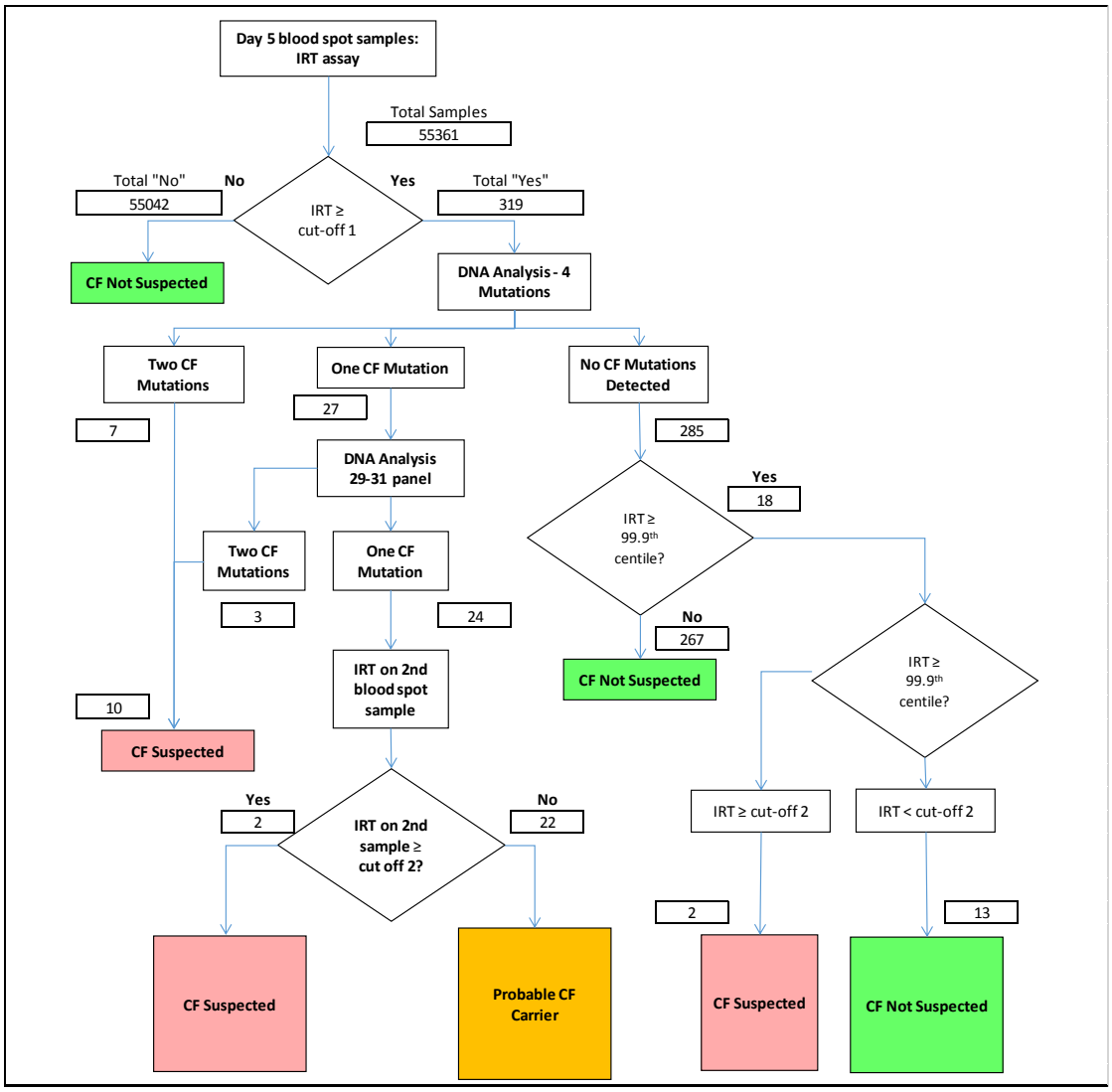

Figure 8: CF screening algorithm displaying the numbers detected in each category for Manchester Newborn Screening Lab in 2016/17

Year	07/08	08/09	09/10	10/11	11/12	12/13	13/14	14/15	15/16	16/17
Babies Screened	26931	55627	56720	57281	57142	56585	55603	55469	55407	55361
Samples referred for DNA	116 (0.43%)	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%)
CF Suspected	11 (11)	17 (23)	24 (23)	23 (23)	21 (23)	26 (23)	21 (23)	17 (23)	26 (23)	15 (23)
2 mutations on 4 mutation panel	6 (8)	12 (17)	11 (17)	14 (17)	16 (17)	16 (17)	8 (17)	12 (17)	12 (17)	7 (17)
2 mutations on extended panel	1 (1)	1 (3)	5 (3)	4 (3)	1 (3)	6 (3)	10 (3)	4 (3)	5 (3)	3 (3)
1 mutation + 2nd IRT >cut-off 2	0 (1)	3 (3)	2 (3)	1 (3)	1 (3)	2 (3)	1 (3)	0 (3)	4 (3)	2 (3)
No mutation + 2nd IRT>cut-off 2	4 (0)	1 (1)	6 (1)	4 (1)	3 (1)	2 (1)	2 (1)	1 (1)	4 (1)	3* (1)
CF probable carriers	5 (13)	13 (28)	16 (28)	22 (28)	12 (29)	6 (28)	17 (28)	13 (28)	21 (28)	22 (28)

Table 8: CF Outcome Data for CF Since Programme Implementation

Figures in parentheses are numbers predicted from the national algorithm; * includes one baby initially reported as 'not suspected' but subsequent IRT samples were abnormal (not included in figure 8).

The percentage of samples referred for DNA testing was 0.58%, which is slightly above the target of 0.5%. However this figure did fluctuate throughout the year (0.29-0.77%) probably due to lot to lot variation of the IRT kits. 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.

The total number of babies who were screen positive was much lower than previous years and lower than the figure predicted from the national algorithm. This is likely to be due to normal fluctuations in the positive rate, due to chance. This year there were no babies detected prior to screening due to having an affected sibling. The number of carriers identified was similar to last year and higher than most other years.

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 14–22 days). The median age at first clinic appointment for this group was 20 days and the achievable standard was met (range 15-23 days).

Of the CF positives identified following a second raised IRT 75% (3/4) had a clinic appointment by day 35, excluding one baby initially reported as 'not suspected' but whose subsequent IRT samples were abnormal. The median age for referral for this group was 31 days (range 26–35 days). The median age at first clinic appointment was 33 days (range 27-41 days).

As expected, CF was confirmed in all 10 double mutation cases. In those babies with positive results following a repeat IRT, CF was excluded in 4 babies and confirmed in 1 baby, following sweat testing.

Trust	Number of cases	Age at first appointment
Blackpool Teaching Hospitals NHS	1	22
Bolton NHS Foundation Trust	3	15,19,22
Central Manchester University Hospitals NHS Foundation Trust	2	**31,47**
East Lancashire Hospitals NHS Trust	2	20,**27**
Lancashire Teaching Hospitals NHS	1	**41**
Southport And Ormskirk Hospital NHS	3	19,23,**34**
Tameside And Glossop Integrated	2	20,21
Wrightington, Wigan And Leigh NHS Foundation Trust	1	16

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.

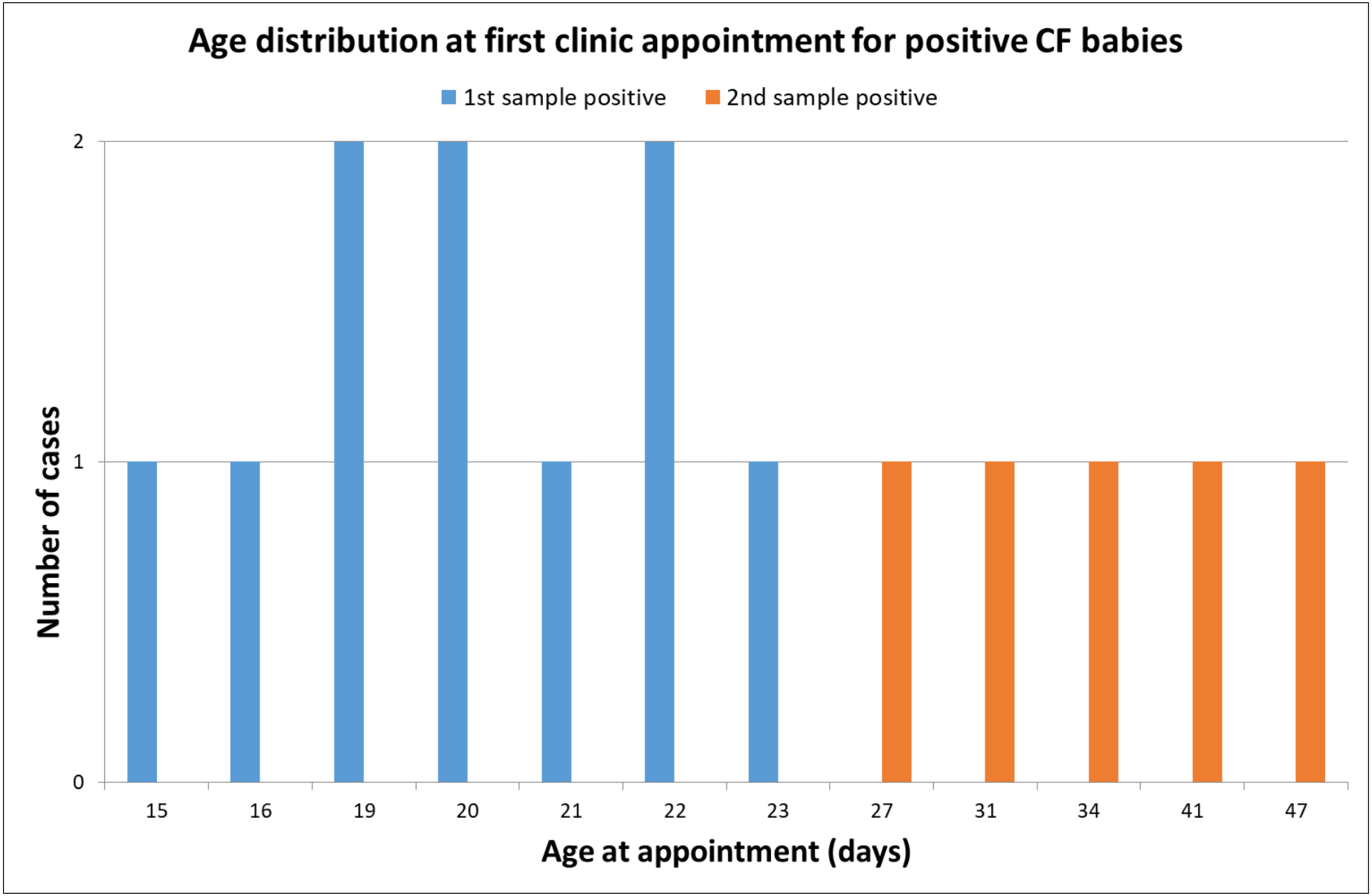

Figure 9: Graph to show the age at first clinic appointment for CF Suspected cases.

In 2016/17, of 300 babies missing CF screening, 298 (99%) were born outside 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. Two UK–born babies missed CF screening. One was born in Scotland and is likely to have been screened there. The other baby, born at St. Mary's, has a sample collected on day 4 (too early). The repeat sample was collected after 8 weeks of age. Figures 10 and 11 give a breakdown of babies who missed CF screening by CCG. In figure 11 the numbers are expressed as a rate per 10,000 babies screened to enable better comparison between the CCGs.

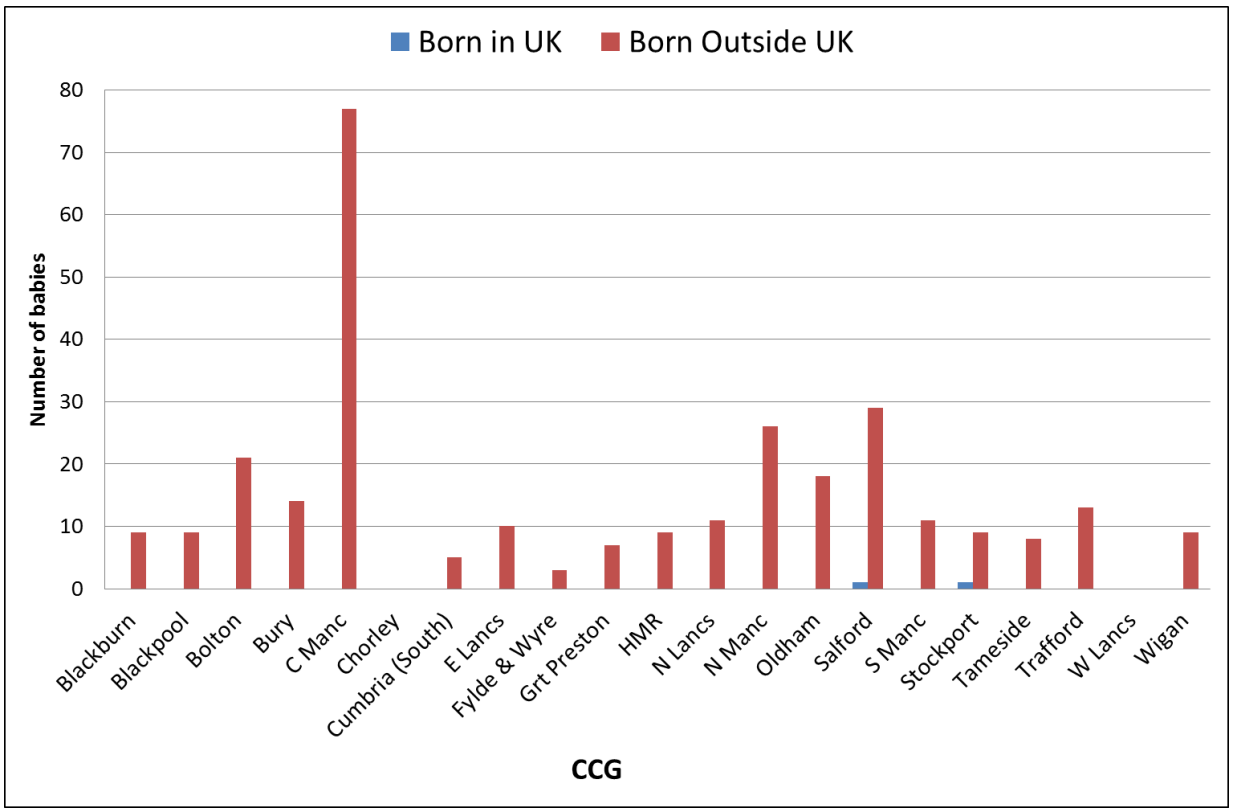

Figure 10: The number of babies who missed CF screening by CCG

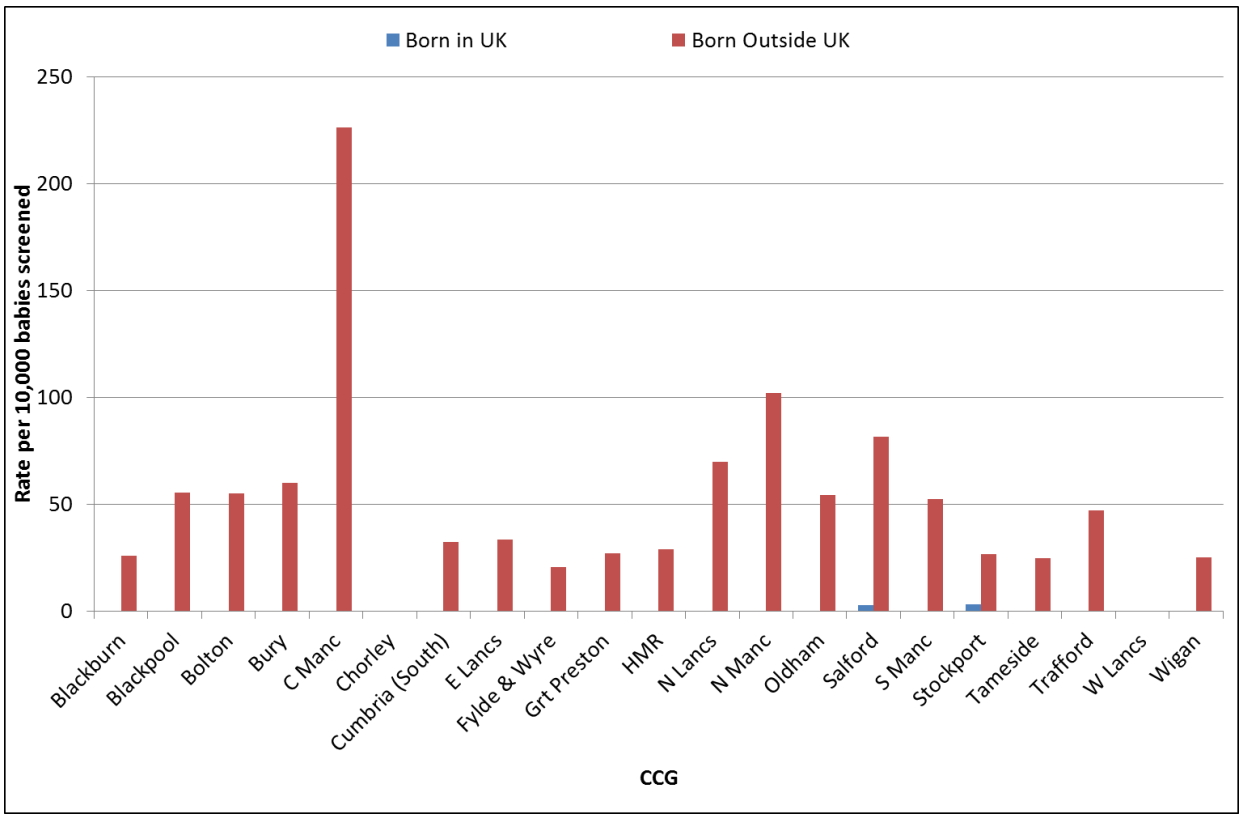

Figure 11: The number of babies who missed CF screening per 10,000 babies screened by each CCG

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 iso-electric focussing which is carried out within the haematology department of Manchester Royal Infirmary. The laboratory sent 660 samples for confirmatory testing, 50 of which were subsequently reported as not suspected for Sickle Cell Disease. The 50 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 9 babies identified as having sickle cell disease (8 FS and 1 FSC) and 2 babies identified with thalassaemia (HbF).

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. National standard NP3 stipulates that 90% of positive screening results for sickle cell disease should be communicated to parents by 4 weeks of age (Standards for the linked Antenatal and Newborn Screening Programme, Second Edition, October 2011).

Local laboratory turnaround time standards (developed in 2012 following an audit):

L1: receipt of sample in NBS Lab to referral of sample to haematology lab for isoelectric focusing – 3 working days.

L2: Receipt of sample in haematology lab to entry of IEF result into screening information system – 5 working days.

L3: Entry of IEF result into screening information system to printing of referral letters – 1 working day.

The Manchester Sickle Cell and Thalassaemia Centre (MSCTC) agreed to inform parents of positive screening results within 5 days of receiving the results or sooner if the baby is approaching 4 weeks of age. Therefore, to meet Standard NP3, the NBS lab should aim to report results to the MSCTC before the baby reaches 24 days of age. Between April 2016 and March 2017, all of the clinically significant disorders identified were reported by 22 days of age (median 16 days; range 13-22 days). The laboratory was notified of the 'at-risk' pregnancy in advance, in 45% of the positive cases (5/11; table 12).

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 Foundation Trust	0	0	0	0	0	0	0	0	7	0	2	4	0
Bolton NHS Foundation Trust	4	0	0	0	0	0	0	0	48	3	11	4	0
Central Manchester University Hospitals NHS Foundation Trust	0	0	0	0	0	0	0	0	100	18	15	9	0
East Lancashire Hospitals NHS Trust	1	0	0	0	1	0	0	0	11	2	8	8	0
Lancashire Teaching Hospitals NHS Foundation Trust	1	0	0	0	0	0	0	0	18	1	4	0	0
Not Stated/ Health Visitor	0	0	0	0	0	0	0	0	28	3	5	4	0
Pennine Acute Hospitals NHS Trust	2	0	0	0	1	0	1	0	120	21	31	22	0
Southport And Ormskirk Hospital NHS Trust	0	0	0	0	0	0	0	0	0	0	1	0	0
Stockport NHS Foundation Trust	0	0	0	0	0	0	0	0	15	2	2	1	0
Tameside And Glossop Integrated Care NHS Foundation Trust	0	1	0	0	0	0	0	0	10	3	3	7	0
University Hospital Of South Manchester NHS Foundation Trust	0	0	0	0	0	0	0	0	17	6	7	3	0
University Hospitals Of Morecambe Bay NHS Foundation Trust	0	0	0	0	0	0	0	0	3	0	0	2	0
Wrightington, Wigan And Leigh NHS Foundation Trust	0	0	0	0	0	0	0	0	8	0	1	0	0
Total	**8**	**1**	**0**	**0**	**2**	**0**	**1**	**0**	**385**	**59**	**90**	**64**	**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	0	0	0	0	0	0	0	0	19	7	19	4	0
B - Irish	0	0	0	0	0	0	0	0	0	0	0	0	0
C - Any other White background	1	0	0	0	0	0	0	0	4	1	0	1	0
D - White and Black Caribbean	0	0	0	0	0	0	0	0	18	5	0	0	0
E - White and Black African	0	0	0	0	0	0	0	0	37	5	0	0	0
F - White and Asian	0	0	0	0	0	0	0	0	1	0	3	8	0
G - Any other Mixed background	0	0	0	0	0	0	0	0	20	6	4	5	0
H - Indian	1	0	0	0	0	0	0	0	7	0	4	3	0
J - Pakistani	0	0	0	0	1	0	1	0	4	0	49	4	0
K - Bangladeshi	0	0	0	0	0	0	0	0	0	0	3	28	0
L - Any other Asian background	0	0	0	0	0	0	0	0	5	0	5	6	0
M - Caribbean	0	0	0	0	0	0	0	0	18	4	0	0	0
N - African	6	1	0	0	0	0	0	0	218	24	0	0	0
P - Any other Black background	0	0	0	0	0	0	0	0	19	3	0	0	0
R - Chinese	0	0	0	0	1	0	0	0	0	0	0	0	0
S - Any other ethnic category	0	0	0	0	0	0	0	0	9	1	3	2	0
Z - Not stated	0	0	0	0	0	0	0	0	6	3	0	3	0
Totals	**8**	**1**	**0**	**0**	**2**	**0**	**1**	**0**	**385**	**59**	**90**	**64**	**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?	Were the 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) at first visit to paediatrician
FS	No	No	5	7	16	44
F-only	Yes - Antenatal alert form	No	5	6	13	62
FS	No	No	5	6	21	69
FS	No	No	5	9	19	34
F-only	No	No	5	10	13	34
FS	Yes - Antenatal alert form	No	5	8	14	49
FSC	Yes - Antenatal alert form	No	5	7	16	39
FS	Yes - Recorded on blood spot card	Yes	5	6	15	83
FS	Yes - Antenatal alert form	Yes	6	10	18	53
FS	Yes - Antenatal alert form	Yes	6	7	22	52
FS	No	No	5	7	13	77

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

6. Summary of Audit Work and Adherence to National Standards

NHS Newborn Blood Spot Screening Programme Process Standards

- Standard 3 - Baby's NHS number is included on the blood spot card: In 2016/17 99.7% of cards included the baby's NHS number (National Standard 100%). There was a large variation between maternity units in usage of bar-coded labels and for some this remains low. Overall there has been an increase in the usage of bar-coded labels (from 73% to 80%).
- Standard 4 - Timely sample collection: All maternity units met this standard. Overall 98% of first samples were collected on days 5-8, which was similar to 2015/16 (97.6%).
- Standard 5 - Timely sample receipt in the lab: 99.2% samples were received within 4 working days which is similar to the last three years (target 100%).
- Standard 6 - Quality of Blood spot Sample: 12 out of 21 CCGs achieved this standard which represents an improvement in performance from last year (3 out of 21 CCGs). The percentage avoidable repeat rate ranged from 1.3 to 3.8%.

Clinical Referral of PKU, MCADD and CHT Positive Cases

- The standard for clinical referral of positive PKU babies states that the diet should be commenced by 17 days of age (acceptable standard) with an achievable standard of 14 days. Clinical referral guidelines published in January 2013 define the acceptable standards for timeliness of clinical referral as 17 days and 24 days for babies identified as CHT positive on the initial screening sample and those who are screen positive on a borderline repeat sample respectively. The corresponding achievable standards are defined as 14 and 21 days. 100% of PKU positive babies had their first clinic appointment by 17 days and 86% by 14 days. For CHT positive babies identified on the initial screening sample all had their first clinic appointment by 14 days. Of the babies identified as CHT positive following repeat testing (borderline first sample) 76% had their first appointment by 24 days.
- Clinical referral for PKU, MCADD and CHT screen positive babies should be initiated within 4 working days of sample receipt by the laboratory. All referrals for PKU, MCADD and CHT were initiated within 3 working days.

Cystic Fibrosis Programme

- Overall, an appropriate number of samples (0.58%) were referred for DNA testing.
- The number of babies who were screen positive was lower than the figure predicted from the national algorithm. The number of carriers identified was higher than most previous years.

- Of the 10 positive cases with two mutations, 100% were assessed by the CF team by 23 days of age (national standard 28 days).
- Of 4 CF suspected cases identified following a second raised IRT, 75% had a clinic appointment by day 35.
- The number of babies who missed CF screening because a satisfactory sample was not collected before 8 weeks of age decreased from 339 in 2015/16 to 300. The proportion of "movers in" (born outside of the UK) increased from 95% to 99%.

Sickle Programme

- In 2016/17 9 babies with sickle cell disease and 2 with β thalassaemia were identified as well as 385 carriers of the sickle gene and 213 carriers of haemoglobins C, D and E.
- Age at referral for babies screen positive for sickle cell and β thalassaemia ranged from 13–22 days (median 16 days). Local laboratory turnaround time standards have been set to ensure that results can be reported to parents by 4 weeks of age (the national standard). These state that results should be reported by the laboratory to MSCTC before 24 days of age. All 14 screen positive babies were reported at less than or equal to 22 days of age.

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 11 and by location in Figure 12. 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 87% of the total incidents. 5% of incidents were due to laboratory errors. A description of each of the level 3 & 4 incidents can be found in Appendix 3.

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.

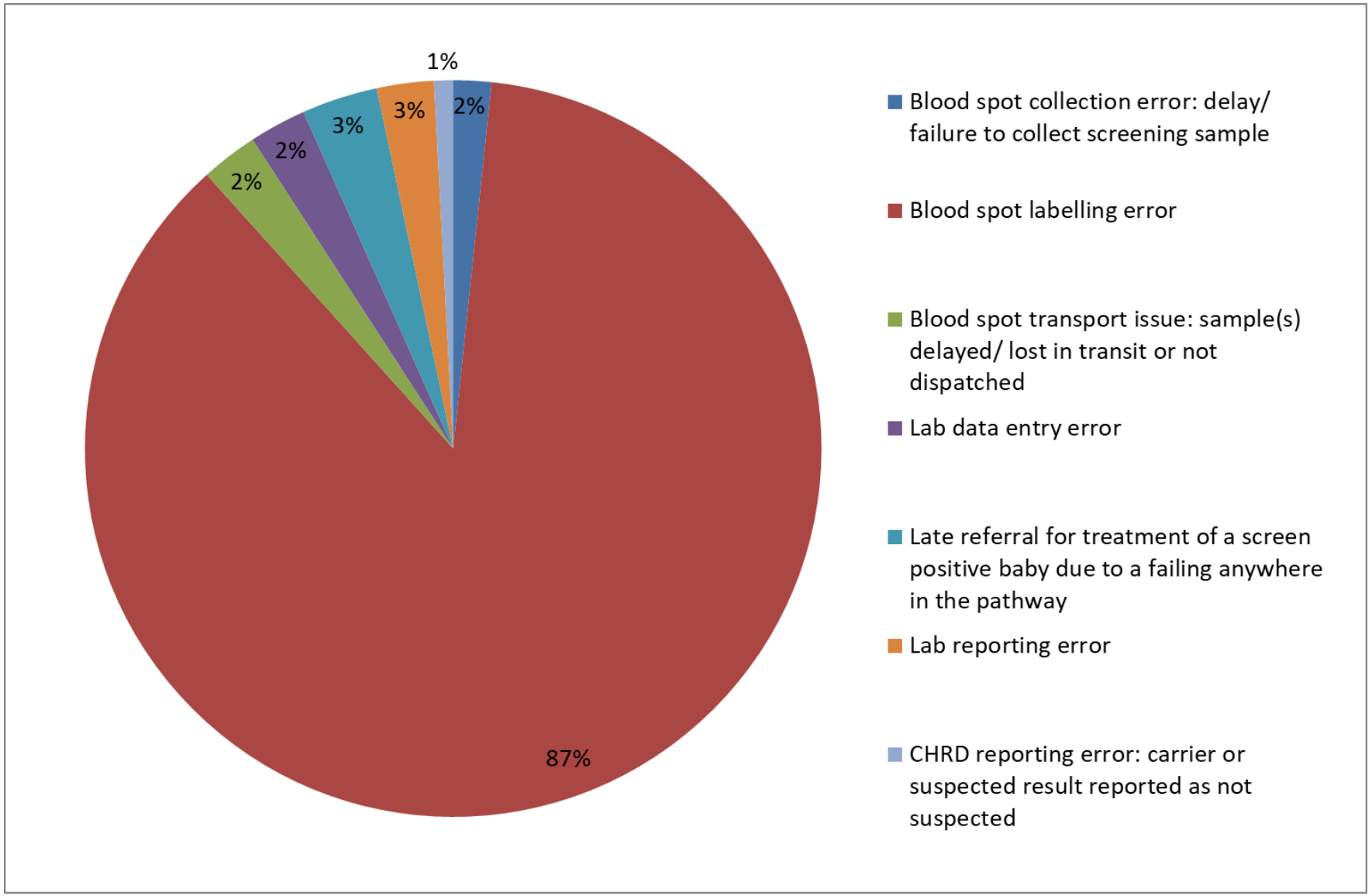

Figure 12: Newborn blood spot screening clinical incidents by cause

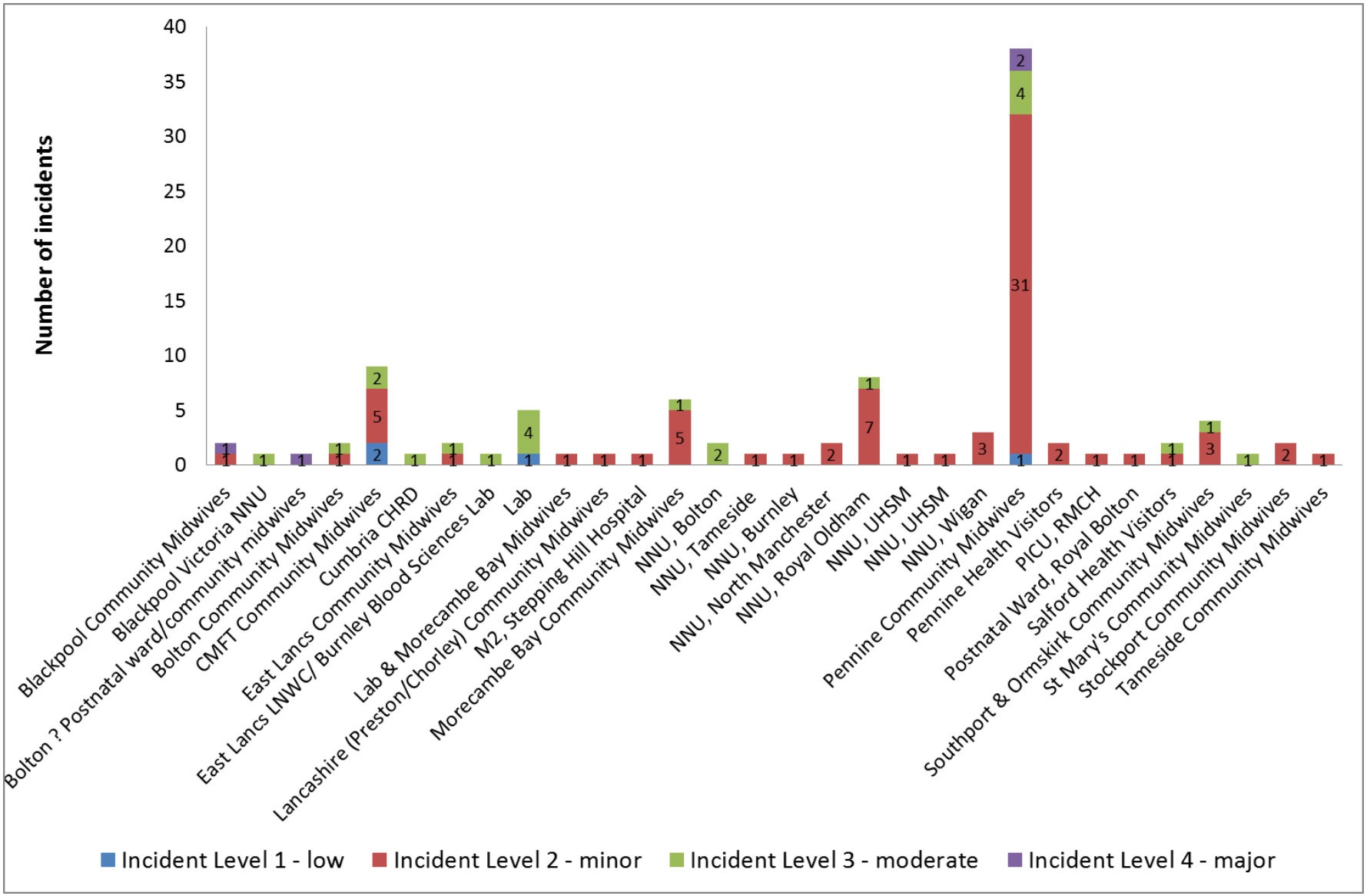

Figure 13: Newborn blood spot incidents (logged by CMFT) by location of incident; Key: CMW – Community midwives, HV – Health Visitors, CHRD -Child Health Records Dept, NNU – Neonatal Unit, MW – Maternity Ward

7. Current and Future Developments

- The NBS laboratory has continued to progress the work with Perkin Elmer and Northgate IS on the implementation of the failsafe programme - a web based system which allows maternity units in the geographical area served by Manchester NBS laboratory to determine that samples have been received by the laboratory and to view results. The laboratory now uploads full result codes in addition to the 01 (sample received) code and also receives a daily download of demographic data which improves the accuracy of data and helps to alleviate pressures on the limited clerical resources in the laboratory. The Principal Clinical Scientist in the Newborn Screening Laboratory is a member of the Newborn Bloodspot Failsafe User Group.
- The NBS laboratory continues to work with CMFT IT leads, Perkin Elmer and Child Health Records systems providers and IT leads to roll out electronic reporting. The process involves transmitting a copy of the csv file being configured for the failsafe via the Trust Integration Engine to the Child Health systems. Electronic reporting is now in place for Manchester, Bolton, Stockport and Tameside CHRDs. All of these CHRDs use the same IT system (System C CarePlus). Further progress is dependent on a commitment from other Child Health system providers to work with us to develop the links.
- The NBS laboratory continues to be been involved in work locally and nationally to improve blood spot quality. Bloodspot quality data is included in the NBS laboratory quarterly reports and is discussed at the Trust Antenatal and Newborn Screening Board and Greater Manchester and Lancashire NHS England Antenatal and Newborn Screening Board meetings. Locally the laboratory works closely with the clinical and education leads for St Mary's and Royal Manchester Children's Hospitals on improving quality.
- Involvement has been on-going in the national project to improve and standardise the setting of the 99.5th centile cut-off for IRT and to reduce the uncertainty associated with the impact of kit lot to lot variation in IRT. This involves working within "buddy groups" to obtain sufficient data for each new kit lot in advance of implementation of that kit in order to enable more robust cut-offs to be set.
- The Willink Biochemical Genetics Laboratory has continued to participate in the project led by Viapath GSTS to determine whether using a common internal standard would improve the harmonisation of screen results for Inherited Metabolic Diseases (IMD) in the long term. All together there are five UK NBS laboratories in this project: Viapath, Leeds, Birmingham, Cardiff and Manchester. Viapath regularly circulate population data to the participating laboratories, this is additional information useful for laboratory assessment of the quality of the screening test for the Inherited Metabolic Disorders.
- The laboratory has obtained significant investment from the Trust for the upgrade of equipment and IT and for modifications to the laboratory space to accommodate the new equipment. The

Autodelfias (which perform the analyses for CHT and CF screening) are to be replaced with Genetic Screening Processors (GSPs) and identical Tandem MS analysers are to be procured for the Willink and NBS laboratories which will facilitate the move from HPLC technology for sickle cell screening and provide mutual back-up for the IMD and sickle cell elements of the Newborn Bloodspot programme. The laboratory screening IT system (Specimen Gate Lifecycle Neonatal Solution) is to be upgraded to Specimen Gate Screening Centre. It is anticipated that the estates work will be completed in Spring 2018 allowing the new equipment to be installed and new analytical processes verified. Work on configuring the new IT system will also commence in early 2018.

Appendix 1: Research and Development and Audit

Poster & Oral Presentations

Review of Cystic Fibrosis in Infants Referred with 2 Raised Immunoreactive Trypsinogen and No Common Mutations by Manchester Screening Laboratory.
J Edgar, L Tetlow, B Hird, O Narayan 39th European Cystic Fibrosis Conference, Basel, Switzerland, June 2016 (oral presentation)

CF Screening in Manchester, UK: A Review of Cases Detected from a Repeat IRT Taken at Day 21-28
L Tetlow, B Hird, M Pickersgill, J Edgar, J Henchliffe, J Brock, A Shenton
9th ISNS International Meeting, The Hague (Netherlands), Sept 2016

Appendix 2: Data by Maternity Unit

Trust	Number of all samples (including repeats)	Number of blood spot cards including babies' NHS number	Number of blood spot cards including ISB label bar-coded babies' NHS number	Percentage with NHS number	Percentage with bar-coded NHS number
Blackpool Teaching Hospitals NHS Foundation Trust	3217	3209	2686	99.75%	83.49%
Bolton NHS Foundation Trust	6340	6330	4206	99.84%	66.34%
Central Manchester University Hospitals NHS Foundation Trust	5776	5766	5174	99.83%	89.58%
East Lancashire Hospitals NHS Trust	5622	5617	5129	99.91%	91.23%
Health Visitor	231	229	22	99.13%	9.52%
Lancashire Teaching Hospitals NHS Foundation Trust	4632	4629	4351	99.94%	93.93%
Not Stated	5312	5257	3949	98.96%	74.34%
Pennine Acute Hospitals NHS Trust	11016	10972	7940	99.60%	72.08%
Southport And Ormskirk Hospital NHS Trust	868	865	275	99.65%	31.68%
Stockport NHS Foundation Trust	3292	3287	2874	99.85%	87.30%
Tameside And Glossop Integrated Care NHS Foundation Trust	3003	3001	2635	99.93%	87.75%
University Hospital Of South Manchester NHS Foundation Trust	4471	4469	4225	99.96%	94.50%
University Hospitals Of Morecambe Bay NHS Foundation Trust	2273	2266	1801	99.69%	79.23%
Wrightington, Wigan And Leigh NHS Foundation Trust	3488	3478	2311	99.71%	66.26%
Total	**59541**	**59375**	**47578**	**99.72%**	**79.91%**

Table A1: Data for Standard 3 showing the number of cards that include NHS number, by maternity unit

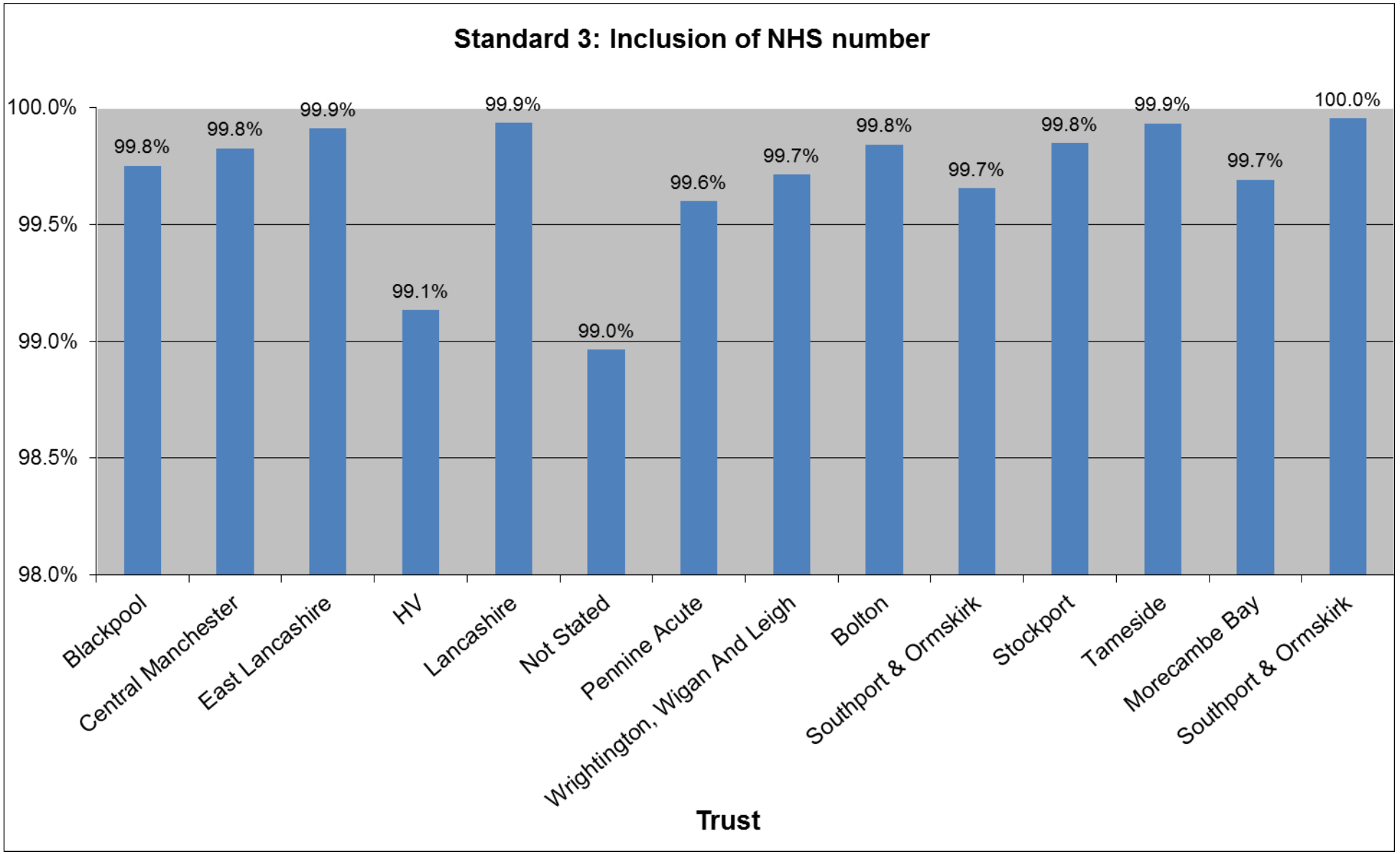

Figure A1: Graph to show percentage of cards that included NHS number for period April 2016 – March 2017

Trust	Number of first samples taken			Percentage of first samples taken		
	on or before day 4	between day 5-8	on or after day 9	on or before day 4	between day 5-8	on or after day 9
Blackpool Teaching Hospitals NHS Foundation Trust	8	3067	32	**0.26%**	**98.71%**	**1.03%**
Central Manchester University Hospitals NHS Foundation Trust	10	4903	60	**0.20%**	**98.59%**	**1.21%**
East Lancashire Hospitals NHS Trust	14	5235	99	**0.26%**	**97.89%**	**1.85%**
Health Visitor	0	0	193	**0.00%**	**0.00%**	**100.00%**
Lancashire Teaching Hospitals NHS Foundation Trust	11	4391	19	**0.25%**	**99.32%**	**0.43%**
Not Stated	22	3988	279	**0.51%**	**92.98%**	**6.51%**
Pennine Acute Hospitals NHS Trust	17	10441	112	**0.16%**	**98.78%**	**1.06%**
Wrightington, Wigan And Leigh NHS Foundation Trust	8	3288	23	**0.24%**	**99.07%**	**0.69%**
Bolton NHS Foundation Trust	6	5761	45	**0.10%**	**99.12%**	**0.77%**
Southport And Ormskirk Hospital NHS Trust	3	817	6	**0.36%**	**98.91%**	**0.73%**
Stockport NHS Foundation Trust	8	3079	28	**0.26%**	**98.84%**	**0.90%**
Tameside And Glossop Integrated Care NHS Foundation Trust	9	2847	34	**0.31%**	**98.51%**	**1.18%**
University Hospitals Of Morecambe Bay NHS Foundation Trust	7	2141	11	**0.32%**	**99.17%**	**0.51%**
University Hospital Of South Manchester NHS Foundation Trust	8	4337	21	**0.18%**	**99.34%**	**0.48%**
Total	131	54295	962	**0.24%**	**98.03%**	**1.74%**

Table A2: Data for Standard 4 showing the number of cards taken between days 5-8, by maternity unit

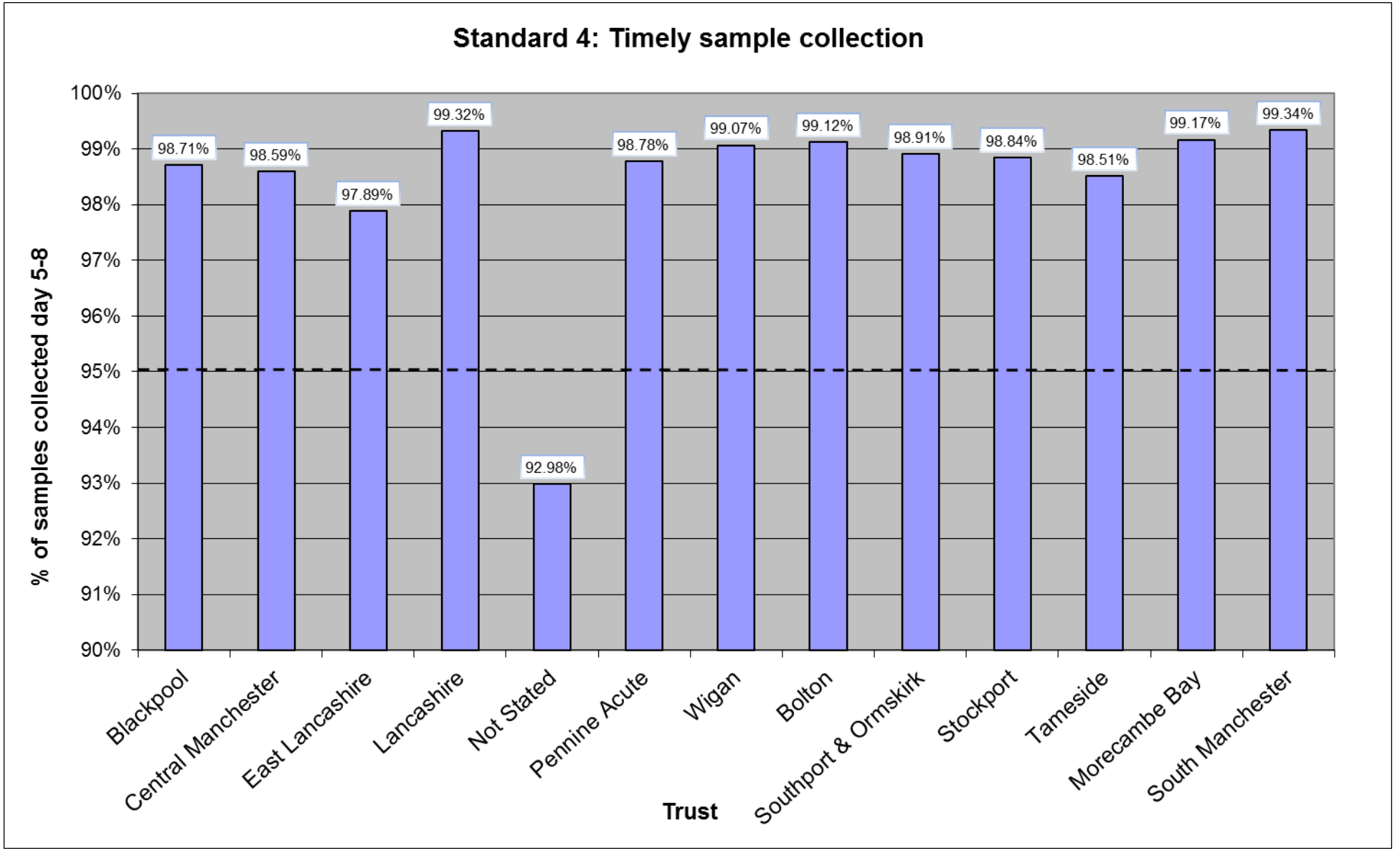

Figure A2: Graph to show percentage of samples taken 5-8 days after birth

Trust	Number of samples received			Percentage of samples received		
	in 3 or fewer working days of sample being taken	in 4 or fewer working days of sample being taken	on or after 5 working days of sample being taken	in 3 or fewer working days of sample being taken	in 4 or fewer working days of sample being taken	on or after 5 working days of sample being taken
Blackpool Teaching Hospitals NHS Foundation Trust	3108	3179	23	97.06%	99.28%	0.72%
Central Manchester University Hospitals NHS Foundation Trust	5219	5228	13	99.58%	99.75%	0.25%
East Lancashire Hospitals NHS Trust	5477	5506	11	99.27%	99.80%	0.20%
Health Visitor	206	211	10	93.21%	95.48%	4.52%
Lancashire Teaching Hospitals NHS Foundation Trust	4562	4576	0	99.69%	100.00%	0.00%
Not Stated	4611	4735	78	95.80%	98.38%	1.62%
Pennine Acute Hospitals NHS Trust	10479	10840	87	95.90%	99.20%	0.80%
Wrightington, Wigan And Leigh NHS Foundation Trust	3389	3450	14	97.83%	99.60%	0.40%
Bolton NHS Foundation Trust	6036	6049	3	99.74%	99.95%	0.05%
Southport And Ormskirk Hospital NHS Trust	721	834	24	84.03%	97.20%	2.80%
Stockport NHS Foundation Trust	3037	3181	88	92.90%	97.31%	2.69%
Tameside And Glossop Integrated Care NHS Foundation Trust	2911	2941	31	97.95%	98.96%	1.04%
University Hospitals Of Morecambe Bay NHS Foundation Trust	3207	3253	33	97.60%	99.00%	1.00%
University Hospital Of South Manchester NHS Foundation Trust	3293	3399	22	96.26%	99.36%	0.64%
Total	56256	57382	437	**97.30%**	**99.24%**	**0.76%**

Table A3: Data for standard 5 showing the number of samples dispatched and received in a timely manner, by maternity unit

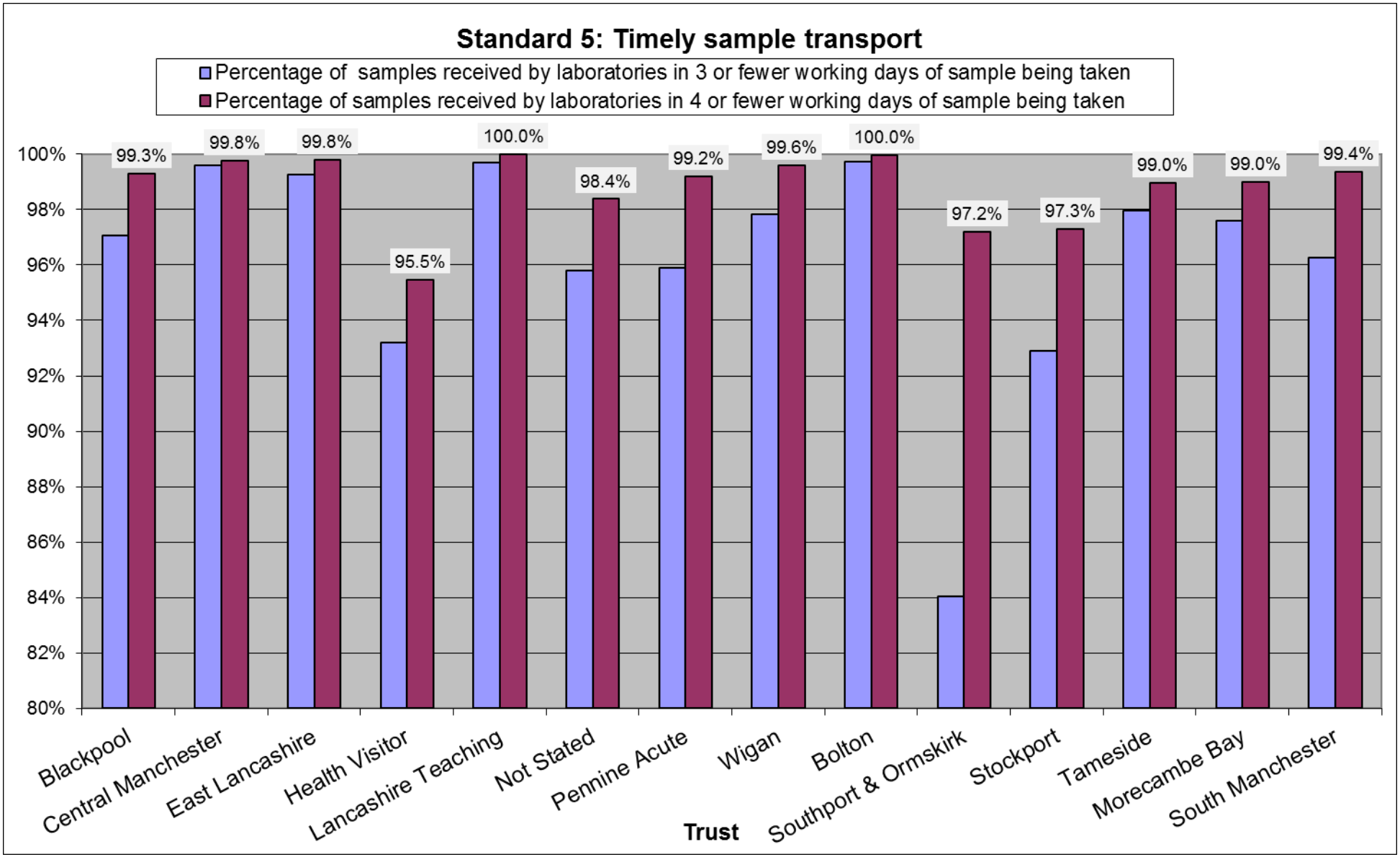

Figure A3: Graph to show percentage of samples received within 3 and 4 working days of being taken, by Trust

Trust	Number of first samples received/ babies tested	Status code 0301: too young for reliable screening (≤ 4 days)	Status code 0302: too soon after transfusion (<72 hours)	Status code 0303: insufficent sample	Status code 0304: unsuitable sample (blood quality): incorrect blood application	Status code 0305: unsuitable sample (blood quality): compressed / damaged	Status code 0306: unsuitable sample: day 0 and day 5 on same card	Status code 0307: unsuitable sample for CF: discrepant IRT replicates, possible faecal contamination	Status code 0308: unsuitable sample: NHS number missing/not accurately recorded	Status code 0309: unsuitable sample: date of sample missing/not accurately recorded	Status code 0310: unsuitable sample: date of birth not accurately matched	Status code 0311: unsuitable sample: expired card used	Status code 0312: unsuitable sample: >14 days in transit, too old for analysis	Status code 0313: unsuitable sample: damaged in transit	Avoidable Repeat Requests Rate
Blackpool Teaching Hospitals NHS Foundation Trust	3114	9	0	18	1	1	0	1	8	10	0	2	0	0	**1.6%**
Central Manchester University Hospitals NHS Foundation Trust	4996	14	40	43	3	10	0	9	18	32	0	3	1	0	**2.7%**
East Lancashire Hospitals NHS Trust	5354	19	20	70	0	2	0	3	4	9	0	5	0	0	**2.1%**
Health Visitor	202	0	0	3	0	0	0	0	2	1	1	2	0	0	**4.5%**
Lancashire Teaching Hospitals NHS Foundation Trust	4440	11	11	35	1	2	0	6	1	19	0	4	0	0	**1.8%**
Not Stated	4368	2	1	7	1	1	0	7	3	2	0	0	0	0	**0.5%**
One-to-One Midwifery	1	0	0	0	0	0	0	0	0	0	0	0	0	0	**0.0%**
Pennine Acute Hospitals NHS Trust	10609	19	6	92	4	12	0	12	48	38	1	6	0	0	**2.2%**
Wrightington, Wigan And Leigh NHS Foundation Trust	3341	8	2	48	0	1	0	1	12	24	0	1	1	0	**2.9%**
Bolton NHS Foundation Trust	5819	5	11	49	3	4	0	15	7	3	0	3	0	0	**1.5%**
Southport And Ormskirk Hospital NHS Trust	836	3	2	7	1	1	0	3	4	14	0	0	0	0	**3.9%**
Stockport NHS Foundation Trust	3132	11	1	44	2	2	0	10	7	20	0	7	1	2	**3.4%**
Tameside And Glossop Integrated Care NHS Foundation Trust	2892	10	0	17	2	0	0	11	3	4	1	7	0	0	**1.9%**
University Hospitals Of Morecambe Bay NHS Foundation Trust	2184	8	0	18	7	4	0	1	14	36	0	2	1	0	**4.2%**
University Hospital Of South Manchester NHS Foundation Trust	4373	9	1	27	9	3	0	10	3	7	0	1	1	0	**1.6%**
Total	55661	128	95	478	34	43	0	89	134	219	3	43	5	2	**2.1%**

Table A4: Data for Standard 6 showing avoidable repeat rate, by Trust

0302 not currently included in calculation of avoidable repeat rate

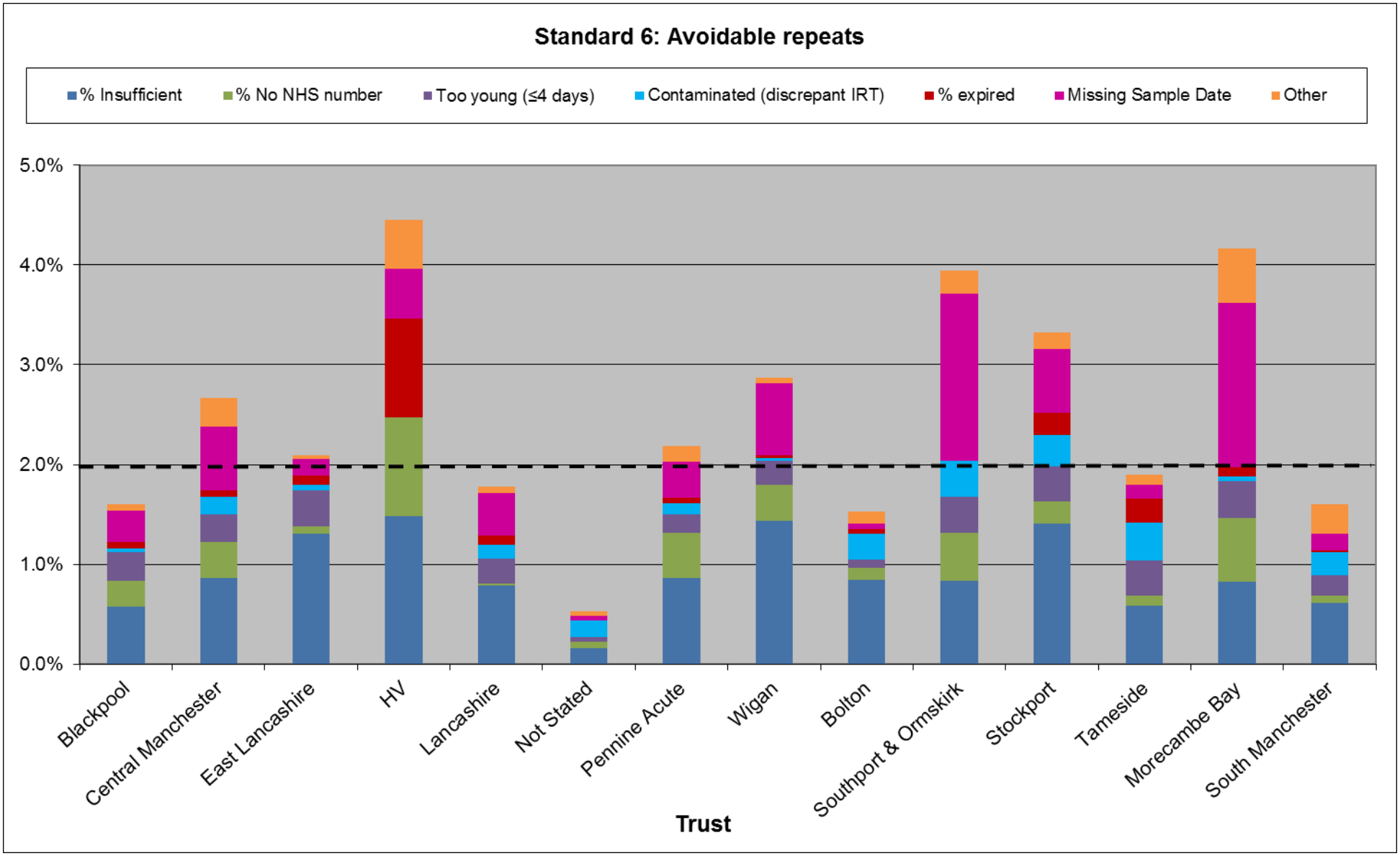

Figure A4: Graph to show avoidable repeat rate by Trust

Appendix 3 – Summary of Incidents of Moderate and Major Severity (level 3 and level 4)

Incident Number	Incident Date	Incident Level	Near miss or actual harm	Summary of incident	Further details	Lab/ Ward/ Maternity Unit
1	09/03/16	3	1 (no harm)	Blood spot labelling error: handwritten NHS number belonging to another baby (other demographic details correct)	Amended report issued as results already released.	Salford Health Visitors
2	20/04/16	3	1 (no harm)	Lab reporting error: result reported as not suspected instead of carrier	Newborn screening result reported as not suspected for sickle cell disease instead of carrier. Incident investigation & action plan done	Lab
3	29/04/16	4	Actual harm (level 2)	Blood spot labelling error: another baby's bar-coded demographic sticker and reported against wrong baby.	Mismatch between details on barcoded label and mother's details. Both babies on same ward. Unclear which baby the sample was collected on.	Ward C2, UHSM
4	18/07/16	3	Actual harm (level 2)	Blood spot labelling error: handwritten NHS number belonging to another baby (other demographic details correct)		Wigan Community Midwives
5	02/08/16	4	Actual harm (level 2)	Blood spot labelling error: another baby's bar-coded demographic sticker and reported against wrong baby.		Pennine Community Midwives
6	13/08/16	3	Actual harm (level 2)	Blood spot labelling error: handwritten NHS number belonging to another baby (other demographic details correct) & results reported to CHRD against wrong person	Error detected by Child Health.	Royal Bolton Hospital (Ward M4/M5)
7	22/08/16	3	Actual harm (level 2)	Blood spot labelling error: handwritten NHS number belonging to another baby (other demographic details correct)		Morecambe Bay Community midwives
8	30/08/16	3	1 (no harm)	Late referral for treatment of a screen positive baby due to a failing anywhere in the pathway	CHT positive (double borderline). Baby assessed by endocrine team on day 28; 12 days between repeat request and repeat sample collection	St Mary's Community Midwives

Incident Number	Incident Date	Incident Level	Near miss or actual harm	Summary of incident	Further details	Lab/ Ward/ Maternity Unit
9	30/08/16	3	1 (no harm)	Late referral for treatment of a screen positive baby due to a failing anywhere in the pathway	CHT positive (double borderline). Baby assessed by endocrine team on day 26; 6 days between repeat request and repeat sample collection	Pennine community midwives
10	04/09/16	3	Actual harm (level 2)	Labelling of blood spot sample inconsistent with audit form (other twin). ? Sample labelled incorrectly or audit form incorrect. Unclear which twin was bled.		East Lancs LNWC/ Burnley Blood Sciences Lab
11	09/09/16	3	Actual harm (level 2)	Blood spot labelling error: handwritten NHS number belonging to another baby (other demographic details correct)		Pennine community midwives
12	29/09/16	3	Actual harm (level 2)	Blood spot labelling error: another baby's bar-coded demographic sticker and reported against wrong baby.	Sticker from deceased twin	Blackpool Victoria NNU
13	10/11/16	3	Actual harm (level 2)	Blood spot labelling error: handwritten NHS number belonging to another person (other demographic details correct)	Sample collected by neonatal outreach, SMH. Allocated wrong NHS number by NMGH (place of birth)	Pennine
14	22/11/16	3	Actual harm (level 2)	Blood spot transport issue: sample(s) delayed/ lost in transit or not dispatched, resulting in retesting of baby	Sample found in diary. Picked up by Northgate failsafe system	CMFT Community Midwives
15	20/11/16	3	Actual harm (level 2)	Blood spot labelling error: handwritten NHS number belonging to another baby (other demographic details correct)		Pennine Community Midwives
16	03/01/17	3	Actual harm (level 2)	Blood spot labelling error: demographic sticker contained errors e.g. another baby's NHS number (some details correct)		Bolton ?NICU
17	14/12/16	4	Actual harm (level 2)	Blood spot labelling error: another baby's bar-coded demographic sticker and reported against wrong baby.	Error noticed by lab on receipt of repeat sample.	Bolton ? Postnatal ward/community midwives

Incident Number	Incident Date	Incident Level	Near miss or actual harm	Summary of incident	Further details	Lab/ Ward/ Maternity Unit
18	02/01/17	3	Actual harm (level 2)	Blood spot labelling error: handwritten NHS number belonging to another baby (other demographic details correct)	NHS number belonged to twin.	Southport & Ormskirk Community Midwives
19	09/01/17	3	Actual harm (level 2)	Lab reporting error: result reported as not suspected instead of repeat required	Sample repeated. Incident investigation & action plan.	Lab
20	15/01/17	3	Actual harm (level 2)	Blood spot labelling error: another baby's bar-coded demographic sticker, detected prior to reporting	Sticker belonged to baby's older sibling. Level 3 as due to age of child on sticker, not at risk of being confused with another baby.	East Lancs Community Midwives
21	10/01/17	3	Actual harm (level 2)	Late referral for treatment of a screen positive baby due to a failing anywhere in the pathway	Delay in referral of CHT suspected baby. Repeat sample following a borderline CHT result was collected 14 days after repeat request sent from lab. Coincided with Christmas and New Year. ? Confusion about need for repeat as the borderline result was on a day 28 CHT repeat.	Bolton NICU
22	09/02/17	3	1 (no harm)	Lab data entry error: incorrect NHS number (incorrect digit(s)) entered into the laboratory screening IT system	2 hand-written digits, difficult to read. Incorrect number corresponded to another baby living in another part of country. Match not adequately checked by data entry clerk. Error detected at manual validation on the NBSFS. The two babies had different results. Investigation report written. Extra checking step introduced for staff member involved.	Lab
23	11/02/17	4	Actual harm (level 2)	Blood spot labelling error: another baby's bar-coded demographic sticker, detected prior to reporting	Error detected in the laboratory prior to reporting. Sticker discrepant with handwritten mother's details.	Blackpool Community Midwives

Incident Number	Incident Date	Incident Level	Near miss or actual harm	Summary of incident	Further details	Lab/ Ward/ Maternity Unit
24	15/02/17	4	Actual harm (level 2)	Blood spot labelling error: another baby's bar-coded demographic sticker and reported against wrong baby.	Twins. No hand-written discrepant details. Two records noticed on Failsafe and ward telephoned to investigate.	Pennine Community Midwives
25	14/02/17	3	1 (no harm)	Lab reporting error: result reported as not suspected instead of repeat required	Metabolic screening results reported incorrectly as 'not suspected', rather than repeat required. Correct option selected in the system but step does not appear to have completed correctly. The system was running slow, which may have contibuted to the error. Error did not reach patient. CHRD aksed to amend system.	Lab
26	01/03/17	3	Actual harm (level 2)	Blood spot labelling error: handwritten NHS number belonging to another baby (other demographic details correct)		Bolton Community Midwives
27	06/03/17	3	1 (no harm)	Blood spot transport issue: sample(s) delayed/ lost in transit or not dispatched, resulting in retesting of baby	6 samples identified on Failsafe. Courier contacted.	CMFT Community Midwives (Salford)
28	06/03/17	3	1 (no harm)	CHRD reporting error: carrier or suspected result reported as not suspected	MCADD positive baby reported as not suspected	Cumbria CHRD
29	20/03/17	3	Actual harm (level 2)	Blood spot labelling error: handwritten NHS number belonging to another baby (other demographic details correct)		Royal Oldham NNU
30	22/03/17	3	1 (no harm)	Blood spot collection error: delay/ failure to collect screening sample	Admitted on day 5	Ward 85 RMCH