Central Manchester University Hospitals NHS
NHS Foundation Trust

Newborn Screening Laboratory
Clinical Biochemistry Department
Central Manchester University Hospitals NHS Foundation Trust

Manchester Newborn Screening Laboratory Annual Report 2015-2016

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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, Lancashire and (for S Cumbria) Cumbria Northumberland Tyne and Wear 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 2015

CMFT 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)*
- Helen Jopling BSc MSc PhD Senior Clinical Scientist (rotational post) (1.0 WTE)*
- Laura Green BSc MSc 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.

Claire Manfredonia changed hours to 0.8 WTE in February 16
Helen Jopling left in January 2016. Laura Green was appointed in January 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)

Turan Hall was appointed in June 2015

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 2016) is depicted in the following organisational chart.

Newborn Screening Staffing Structure

CMFT 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

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/ASSCIATE GENETIC TECHNOLOGIST (1.8)
Dale Taylor/ Stephen Dent

ASSISTANT GENETIC TECHNOLOGIST (1.3)
Anita Lau / Liz Nixon

**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™)
- 3 x Waters LC-MS/MS instruments (collectively used to provide both screening and diagnostic services by Willink laboratory).

Workload

A total of 60608 samples were received in the laboratory which included 56058 first samples, 3117 repeat samples and 1433 pre-transfusion 'day 0' samples.

This includes 450 samples (337 first samples, 60 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 152 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 investigation 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 9CHRD). 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 CHRD.

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). Both laboratories have full CPA accreditation status. CPA is now part of UKAS (United Kingdom Accreditation Service) and from October 2013, CPA accredited laboratories are assessed against ISO 15189. Both laboratories are currently awaiting inspection. Work is on-going nationally to map the NHS Newborn Blood Spot Screening Programme standards to ISO 15189 and there are discussions regarding assessment of screening laboratories with respect to these standards and the broader role of the laboratory within the screening programme.

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. Matters in relation to metabolic screening are discussed at the monthly Willink Unit Heads of Department meeting (attended by clinicians, dieticians, laboratory and administration leads) and the Newborn Screening Operational Group Meeting (held every other month) which has representation from both the clinical and operational leads of the Newborn Screening

and Willink laboratories. 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, Lancashire and Cumbria Northumberland Tyne and Wear Quality and Commissioning Groups.

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, Lancashire and Cumbria Northumberland Tyne and Wear Quality and Commissioning Groups.
- 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 UK National Screening Programme Centre and National Sickle Cell and Thalassaemia Programme.

Due to staffing pressures including vacancies and maternity leave the department has been less active than usual in this area in 2015/16 but there are plans to progress a number of projects in 2016/17.

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.

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 2015 through to March 2016.
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 similar to last year (99.5%). 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 41% to 90%. Overall the usage of bar-coded labels has increased from 64% in 2014/15 to 73%, but remains significantly 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	3926	3918	**99.8%**	**87.3%**
Blackpool	1758	1752	**99.7%**	**70.8%**
Bolton	4211	4201	**99.8%**	**64.0%**
Bury	2677	2668	**99.7%**	**73.9%**
C Manc	3681	3672	**99.8%**	**82.5%**
Chorley	2082	2079	**99.9%**	**60.5%**
S Cumbria	1689	1685	**99.8%**	**66.0%**
E Lancs	3323	3320	**99.9%**	**89.5%**
Fylde & Wyre	1589	1582	**99.6%**	**71.0%**
Grt Preston	2759	2754	**99.8%**	**69.6%**
HMR	3106	3095	**99.6%**	**65.1%**
N Lancs	1710	1698	**99.3%**	**62.6%**
N Manc	2866	2854	**99.6%**	**78.3%**
Oldham	3449	3429	**99.4%**	**65.5%**
Salford	3896	3882	**99.6%**	**73.5%**
S Manc	2428	2417	**99.5%**	**86.7%**
Stockport	3716	3702	**99.6%**	**81.3%**
Tameside	3487	3475	**99.7%**	**82.8%**
Trafford	2938	2927	**99.6%**	**85.5%**
W Lancs	934	930	**99.6%**	**47.0%**
Wigan	3933	3911	**99.4%**	**41.0%**
Out of region	450	448	**99.6%**	**44.9%**
Total	**60608**	**60399**	**99.7%**	**72.6%**

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

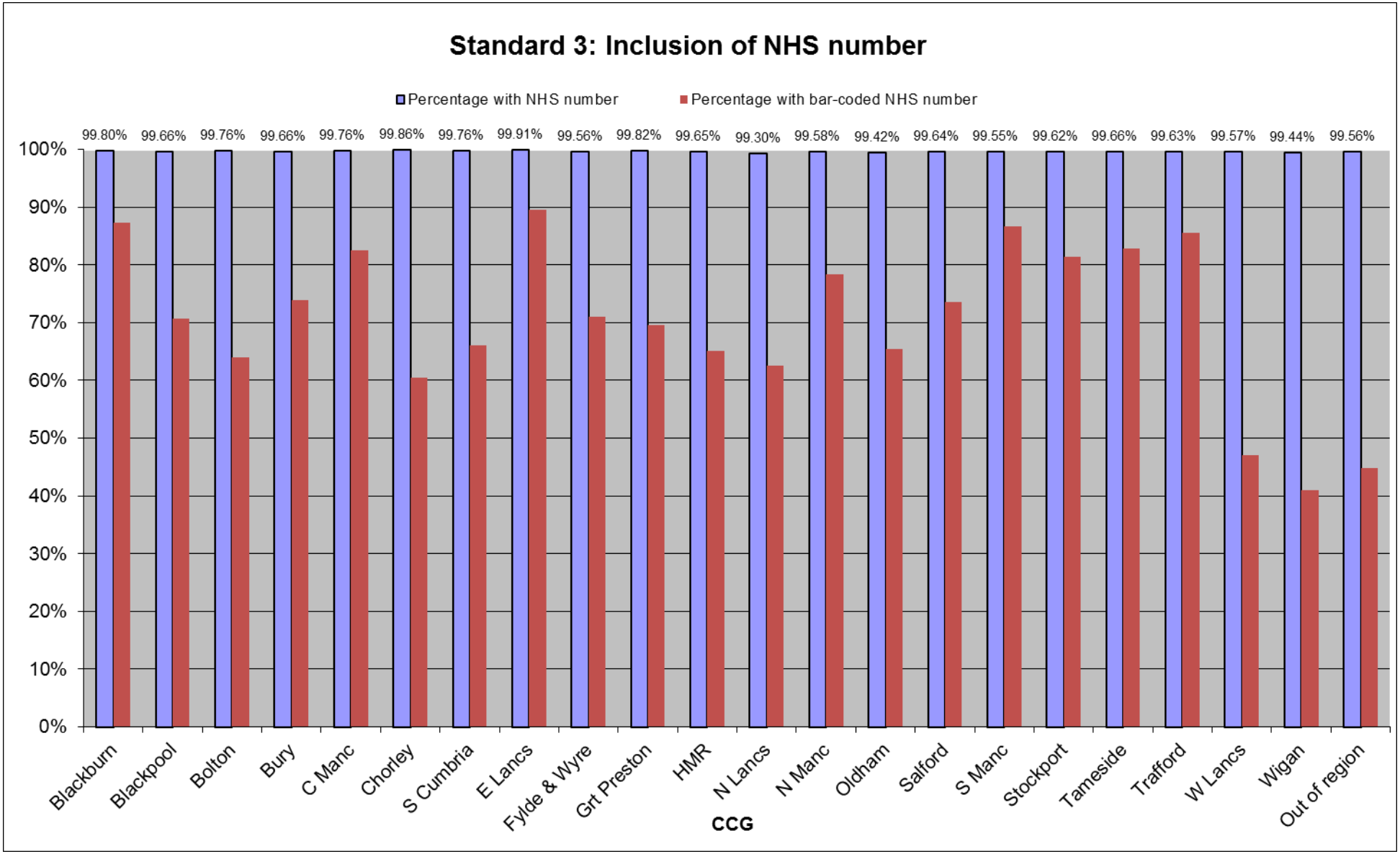

Figure 1: Graph to show percentage of cards that included NHS number for period April 2015–March 2016

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 97.6% of first samples were collected on days 5-8, which is similar to 2014/15 (98.0%). The 'achievable' threshold of 99% was met by 5 CCGs (Bury, Cumbria, Oldham, Trafford and Wigan). The percentage collected on day 5 varied throughout the region ranging from 43% for Blackburn CCG to 91% for Cumbria CCG (75% 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	5-8 days
Blackburn	8	1532	1233	505	126	148	**0.2%**	**43.1%**	**34.7%**	**14.2%**	**3.5%**	**4.2%**	**95.6%**
Blackpool	5	1221	264	96	29	31	**0.3%**	**74.2%**	**16.0%**	**5.8%**	**1.8%**	**1.9%**	**97.8%**
Bolton	6	2493	836	334	97	62	**0.2%**	**65.1%**	**21.8%**	**8.7%**	**2.5%**	**1.6%**	**98.2%**
Bury	6	1627	647	157	20	32	**0.2%**	**65.4%**	**26.0%**	**6.3%**	**0.8%**	**1.3%**	**98.5%**
C Manc	3	2858	318	34	14	126	**0.1%**	**85.2%**	**9.5%**	**1.0%**	**0.4%**	**3.8%**	**96.2%**
Chorley	5	1033	688	107	14	65	**0.3%**	**54.0%**	**36.0%**	**5.6%**	**0.7%**	**3.4%**	**96.3%**
S Cumbria	1	1450	101	20	5	18	**0.1%**	**90.9%**	**6.3%**	**1.3%**	**0.3%**	**1.1%**	**98.8%**
E Lancs	5	1506	1119	274	56	82	**0.2%**	**49.5%**	**36.8%**	**9.0%**	**1.8%**	**2.7%**	**97.1%**
Fylde & Wyre	6	1089	209	124	25	26	**0.4%**	**73.6%**	**14.1%**	**8.4%**	**1.7%**	**1.8%**	**97.8%**
Grt Preston	6	1295	986	169	24	100	**0.2%**	**50.2%**	**38.2%**	**6.6%**	**0.9%**	**3.9%**	**95.9%**
HMR	1	2615	249	31	8	47	**0.0%**	**88.6%**	**8.4%**	**1.1%**	**0.3%**	**1.6%**	**98.4%**
N Lancs	10	1334	183	28	8	19	**0.6%**	**84.3%**	**11.6%**	**1.8%**	**0.5%**	**1.2%**	**98.2%**
N Manc	3	2120	358	50	14	76	**0.1%**	**80.9%**	**13.7%**	**1.9%**	**0.5%**	**2.9%**	**97.0%**
Oldham	3	2849	302	53	10	47	**0.1%**	**87.3%**	**9.3%**	**1.6%**	**0.3%**	**1.4%**	**98.5%**
Salford	6	2950	450	97	13	67	**0.2%**	**82.3%**	**12.6%**	**2.7%**	**0.4%**	**1.9%**	**98.0%**
S Manc	1	1996	188	27	6	43	**0.0%**	**88.3%**	**8.3%**	**1.2%**	**0.3%**	**1.9%**	**98.1%**
Stockport	10	2879	407	62	16	57	**0.3%**	**83.9%**	**11.9%**	**1.8%**	**0.5%**	**1.7%**	**98.0%**
Tameside	6	2767	359	58	13	55	**0.2%**	**84.9%**	**11.0%**	**1.8%**	**0.4%**	**1.7%**	**98.1%**
Trafford	6	2479	179	27	5	36	**0.2%**	**90.7%**	**6.6%**	**1.0%**	**0.2%**	**1.3%**	**98.5%**
W Lancs	0	740	108	24	11	18	**0.0%**	**82.1%**	**12.0%**	**2.7%**	**1.2%**	**2.0%**	**98.0%**
Wigan	10	2846	470	193	35	29	**0.3%**	**79.4%**	**13.1%**	**5.4%**	**1.0%**	**0.8%**	**98.9%**
Out of region	2	199	82	19	7	28	**0.6%**	**59.1%**	**24.3%**	**5.6%**	**2.1%**	**8.3%**	**91.1%**
Total	**109**	**41878**	**9736**	**2489**	**556**	**1212**	**0.2%**	**74.8%**	**17.4%**	**4.4%**	**1.0%**	**2.2%**	**97.6%**

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

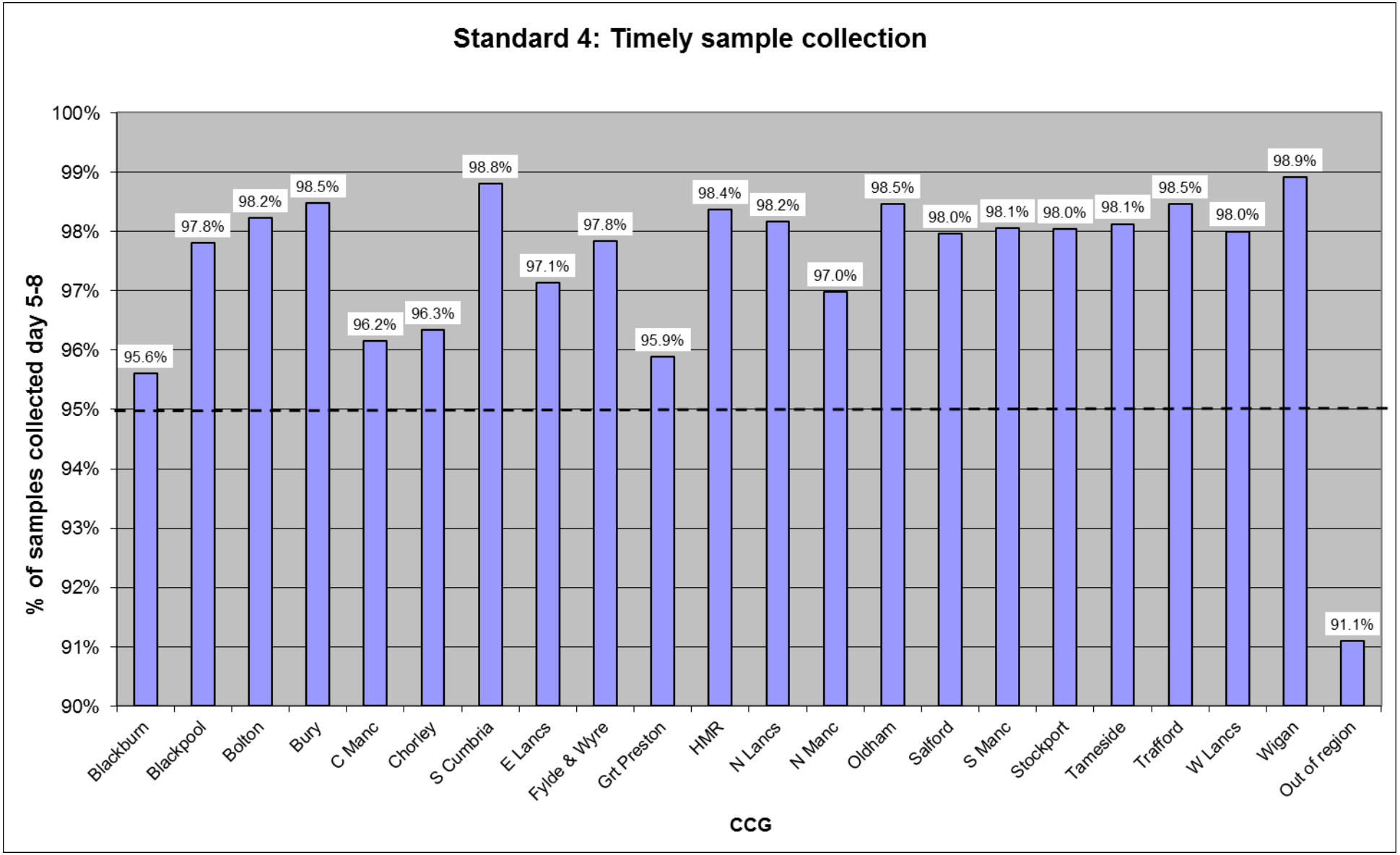

Figure 2: Graph to show percentage of samples taken 5-8 days after birth

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 99.0% were received within 4 working days (range 96.5-99.9%), which is the same as the two previous years. The achievable target for standard 5 is that 100% of cards are received within 3 working days. The percentage of cards that were received within 3 working days ranged from 61.8% for West Lancashire CCG to 99.6 % for Bolton (overall 96.8%).

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	3702	3718	11	**99.3%**	**99.7%**	**0.3%**
Blackpool	1662	1718	26	**95.3%**	**98.5%**	**1.5%**
Bolton	4010	4022	5	**99.6%**	**99.9%**	**0.1%**
Bury	2534	2581	18	**97.5%**	**99.3%**	**0.7%**
C Manc	3478	3499	23	**98.8%**	**99.3%**	**0.7%**
Chorley	1987	2004	63	**96.1%**	**97.0%**	**3.0%**
S Cumbria	1602	1630	35	**96.2%**	**97.9%**	**2.1%**
E Lancs	3153	3169	4	**99.4%**	**99.9%**	**0.1%**
Fylde & Wyre	1498	1566	11	**95.0%**	**99.3%**	**0.7%**
Grt Preston	2666	2698	46	**97.2%**	**98.3%**	**1.7%**
HMR	2978	3038	25	**97.2%**	**99.2%**	**0.8%**
N Lancs	1568	1657	39	**92.5%**	**97.7%**	**2.3%**
N Manc	2693	2751	43	**96.4%**	**98.5%**	**1.5%**
Oldham	3347	3400	13	**98.1%**	**99.6%**	**0.4%**
Salford	3702	3732	20	**98.7%**	**99.5%**	**0.5%**
S Manc	2343	2376	9	**98.2%**	**99.6%**	**0.4%**
Stockport	3437	3570	86	**94.0%**	**97.6%**	**2.4%**
Tameside	3293	3384	21	**96.7%**	**99.4%**	**0.6%**
Trafford	2826	2864	22	**97.9%**	**99.2%**	**0.8%**
W Lancs	575	897	33	**61.8%**	**96.5%**	**3.5%**
Wigan	3791	3852	24	**97.8%**	**99.4%**	**0.6%**
Out of region	358	384	6	**91.8%**	**98.5%**	**1.5%**
Total	57203	58510	583	**96.8%**	**99.0%**	**1.0%**

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)

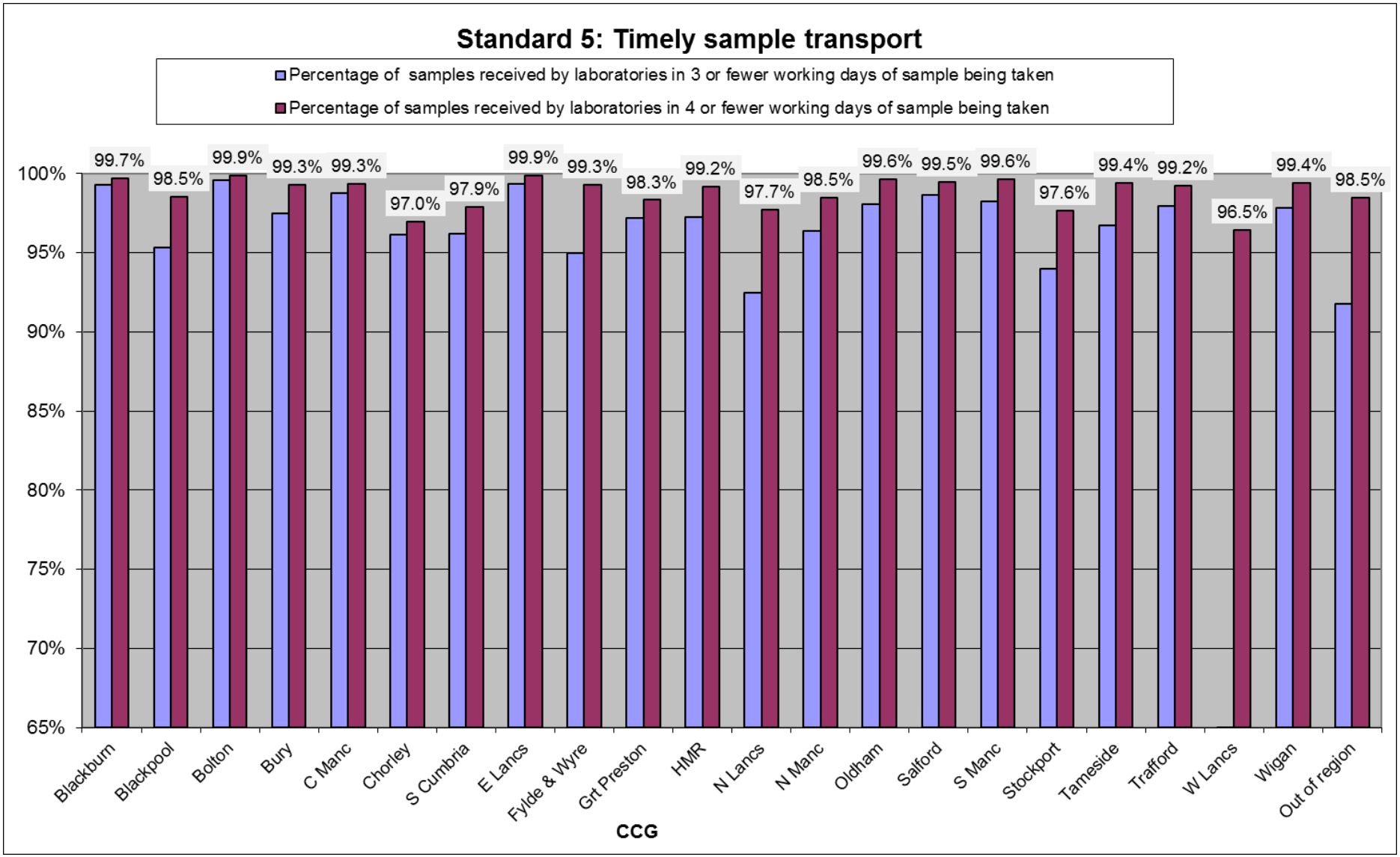

Figure 3: Graph to show percentage of samples received within 3 and 4 working days of being taken

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, 3 out of 21 CCGs achieved the standard (14% of CCGs; compared with 85% of CCGs during 2014/15). The overall percentage avoidable repeat rate was 3.3% (ranging from 1.4 to 5.6%); compared with 2.1% last year (range 1.2 to 3.4%). The change in performance against the standard can be attributed to implementation of new national sample acceptance criteria in April 2015.

The avoidable repeat rate for samples collected from in-patients was over three times higher than the rate for those collected in the community. 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 currently 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 contaminati on	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	3562	7	5	70	2	4	0	2	3	0	0	9	1	1	2.8%
NHS Blackpool CCG	1650	6	5	40	0	1	0	1	6	0	0	4	0	0	3.5%
NHS Bolton CCG	3830	3	3	85	2	10	0	0	7	0	0	13	0	0	3.1%
NHS Bury CCG	2490	6	2	36	0	2	0	1	7	0	0	6	0	0	2.3%
NHS Central Manchester CCG	3356	3	12	59	3	3	0	10	7	0	0	11	2	0	2.9%
NHS Chorley and South Ribble CCG	1914	4	0	41	3	1	0	1	3	0	0	1	53	0	5.6%
NHS Cumbria CCG	1597	0	1	26	2	3	0	0	3	0	0	3	0	0	2.3%
NHS East Lancashire CCG	3044	4	8	51	0	0	0	1	2	0	0	1	0	0	1.9%
NHS Fylde and Wyre CCG	1481	6	1	39	0	1	0	1	7	0	0	5	0	0	4.0%
NHS Greater Preston CCG	2581	6	7	42	2	0	0	2	4	0	0	4	39	0	3.8%
NHS Heywood, Middleton and Rochdale CCG	2953	1	2	11	4	4	0	6	7	0	0	7	0	0	1.4%
NHS Lancashire North CCG	1585	10	1	44	3	3	0	3	11	0	0	5	1	0	5.0%
NHS North Manchester CCG	2623	3	6	70	2	4	0	3	10	0	0	6	0	0	3.7%
NHS Oldham CCG	3271	2	6	28	1	12	0	1	16	0	0	2	0	0	1.9%
NHS Salford CCG	3591	3	5	76	6	7	0	7	9	0	0	9	0	0	3.3%
NHS South Manchester CCG	2265	2	5	46	2	3	0	6	9	0	0	3	0	0	3.1%
NHS Stockport CCG	3439	6	11	135	3	6	0	6	12	0	0	15	0	0	5.3%
NHS Tameside and Glossop CCG	3264	5	7	34	2	6	0	3	10	0	0	10	0	0	2.1%
NHS Trafford CCG	2734	5	5	69	3	4	0	4	10	0	0	5	0	0	3.7%
NHS West Lancashire CCG	902	0	0	12	2	1	0	2	5	0	0	2	0	0	2.7%
NHS Wigan Borough CCG	3589	7	8	146	2	4	0	2	22	0	0	7	0	0	5.3%
Out of region	337	2	14	10	1	1	0	1	1	0	0	1	0	0	5.1%
Total	56058	91	114	1170	45	80	0	63	171	0	0	129	96	1	3.3%

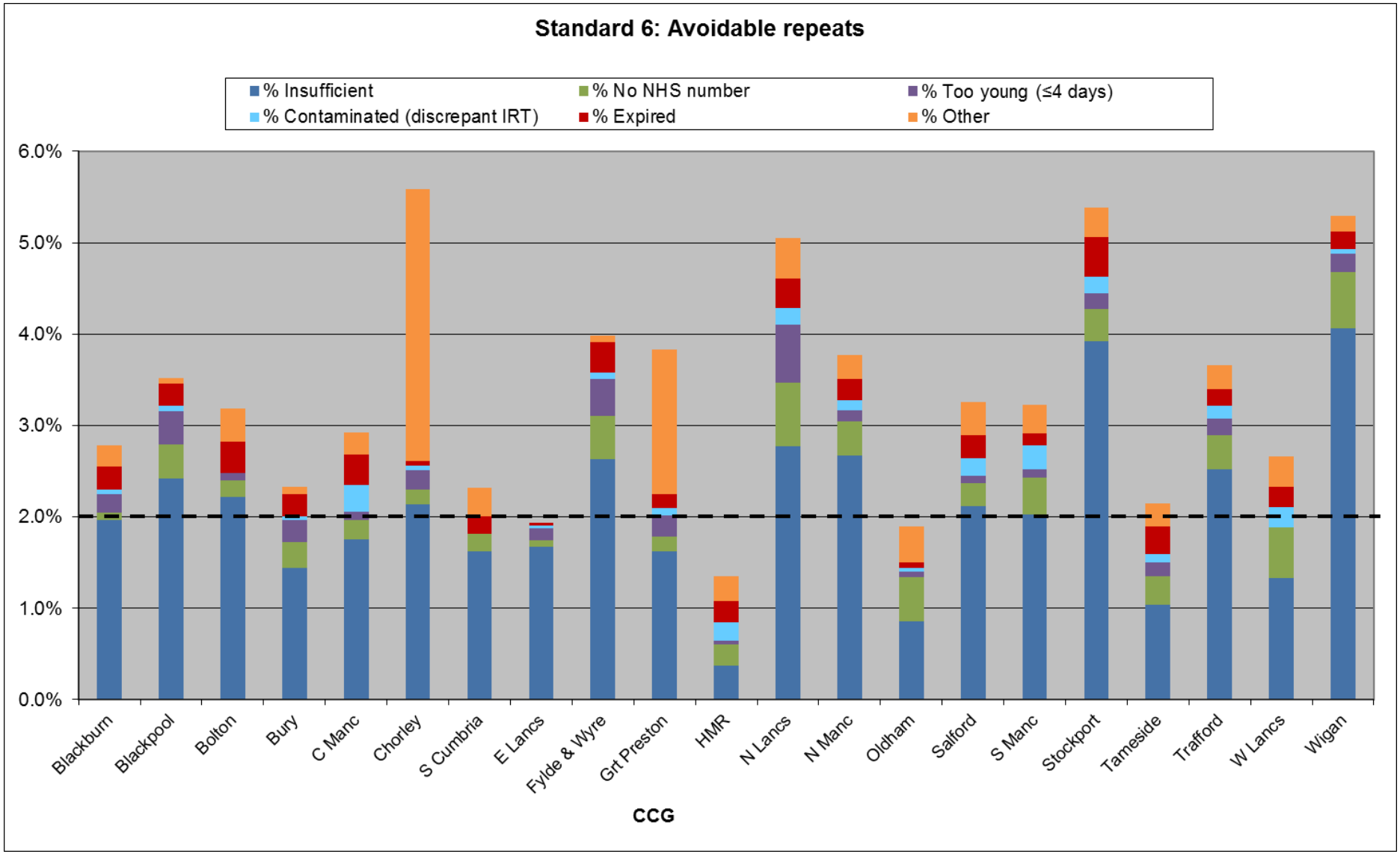

Figure 4: Graph to show avoidable repeat rate by CCG

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	**753**	8	20	31	1	0	0	1	0	0	0	0	0	0	**5.4%**
The Royal Bolton Hospital	**515**	0	14	18	4	3	0	3	1	0	0	2	0	0	**6.0%**
Blackpool Victoria Hospital	**295**	6	1	19	0	1	0	0	0	0	0	0	0	0	**8.8%**
Furness General Hospital	**95**	0	0	4	0	0	0	0	0	0	0	0	0	0	**4.2%**
North Manchester General Hospital	**412**	3	2	22	2	1	0	1	2	0	0	2	0	0	**8.0%**
Not in hospital	**50012**	58	2	889	16	50	0	47	119	0	0	109	87	1	**2.8%**
Ormskirk & District General Hospital	**111**	0	1	5	2	1	0	0	0	0	0	1	0	0	**8.1%**
Royal Albert Edward Infirmary	**281**	1	2	17	3	1	0	0	11	0	0	2	0	0	**12.5%**
Royal Blackburn Hospital	**5**	0	0	0	0	0	0	0	0	0	0	0	0	0	**0.0%**
Royal Lancaster Infirmary	**208**	2	0	15	2	0	0	1	0	0	0	0	0	0	**9.6%**
Royal Manchester Children's Hospital	**28**	0	1	10	1	0	0	1	6	0	0	1	0	0	**67.9%**
Royal Oldham Hospital	**591**	1	12	2	3	6	0	1	10	0	0	1	0	0	**4.1%**
Royal Preston Hospital	**400**	3	7	28	3	2	0	1	1	0	0	0	9	0	**11.8%**
Stepping Hill Hospital	**282**	0	0	17	2	6	0	0	4	0	0	0	0	0	**10.3%**
St Mary's Hospital, Manchester	**1355**	3	47	61	4	4	0	3	6	0	0	7	0	0	**6.5%**
Tameside General Hospital	**229**	1	1	4	0	1	0	1	2	0	0	1	0	0	**4.4%**
University Hospital of South Manchester	**486**	5	4	21	2	4	0	3	9	0	0	3	0	0	**9.7%**
UK Out of Region	**0**	0	0	7	0	0	0	0	0	0	0	0	0	0	**0.0%**
Total	**56058**	91	114	1170	45	80	0	63	171	0	0	129	96	1	**3.3%**

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

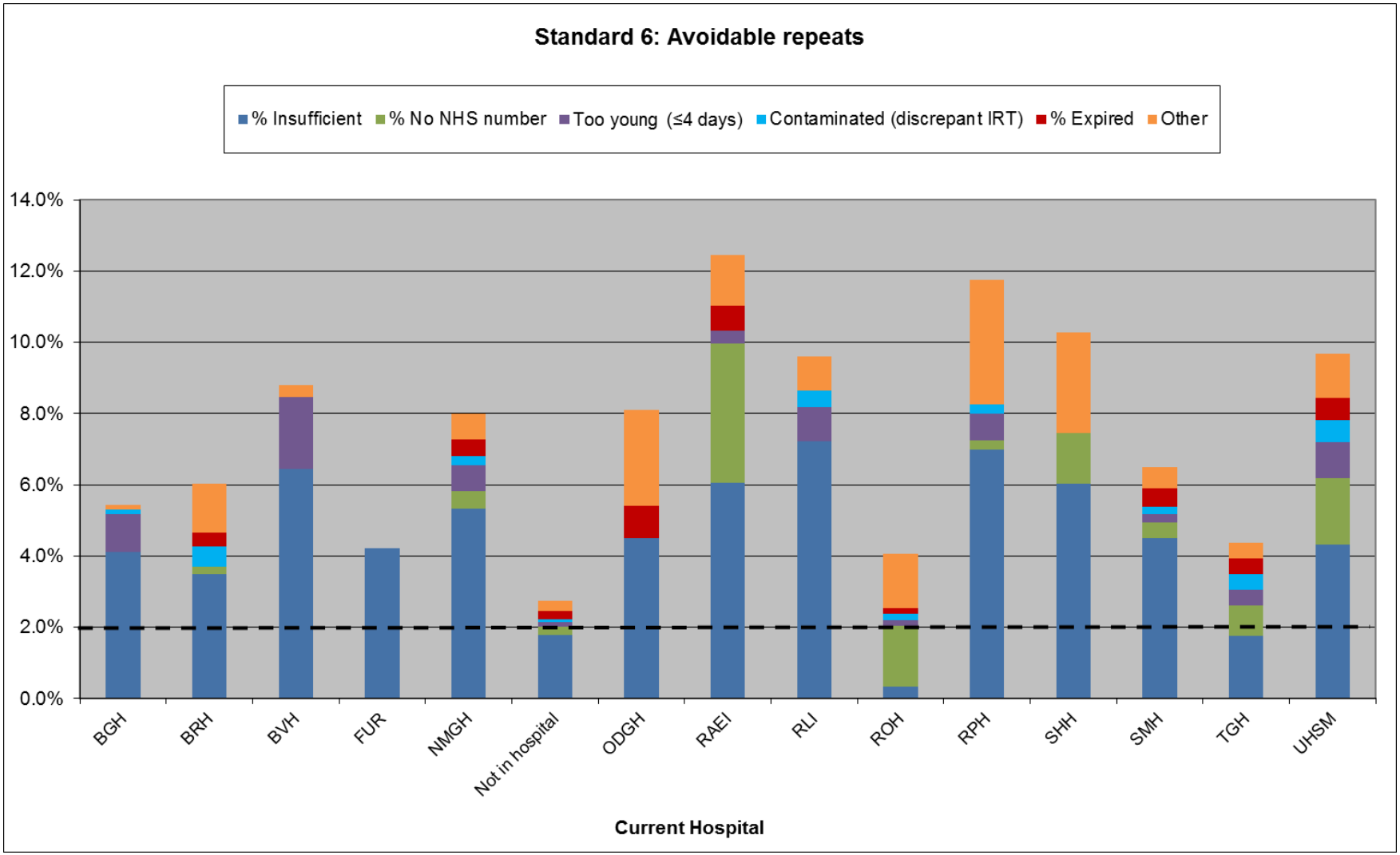

Figure 5: Graph to show avoidable repeat samples collected from babies in hospital compared with samples collected in the community

Note: Royal Manchester Children's Hospital excluded from graph (avoidable repeat rate 68%)

5. Clinical Referral Data

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

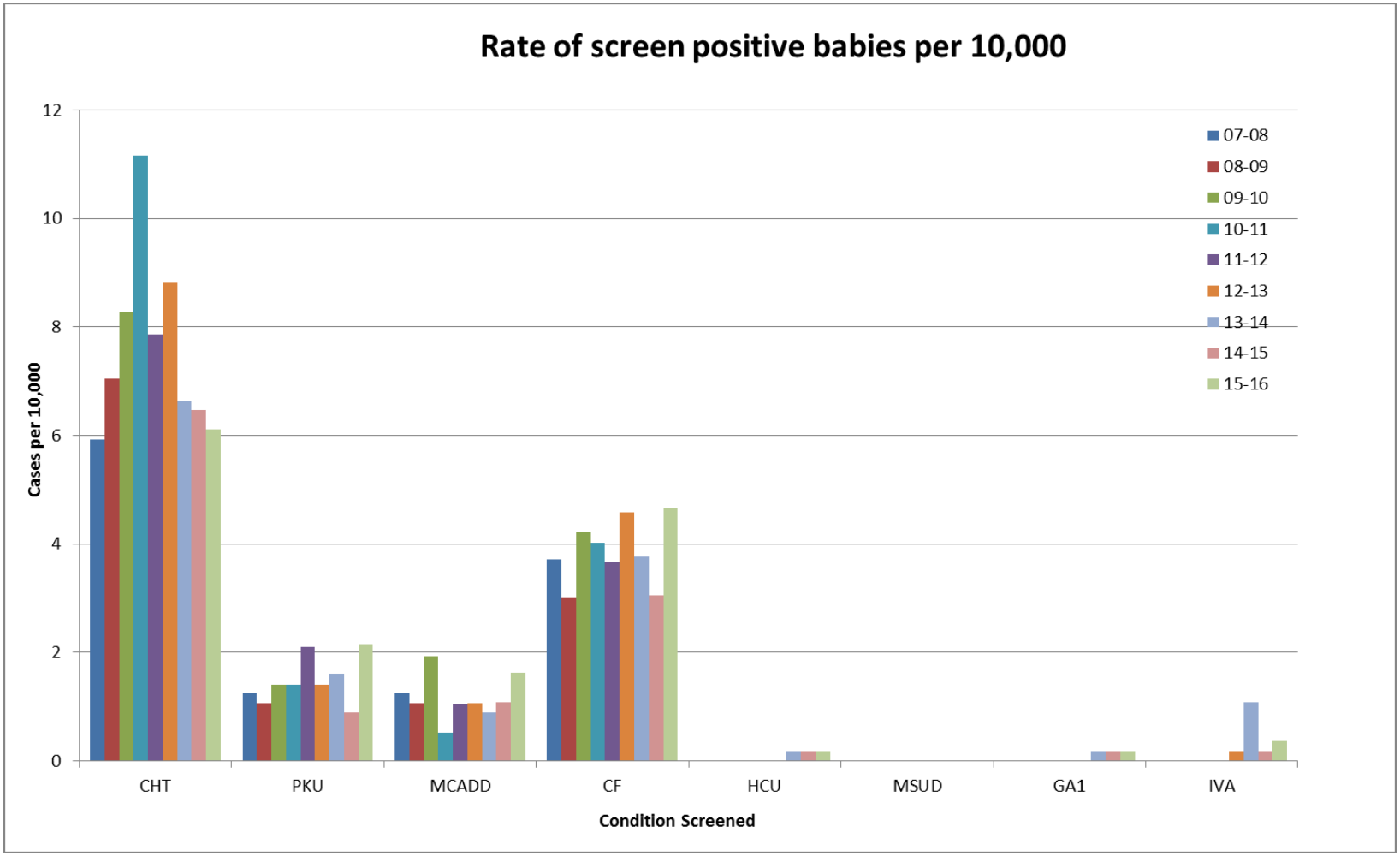

Figure 6: Rate of screen positive babies (per 10000) from 2007 onwards

Positive Cases 2015-2016

PKU Screening

Twelve cases of confirmed raised phenylalanine were followed up clinically by medical staff at the Willink Unit. There were 9 confirmed as PKU cases, giving an estimated incidence of 1: 6191. This figure was calculated based on the number of first samples received by the laboratory which may not truly reflect the birth rate. Of the 3 remaining positive screens, =one was a milder elevation of phenylalanine which requires follow up (hyperphenylalaninaemia), one was a case of galactosaemia and the other was a premature baby with liver and renal failure, who subsequently died. According to the clinical referral guidelines, 100% of positive screening results should be referred within four working days of sample receipt. All cases were referred within 3 working days. The age at referral ranged from 8-14 days. All babies had their first clinical appointment by 13 days of age (range 9-13 days), excluding the baby who died (who was first assessed by the metabolic team prior to screening

MCADD Screening

There were 9 screen positives for MCADD and all 9 were confirmed as MCADD cases, giving an estimated incidence of 1 in 6191. Of the 9 babies, 2 were detected from early screening samples on day 2 due to having affected siblings. The other 7 screen positives were referred within 3 working days. The age at referral ranged from 8-11 days.

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

There were 3 screen positives for other metabolic conditions (2 for IVA and 1 for GA1), all of which were referred within 3 working days. One case, referred on day 10, was a confirmed as IVA. There was no persistent abnormality found in another IVA screen positive, which was thought to be due to maternal antibiotics. There was also a false positive for GA1, referred on day 12. No abnormality was found and the baby was well.

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 20 such cases and the blood spot TSH ranged from 20 mU/L to >285 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 115 initial borderline results (using a local cut off of 8 mU/L as opposed to the national cut off of 10 mU/L), 13 (11%) were treated as positive following repeat sampling with a TSH ranging from 8 to 43 mU/L on repeat.

There was one case of a screen positive result on a premature baby following two borderline results, one of which was a transfusion repeat on day 15 (also collected within 72 hours of a transfusion) and one collected on day 26.

The number of positive cases per CCG 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 13 days (range 10-16 days). The first clinic appointment was attended by day 17 in all cases.

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). The referral ages for babies referred following a second sample are shown in table 7 and detailed as the red in figure 7. The median age at the first clinic appointment was 21 days (range 17-32). The first clinic appointment was attended by day 24 in 11 cases (79%; In-patients evaluated on the day of referral). Three babies exceeded 24 days, including the premature baby with multiple samples (referred on day 32) and a baby seen on day 26 following a delay in collection of the repeat sample. One baby was the subject of a clinical incident due to delayed sample collection (initial sample collected on day 8, repeat sample collected 8 days after repeat request, appointment on day 31; incident number 1056456)).

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 4 working days and 97% were referred within 3 working days.

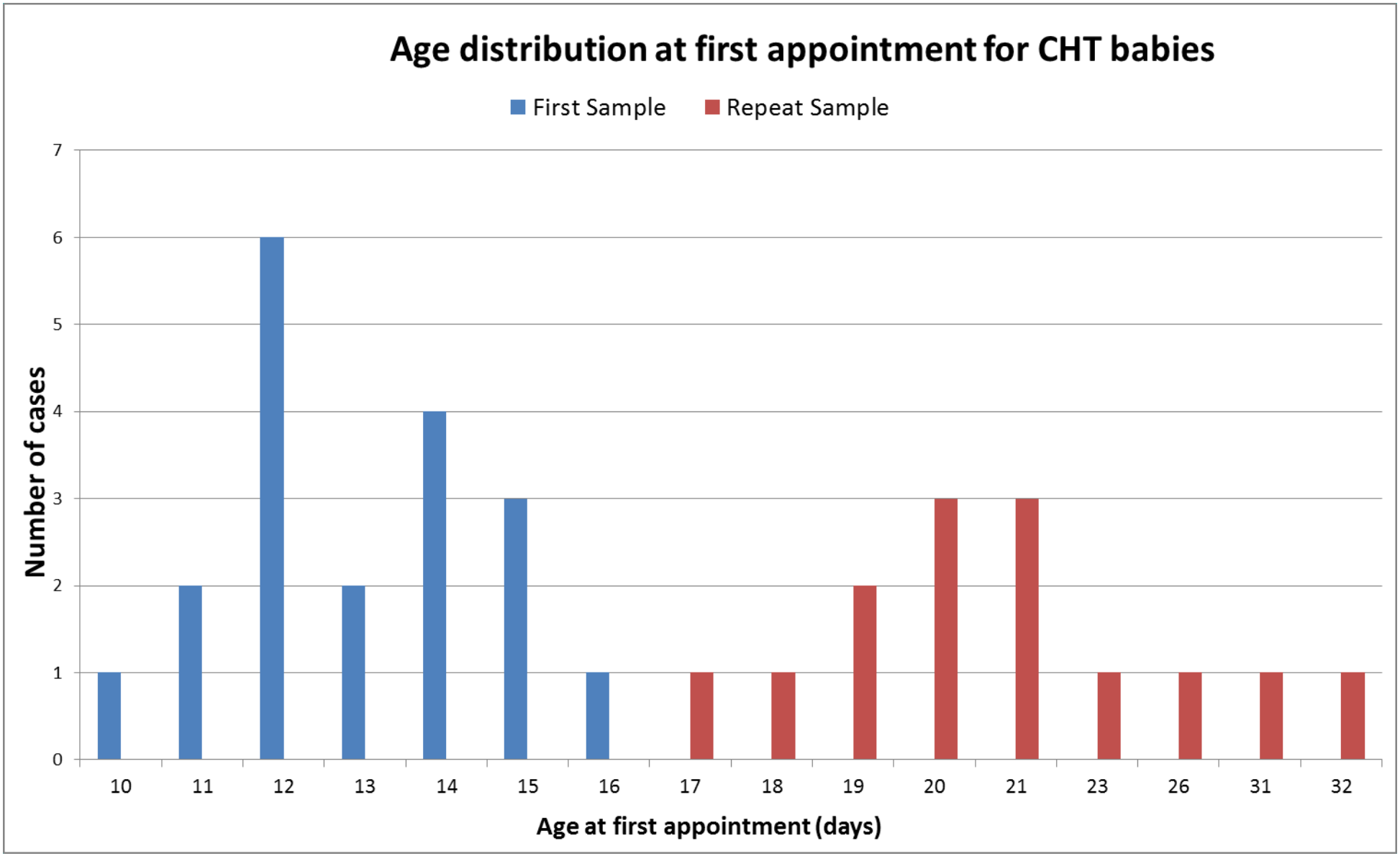

Figure 7: Graph to show age at first appointment for each positive CHT case (in days)

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

CCG	Number of cases	Age at referral (days)
Blackburn with Darwen CCG	1	14
Blackpool CCG	1	12
Bolton CCG	0	
Bury CCG	3	13, 13, 15
Central Manchester CCG	2	10, 12
Chorley and South Ribble CCG	0	
Cumbria CCG	0	
East Lancashire CCG	0	
Fylde and Wyre CCG	1	11
Greater Preston CCG	1	12
Heywood, Middleton and Rochdale CCG	2	14, 15
Lancashire North CCG	0	
North Manchester CCG	1	12
Oldham CCG	1	15
Salford CCG	2	11, 12
South Manchester CCG	0	
Stockport CCG	2	12, 14
Tameside and Glossop CCG	0	
Trafford CCG	0	
Wigan Borough CCG	2	14, 16

Table 6: Location and age at referral of positive CHT babies identified on the first sample (For in-patients: age at referral is used instead of age at appointment, 1 detected prior to screening – Bolton)

CCG	Number of cases	Age at referral (days)
Blackburn with Darwen CCG	1	21
Blackpool CCG	0	
Bolton CCG	1	26
Bury CCG	0	
Central Manchester CCG	1	32
Chorley and South Ribble CCG	0	
Cumbria CCG	0	
East Lancashire CCG	2	17, 18
Fylde and Wyre CCG	1	31
Greater Preston CCG	1	23
Heywood, Middleton and Rochdale CCG	0	
Lancashire North CCG	0	
North Manchester CCG	0	
Oldham CCG	2	19, 20
Salford CCG	1	20
South Manchester CCG	1	19
Stockport CCG	1	21
Tameside and Glossop CCG	1	20
Trafford CCG	1	21
Wigan Borough CCG	0	16

Table 7: Positive CHT babies identified on a second sample and age of referral

CF Screening

CF screening process is carried out according to the national algorithm as detailed on the NHS Newborn Blood Spot Screening Programme 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 2015/16 is shown in figure 8. Summary data since the programme was implemented in 2007 in shown in table 8.

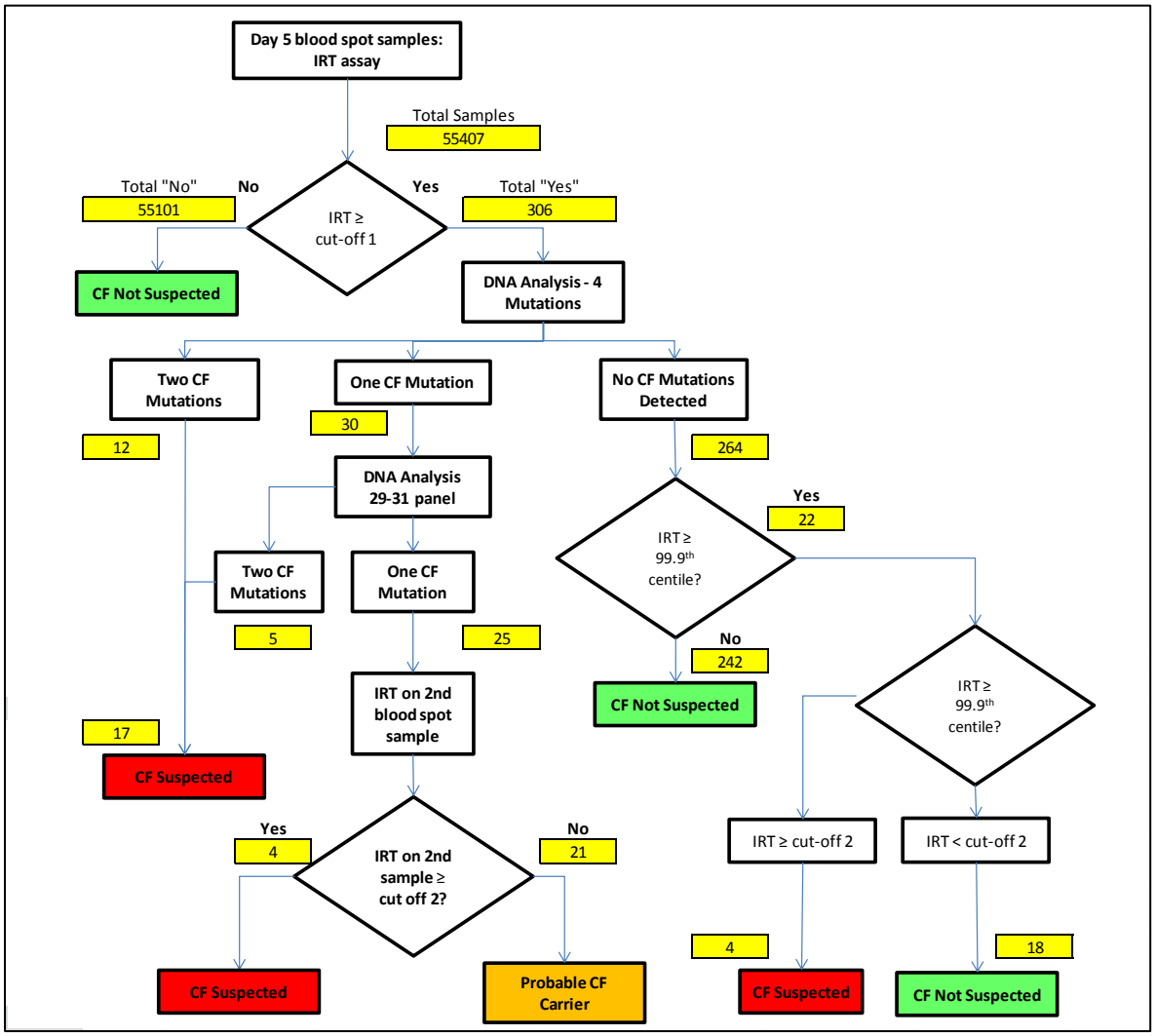

Figure 8: CF screening algorithm displaying the numbers detected in each category for Manchester Newborn Screening Lab in 2015/16

Year	07/08	08/09	09/10	10/11	11/12	12/13	13/14	14/15	15/16
Babies Screened	26931	55627	56720	57281	57142	56585	55603	55469	55407
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%)
CF Suspected	11 (11)	17 (23)	24 (23)	23 (23)	21 (23)	26 (23)	21 (23)	17 (23)	26 (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)
2 mutations on extended panel	1 (1)	1 (3)	5 (3)	4 (3)	1 (3)	6 (3)	10 (3)	4 (3)	5 (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)
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)
CF probable carriers	5 (13)	13 (28)	16 (28)	22 (28)	12 (29)	6 (28)	17 (28)	13 (28)	21 (28)

Table 8: CF Outcome Data for CF Since Programme Implementation
Figures in parentheses are numbers predicted from the national algorithm

The percentage of samples referred for DNA testing was 0.55%, which is slightly above the target of 0.5%. However this figure did fluctuate throughout the year (0.45-0.72%) probably due to lot to lot variation of the IRT kits. Cut-offs are adjusted in response to lot changes but large numbers of data points (approximately 13,000) are required to accurately determine the 99.5th centile, so the kit lot may be in use for 12-13 weeks before an accurate cut-off is established. Since January 2016, we have collaborated 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 is higher than the figure predicted from the national algorithm. The number of carriers identified was lower than the predicted figure from the national algorithm, but that has always been the case since screening commenced in 2007.

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 red. The median age for referral for the double mutation cases was 18 days (range 13–28 days). The median age at first clinic appointment for this group was 20 days (range 16-28 days, excluding 3 babies detected prior to screening as a result of family history of CF).

Of the CF cases identified following a second raised IRT 63% (5/8) had a clinic appointment by day 35. The median age for referral for this group was 27 days (range 23–262 days). The median age at first clinic appointment was 30 days (range 29-279 days, excluding 1 baby who died). The baby who had an appointment with the CF team at 279 days was extremely premature. Genetic testing and a faecal elastase test were performed by the neonatologists, shortly after the referral, on the advice of the CF team. The sweat test was performed aged 279 days, for completeness, when the baby was large enough and well enough.

CCG	Number of cases	Age at first appointment
Bolton CCG	3	19, 24, **30**
Bury CCG	2	16, 20
Central Manchester CCG	2	20 ,**29**
Cumbria CCG	1	22
Rochdale CCG	2	17, 17
Lancashire North CCG	1	27
North Manchester	1	**279**
Oldham CCG	2	19, **29**
South Manchester CCG	1	29
Stockport CCG	1	16
Tameside and Glossop CCG	1	**29**
West Lancashire	1	**40**
Wigan Borough CCG	4	25, 28, 28, **36**

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. Excluding one baby who died aged 5 months prior to appointment with CF team (CF-suspected on day 48 sample, previously not suspected on day 6 sample; extremely premature, complex problems, likely false positive).

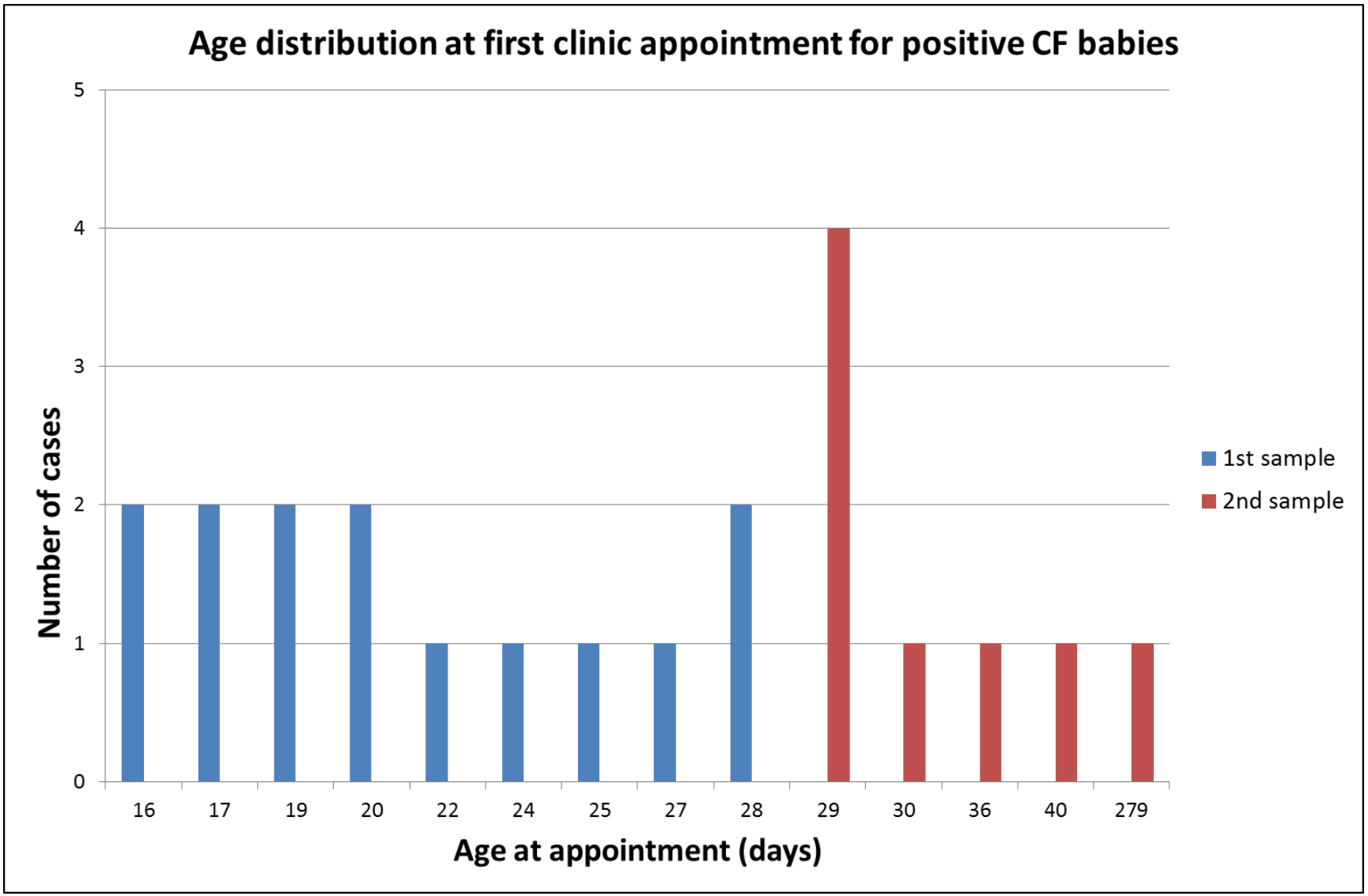

Figure 9: Graph to show the age at first clinic appointment for CF Suspected cases.
The baby referred following receipt of a second blood spot is shown to the right of the graph.

In 2015/16 a total of 339 babies missed CF screening which was higher than the number in 2014/15 (240). 95% (301) of these babies were born outside of the UK (same percentage as the previous year). 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. Of the 18 babies not born outside of the UK who missed CF screening, 13 appear to have had their first sample collected at more than 8 weeks of age. This may include babies where the place of birth was not indicated on the card, so it is possible that some were in fact 'movements in'. Figures 10 and 11 give a breakdown of babies who missed CF screening by CCG. In figure 10 the numbers are expressed as a rate per 10,000 babies screened to enable better comparison between the CCGs.

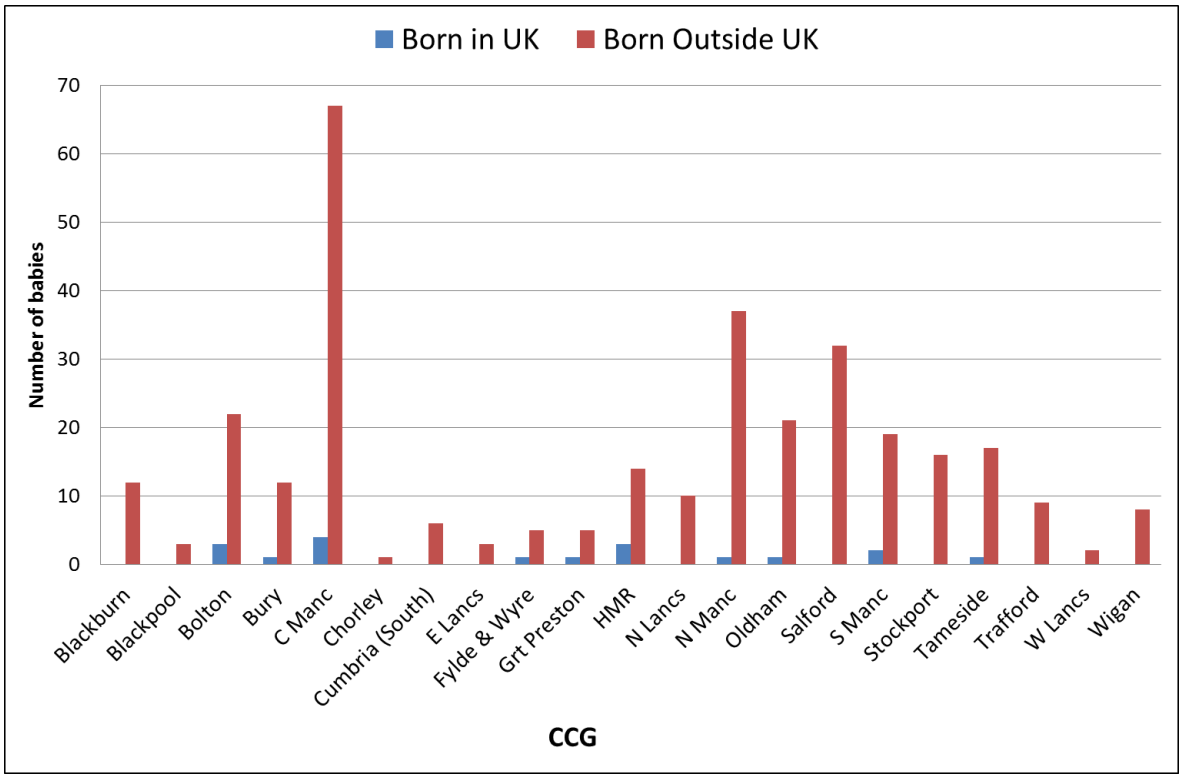

Figure 10: The number of babies who missed CF screening sorted by CCG

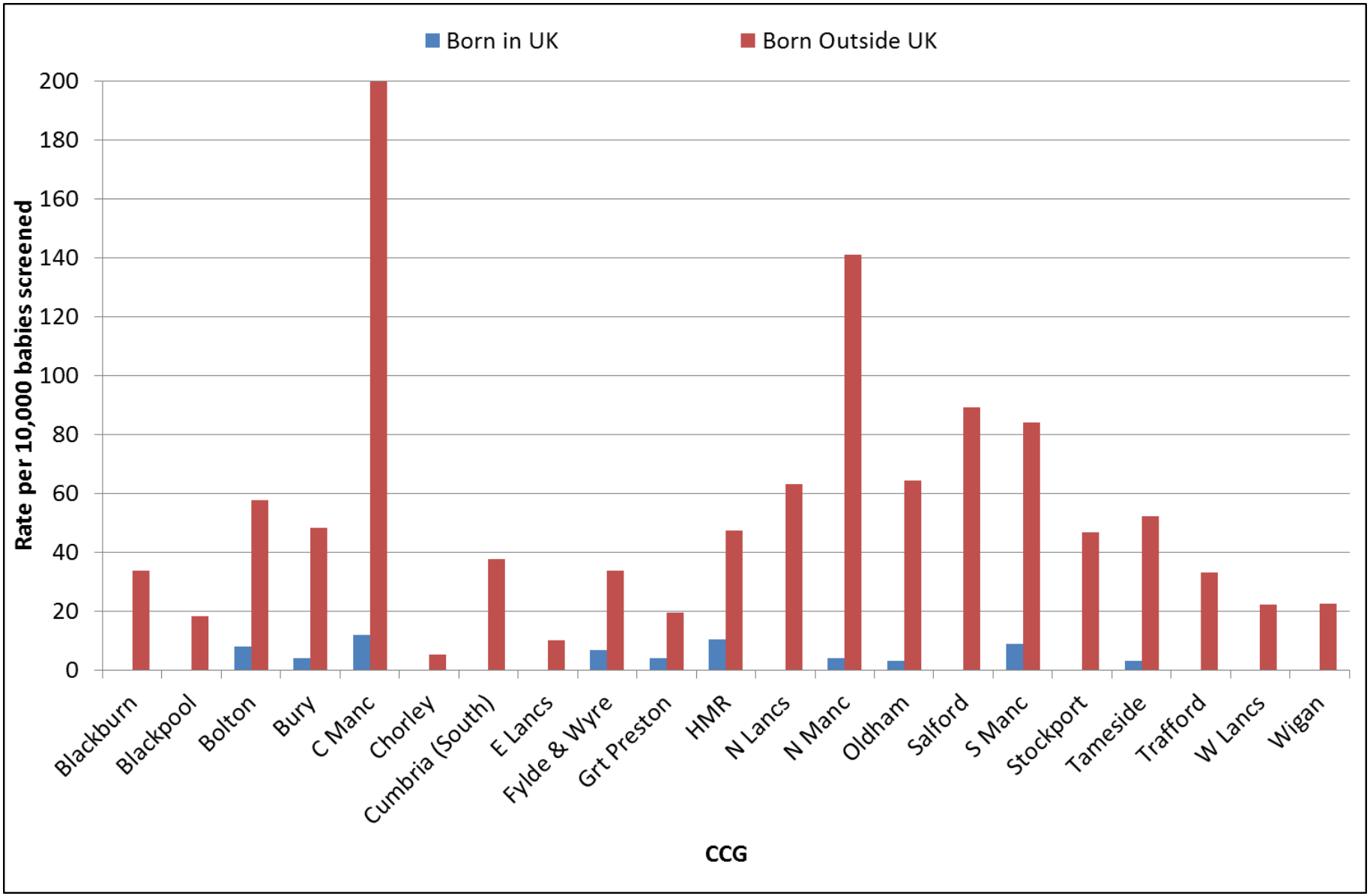

Figure 11: The number of babies who missed CF screening per 10,000 babies screened by each CCG

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 661 samples for confirmatory testing, 60 of which were subsequently reported as not suspected for Sickle Cell Disease. The 60 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 12 babies identified as having sickle cell disease (7 FS and 5 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 2015 and March 2016, all of the clinically significant disorders identified were reported by 21 days of age (median 16 days; range 11-21 days). The laboratory was notified of the 'at-risk' pregnancy in 64% of the positive cases (9/14, excluding FE; table 12).

CCG	Significant Diseases					Non-significant diseases		Carriers			
	FS	FSC	FSA	FE	F only	FC	FD	FAS	FAC	FAD	FAE
Blackburn with Darwen	0	0	0	0	0	0	0	5	2	6	4
Blackpool	0	0	0	0	0	0	0	5	0	2	3
Bolton	1	0	0	0	0	0	0	27	1	3	6
Bury	0	0	0	0	0	1	1	5	1	2	1
Central Manchester	2	2	0	1	0	0	0	78	15	5	9
Chorley and South Ribble	0	0	0	0	0	0	0	2	0	3	0
Cumbria	0	0	0	0	0	0	0	2	1	1	0
East Lancashire	0	0	0	0	0	0	1	4	1	4	8
Fylde and Wyre	0	0	0	0	0	0	0	1	1	0	0
Greater Preston	0	0	0	0	1	0	1	12	1	0	1
Heywood, Middleton and Rochdale	0	0	0	0	0	0	0	18	2	6	7
Lancashire North	0	0	0	0	0	0	0	2	0	0	0
North Manchester	0	1	0	0	1	0	0	91	13	4	1
Oldham	1	0	0	0	0	0	0	16	1	8	21
Salford	2	2	0	0	0	0	0	58	8	4	1
South Manchester	0	0	0	0	0	0	0	16	4	5	0
Stockport	0	0	0	0	0	0	0	10	5	2	3
Tameside and Glossop	1	0	0	0	0	0	0	15	1	4	6
Trafford	0	0	0	0	0	0	0	11	0	1	1
West Lancashire	0	0	0	0	0	0	0	1	0	0	1
Wigan Borough	0	0	0	0	0	0	0	11	0	0	1
Out of region	0	0	0	0	0	0	0	0	1	0	0
Total	7	5	0	1	2	1	3	390	58	60	74

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	FSA	FE	F Only	FC	FD	FAS	FAC	FAD	FAE
White British	0	0	0	0	0	0	0	14	7	10	1
White Irish	0	0	0	0	0	0	0	1	0	0	0
Any other White background	0	0	0	0	0	0	0	6	0	0	0
White and Black Caribbean	0	0	0	0	0	0	0	18	6	1	0
White and Black African	0	0	0	0	0	0	0	31	4	0	0
White and Asian	0	0	0	0	0	0	0	0	0	2	8
Any other mixed background	0	0	0	0	1	0	0	27	4	2	3
Indian	0	0	0	0	0	0	0	10	0	3	2
Pakistani	0	0	0	0	1	0	3	1	0	36	15
Bangladeshi	0	0	0	0	0	0	0	1	0	2	36
Any other Asian background	0	0	0	0	0	0	0	2	0	2	5
Black Caribbean	1	1	0	0	0	0	0	22	7	0	0
Black African	6	4	0	0	0	0	0	221	24	0	1
Any other Black background	0	0	0	0	0	0	0	18	3	0	0
Chinese	0	0	0	0	0	0	0	0	0	0	0
Any other ethnic category	0	0	0	1	0	1	0	11	1	1	3
Not stated	0	0	0	0	0	0	0	7	2	1	0
Total	7	5	0	1	2	1	3	390	58	60	74

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	Yes - Recorded on blood spot card	Yes	5	7	19	57
FSC	Yes - Antenatal alert form	Yes	5	8	16	54
FSC	Yes - Antenatal alert form	Yes	5	8	18	40
FS	No	No	5	7	16	38
FS	Yes - Antenatal alert form	No	5	6	13	36
FE	No	No	5	6	16	104
FS	No	No	9	10	21	88
FS	No	No	5	6	13	40
FSC	Yes - Antenatal alert form	Yes	5	6	11	64
F-only	Yes - Antenatal alert form	No	5	8	17	59
FS	No	No	6	8	21	92
FSC	Yes - Recorded on blood spot card	Yes	6	8	18	57
FS	Yes - Antenatal alert form	Yes	5	6	14	37
FSC	No	No	5	8	19	75
F-only	Yes - Antenatal alert form	No	5	7	16	104

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 2015/16 99.7% of cards included the baby's NHS number (National Standard 100%). There was a large variation between CCGs regarding the use of bar-coded labels and for some usage remains low. Overall there has been an increase in the usage of bar-coded labels (from 64% to 73%).
- Standard 4 - Timely sample collection: All CCGs met this standard. Overall 97.6% of first samples were collected on days 5-8, the same as in 2014/15 (98.0%).
- Standard 5 - Timely sample receipt in the lab: 99.0% samples were received within 4 working days which remains unchanged for the last two years (target 100%).
- Standard 6 - Quality of Blood spot Sample: 3 out of 21 CCGs achieved this standard which represents deterioration in performance from last year. The change in performance can be attributed to implementation of new national sample acceptance criteria in April 2015. The percentage avoidable repeat rate ranged from 1.4% to 5.6%

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 14 days. For CHT positive babies identified on the initial screening sample all had their first clinic appointment by 17 days and 80% by 14 days (range 10-16 days). Of the babies identified as CHT positive following repeat testing (borderline first sample) 79% 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 and MCADD were initiated within 3 working days and 97% of CHT referrals were made within 3 working days (100% within 4 working days).

Cystic Fibrosis Programme

- Overall, an appropriate number of samples (0.55%) were referred for DNA testing.

- The number of babies who were screen positive was lower than the figure predicted from the national algorithm, as in previous years. The number of carriers identified was lower than the predicted figure but this has always been the case since screening commenced.
- Of the 17 positive cases with two mutations, 100% were assessed by the CF team by 28 days of age (the national standard).
- Of 8 CF suspected cases identified following a second raised IRT, 63% 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 increased from 240 in 2014/15 to 339. The proportion of "movers in" (born outside of the UK) was similar to the previous year (95%).

Sickle Programme

- In 2015/16 12 babies with sickle cell disease and 2 with β thalassaemia were identified as well as 390 carriers of the sickle gene and 192 carriers of haemoglobins C, D and E.
- Age at referral for babies screen positive for sickle cell and β thalassaemia ranged from 11–21 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 24 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 86% of the total incidents. 4% 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.

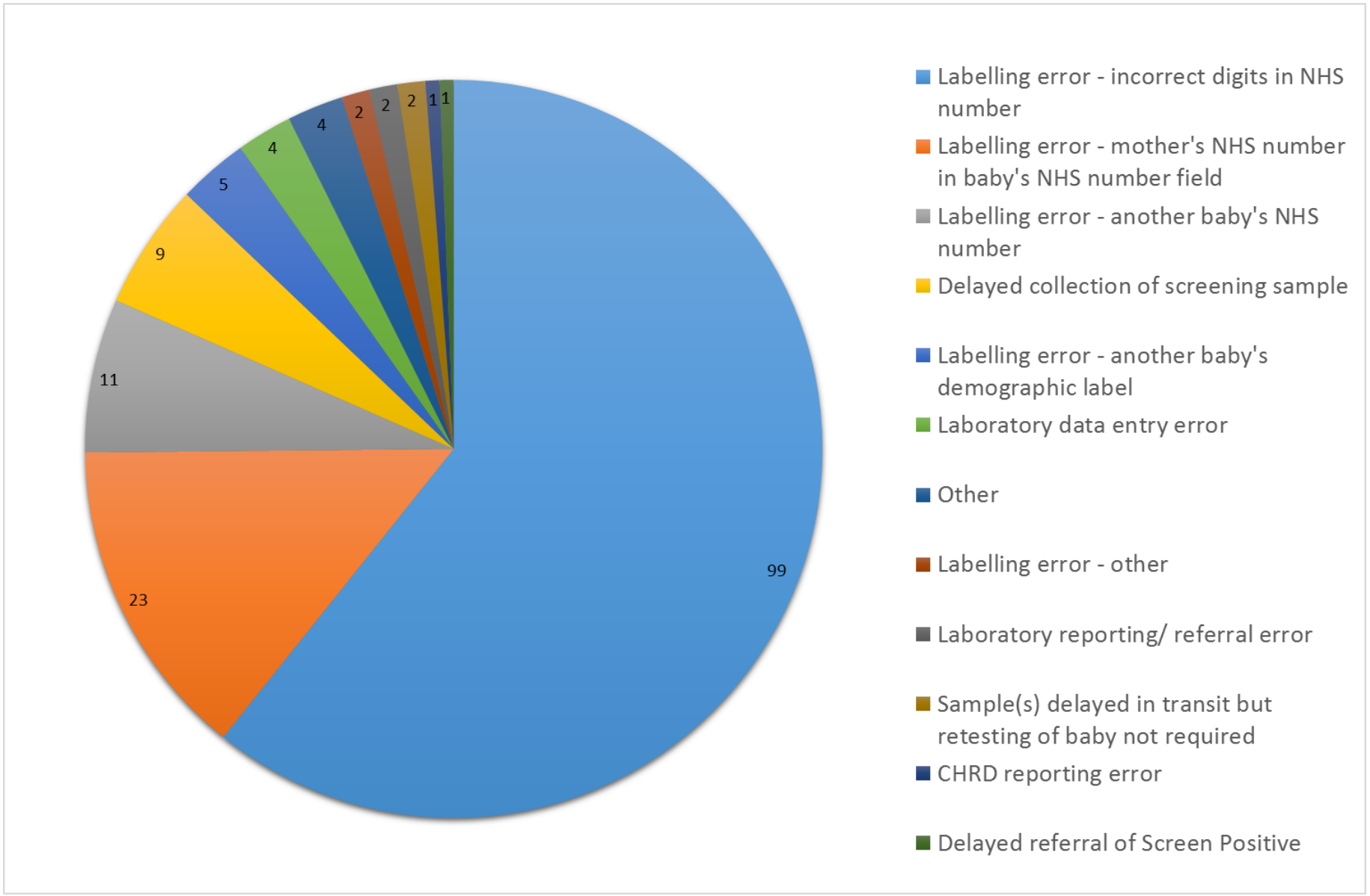

Figure 12: Newborn blood spot screening clinical incidents by cause

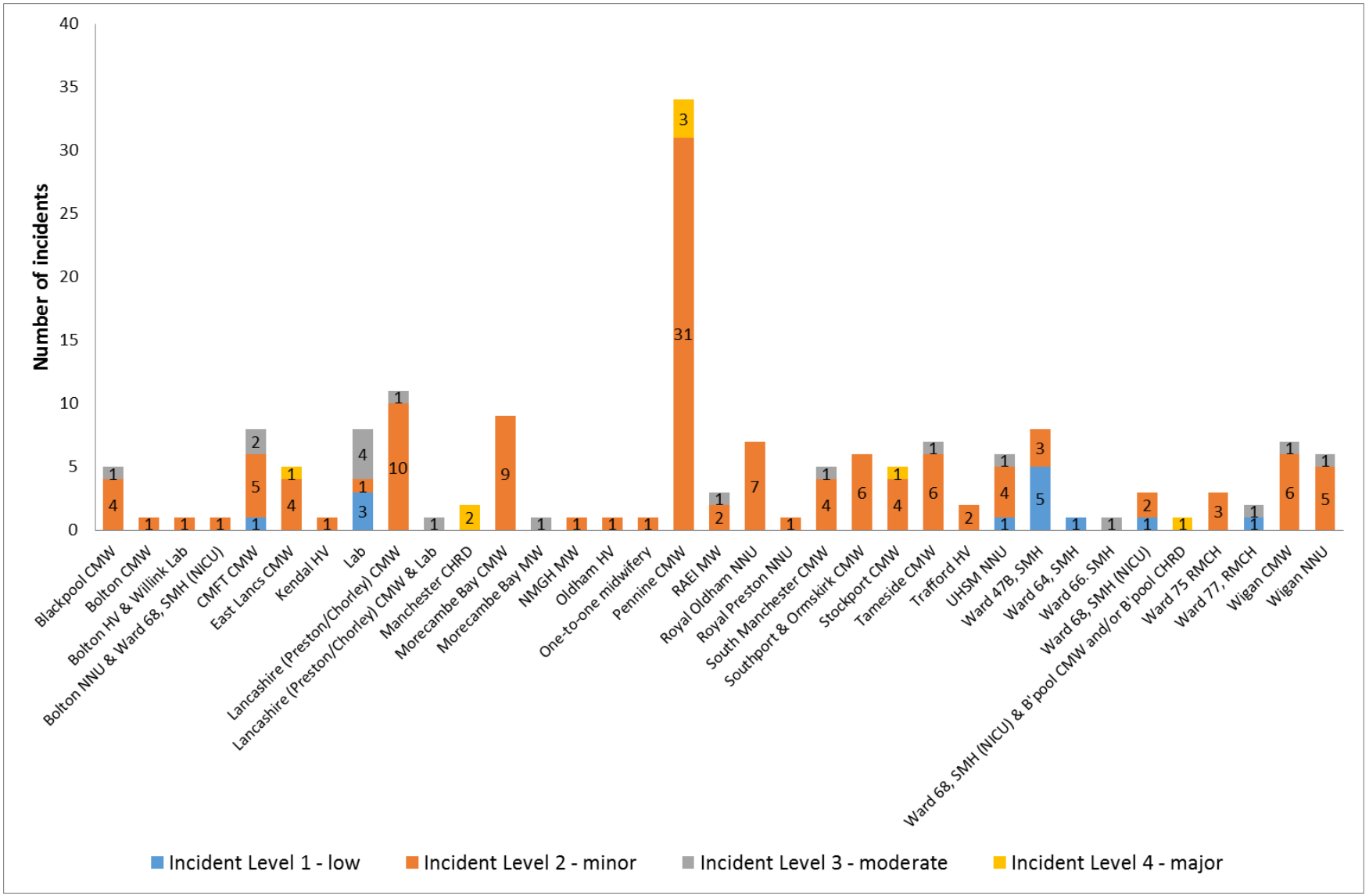

Figure 13: Newborn blood spot incidents (logged by CMFT) by location of incident; Key: CMW – Community midwives, HV – Health Visitors, CHRD -Child Health Records Dept, NNU – Neonatal Unit, MW – Maternity Ward

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 ultimately to view results. From April 2016 the laboratory plans to commence uploading of full result codes in addition to the 01 (sample received) code. The laboratory 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 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. Currently electronic reporting is in place for Manchester with roll-out to Bolton, Stockport and Tameside CHRDs planned for 2016/17. Ultimately the laboratory hopes to move to ITK messaging in line with the national strategy.

- The NBS laboratory continues to be been involved in work locally and nationally to improve blood spot quality. Standardised criteria for blood spot acceptance and rejection were introduced nationally in April 2015 and monthly avoidable repeat data is submitted to the NHS Newborn Bloodspot Programme. Locally the laboratory works closely with the clinical and education leads for St Mary's and Royal Manchester Children's Hospitals on improving quality. Work in 2015/16 included the introduction of "quick heel" devices in the children's hospital as part of dedicated bloodspot collection boxes containing all of the required equipment. Further training on bloodspot collection was conducted in conjunction with this.

- Involvement has been on-going in the BPSU surveillance study for CHT and in audit projects relating to clinical outcomes for CHT and sickle screening initiated by the NHS Newborn Blood Spot Screening Programme and NHS Sickle Cell Screening Programme respectively. Preliminary results from the BPSU study were presented at the annual meeting of the Royal College of Paediatrics and Child Health (RCPCH) in April 2015.

- A project led by Viapath GSTS started in January 2016 to determine whether using a common internal standard would improve the harmonisation of screen results for Inherited Metabolic Diseases (IMD) in the long term. The Willink Biochemical Genetics Laboratory will participate in this project in year 2016/17. All together there will be five UK NBS laboratories in this project: Viapath, Leeds, Birmingham, Cardiff and Manchester.

- There is a need to progress essential equipment and IT upgrades in 2016/17. The Autodelfias (which perform the analyses for CHT and CF screening) are 8 and 11 years old, so well overdue for replacement which will be with Genetic Screening Processors (GSPs). An end of life notice has been received in relation to the dedicated screening IT system Specimen Gate Lifecycle Neonatal Solution which needs therefore to be upgraded to Specimen Gate Screening Centre. The laboratory is also seeking to move to Tandem MS technology for sickle cell screening and consideration is being given to sharing of Tandem MS equipment between the Willink and Newborn screening laboratories.

Appendix 1: Research and Development and Audit

Poster & Oral Presentations

Confirming Congenital Hypothyroidism after Newborn Bloodspot Screening: a UK Surveillance Study.

RL Knowles, J Oerton, T Cheetham, G Butler, L Tetlow, C Cavanagh, C Dezateux

Royal College of Paediatrics and Child Health (RCPCH) Annual Meeting, Birmingham (UK), April 2015

Appendix 2: Data by Maternity Unit

Key

Maternity Unit	Abbreviation
Blackpool Victoria Hospital	Blackpool
Central Manchester University Hospitals	C. Manchester
East Lancashire Hospitals	Blackburn / Burnley
Lancashire Teaching Hospitals	Preston / Chorley
Not Stated	Not Stated
One-to-One Midwifery	1-2-1
Pennine Acute Hospitals	Pennine
Royal Albert Edward Infirmary	RAEI
Royal Bolton Hospital	Bolton
Southport & Ormskirk Hospital	Southport & Orms.
Stockport	Stockport
Tameside General Hospital	Tameside
University Hospitals of Morecambe Bay	Morecambe Bay
University Hospital of South Manchester	UHSM

Maternity Unit	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 Victoria Hospital	3130	3119	2236	99.6%	71.7%
Central Manchester University Hospitals	5681	5669	4607	99.8%	81.3%
East Lancashire Hospitals	5550	5547	4960	99.9%	89.4%
Health Visitor	211	211	36	100.0%	17.1%
Lancashire Teaching Hospitals	4641	4635	3045	99.9%	65.7%
Not stated	6513	6447	4345	99.0%	67.4%
One-to-One Midwifery	117	116	28	99.1%	24.1%
Pennine Acute Hospitals	10884	10840	7797	99.6%	71.9%
Royal Albert Edward Infirmary	3464	3442	1459	99.4%	42.4%
Royal Bolton Hospital	6472	6468	4235	99.9%	65.5%
Southport & Ormskirk Hospital	907	902	452	99.4%	50.1%
Stockport	3224	3215	2700	99.7%	84.0%
Tameside General Hospital	2957	2949	2510	99.7%	85.1%
Out of area	11	11	4	100.0%	36.4%
University Hospitals of Morecambe Bay	2340	2330	1526	99.6%	65.5%
University Hospitals South Manchester	4506	4498	4077	99.8%	90.6%
Total	**60608**	**60399**	**44017**	**99.7%**	**72.9%**

Table 1: Data for Standard 3 showing the number of cards that include NHS number, by maternity unit

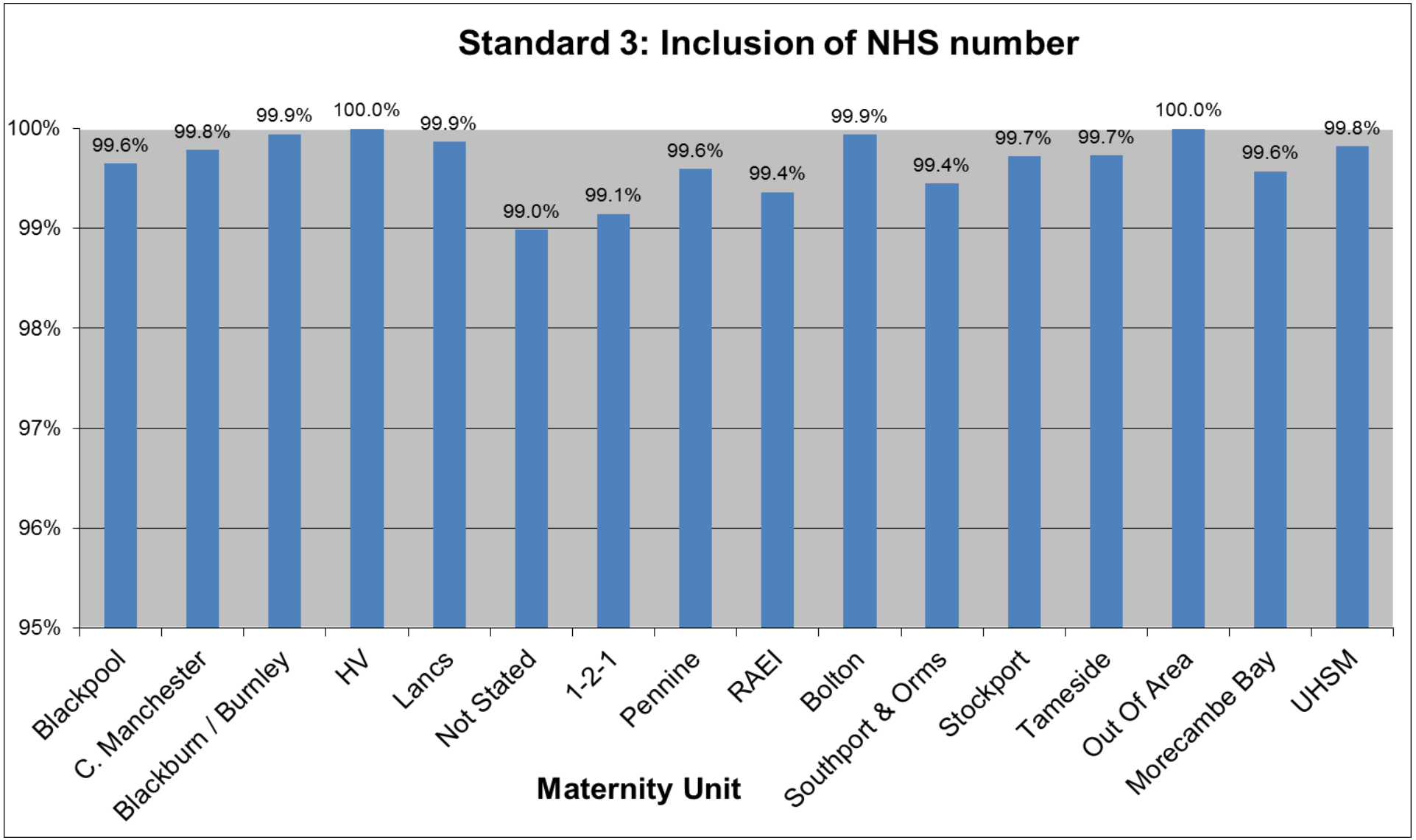

Figure 1: Graph to show percentage of cards that included NHS number for period April 2015 – March 2016

Maternity Unit	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 Victoria Hospital	12	2912	42	0.4%	98.2%	0.2%
Central Manchester University Hospitals	6	4908	55	0.1%	98.8%	0.1%
East Lancashire Hospitals	8	5099	146	0.2%	97.1%	0.1%
Health Visitor	0	13	146	0.0%	8.2%	3.8%
Lancashire Teaching Hospitals	12	4194	152	0.3%	96.2%	0.1%
Not Stated	20	4803	388	0.4%	92.2%	0.1%
One-to-One Midwifery	1	103	2	0.9%	97.2%	5.7%
Pennine Acute Hospitals	10	10325	93	0.1%	99.0%	0.1%
Royal Albert Edward Infirmary	10	3204	11	0.3%	99.3%	0.2%
Royal Bolton Hospital	7	5852	56	0.1%	98.9%	0.1%
Southport & Ormskirk Hospital	0	878	9	0.0%	99.0%	0.7%
Stockport	6	3018	33	0.2%	98.7%	0.2%
Tameside General Hospital	7	2799	31	0.2%	98.7%	0.2%
Unit out of area	0	9	2	0.0%	81.8%	54.5%
University Hospitals of Morecambe Bay	5	2224	9	0.2%	99.4%	0.3%
University Hospital of South Manchester	5	4318	37	0.1%	99.0%	0.1%
Grand Total	109	54659	1212	0.2%	97.6%	0.0%

Table 2: Data for Standard 4 showing the number of cards taken between days 5-8, by maternity unit

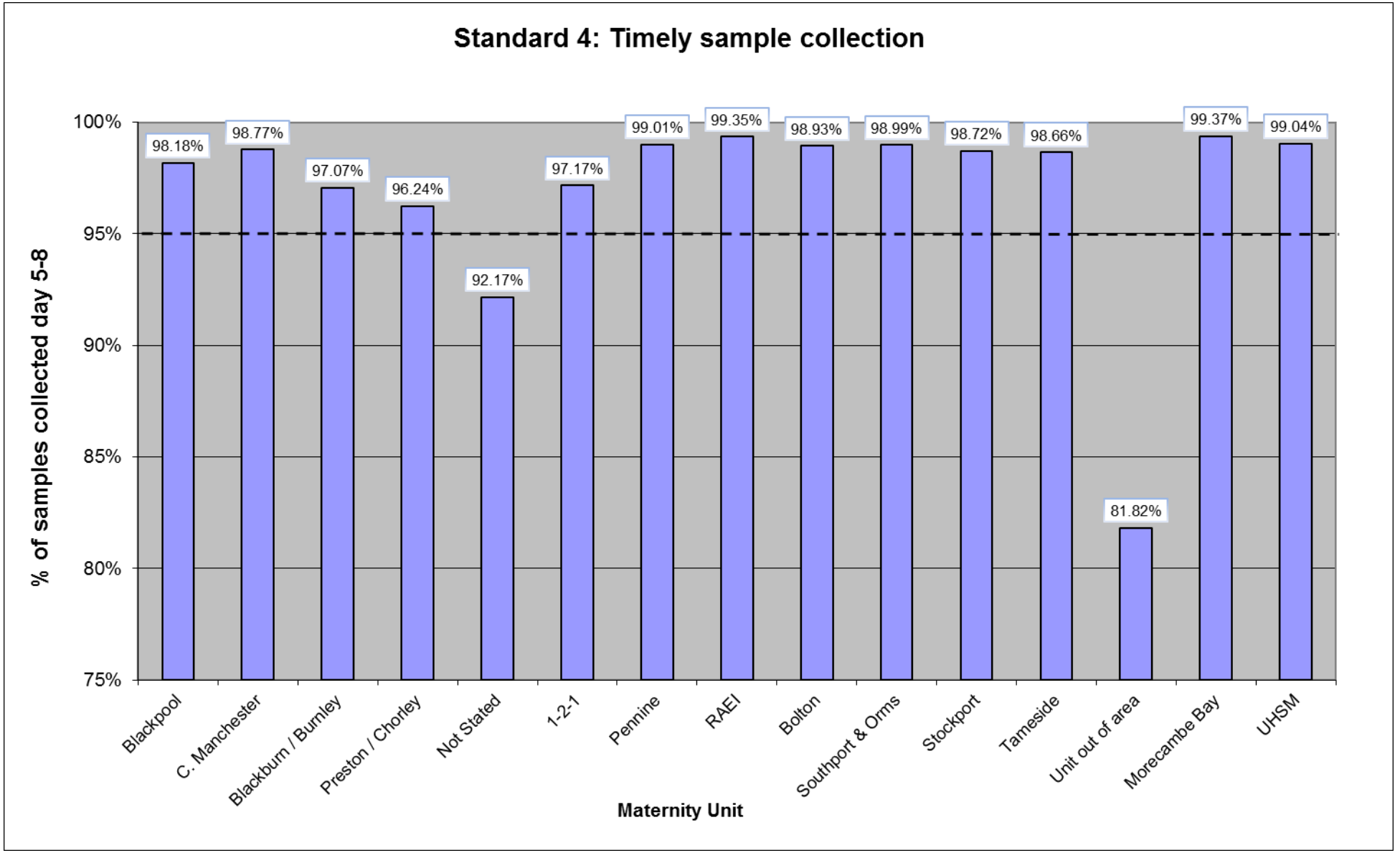

Figure 2: Graph to show percentage of samples taken 5-8 days after birth

Maternity Unit	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 Victoria Hospital	2971	3088	35	**95.1%**	**98.9%**	**1.1%**
Central Manchester University Hospitals	5202	5218	25	**99.2%**	**99.5%**	**0.5%**
East Lancashire Hospitals	5392	5417	7	**99.4%**	**99.9%**	**0.1%**
Health Visitor	193	196	3	**97.0%**	**98.5%**	**1.5%**
Lancashire Teaching Hospitals	4479	4527	103	**96.7%**	**97.8%**	**2.2%**
Not Stated	5721	5854	88	**96.3%**	**98.5%**	**1.5%**
One-to-One Midwifery	112	114	2	**96.6%**	**98.3%**	**1.7%**
Pennine Acute Hospitals	10518	10743	95	**97.0%**	**99.1%**	**0.9%**
Royal Albert Edward Infirmary	3410	3447	17	**98.4%**	**99.5%**	**0.5%**
Royal Bolton Hospital	6185	6200	6	**99.7%**	**99.9%**	**0.1%**
Southport & Ormskirk Hospital	541	866	40	**59.7%**	**95.6%**	**4.4%**
Stockport	3018	3146	72	**93.8%**	**97.8%**	**2.2%**
Tameside General Hospital	2843	2923	16	**96.7%**	**99.5%**	**0.5%**
Unit out of area	11	11	0	**100.0%**	**100.0%**	**0.0%**
University Hospitals of Morecambe Bay	2197	2284	50	**94.1%**	**97.9%**	**2.1%**
University Hospital of South Manchester	4410	4476	24	**98.0%**	**99.5%**	**0.5%**
Total	**57203**	**58510**	**583**	**96.8%**	**99.0%**	**1.0%**

Table 3: Data for standard 5 showing the number of samples dispatched and received in a timely manner, by maternity unit

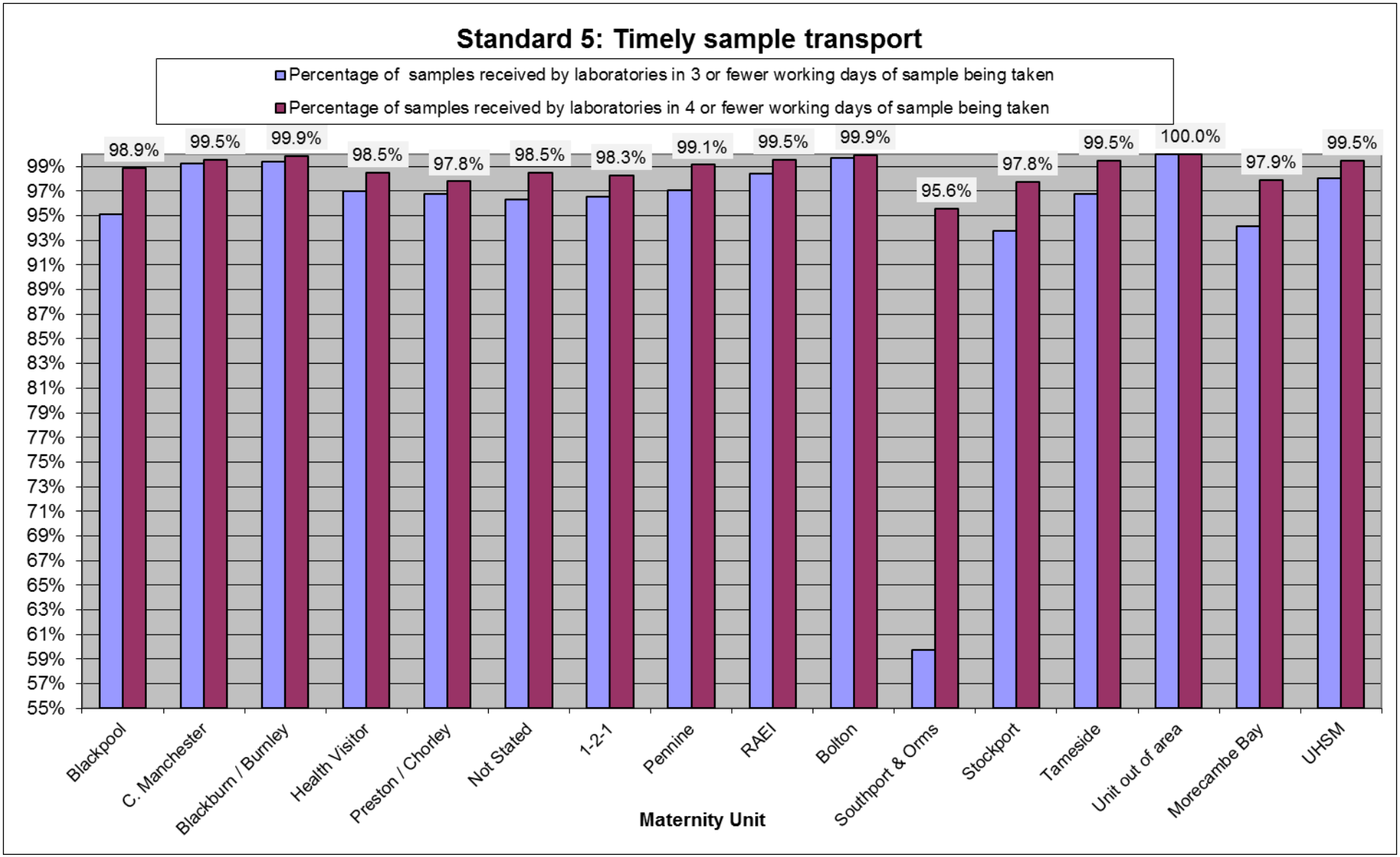

Figure 3: Graph to show percentage of samples received within 3 and 4 working days of being taken, by maternity unit

Maternity Unit	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 Victoria Hospital	**2968**	12	1	80	0	2	0	5	11	0	0	7	1	0	**4.0%**
Central Manchester University Hospi	**4971**	4	36	107	6	9	0	9	7	0	0	13	0	0	**3.1%**
East Lancashire Hospitals	**5256**	9	6	84	2	2	0	2	3	0	0	9	0	0	**2.1%**
Health Visitor	**171**	0	0	1	0	0	0	0	0	0	0	1	0	0	**1.2%**
Lancashire Teaching Hospitals	**4358**	11	5	73	3	3	0	3	5	0	0	2	87	1	**4.3%**
Not Stated	**5256**	14	39	196	10	13	0	8	38	0	0	31	8	0	**6.1%**
One-to-One Midwifery	**107**	1	0	8	0	0	0	0	1	0	0	0	0	0	**9.3%**
Pennine Acute Hospitals	**10432**	9	10	118	5	18	0	11	42	0	0	16	0	0	**2.1%**
Royal Albert Edward Infirmary	**3225**	7	2	124	3	4	0	1	22	0	0	6	0	0	**5.2%**
Royal Bolton Hospital	**5917**	5	10	106	3	11	0	5	3	0	0	14	0	0	**2.5%**
Southport & Ormskirk Hospital	**888**	0	0	15	3	1	0	2	6	0	0	1	0	0	**3.2%**
Stockport	**3057**	4	1	108	2	8	0	3	9	0	0	11	0	0	**4.7%**
Tameside General Hospital	**2837**	5	2	23	1	4	0	3	7	0	0	7	0	0	**1.8%**
Unit out of area	**11**	0	0	0	0	0	0	0	0	0	0	0	0	0	**0.0%**
University Hospitals of Morecambe B	**2240**	5	0	41	5	3	0	3	11	0	0	6	0	0	**3.3%**
UHSM	**4364**	5	2	86	2	2	0	8	6	0	0	5	0	0	**2.6%**
Grand Total	**56058**	91	114	1170	45	80	0	63	171	0	0	129	96	1	**3.3%**

Table 4: Data for Standard 6 showing avoidable repeat rate, by maternity unit

*Not currently included in calculation of avoidable repeat rate

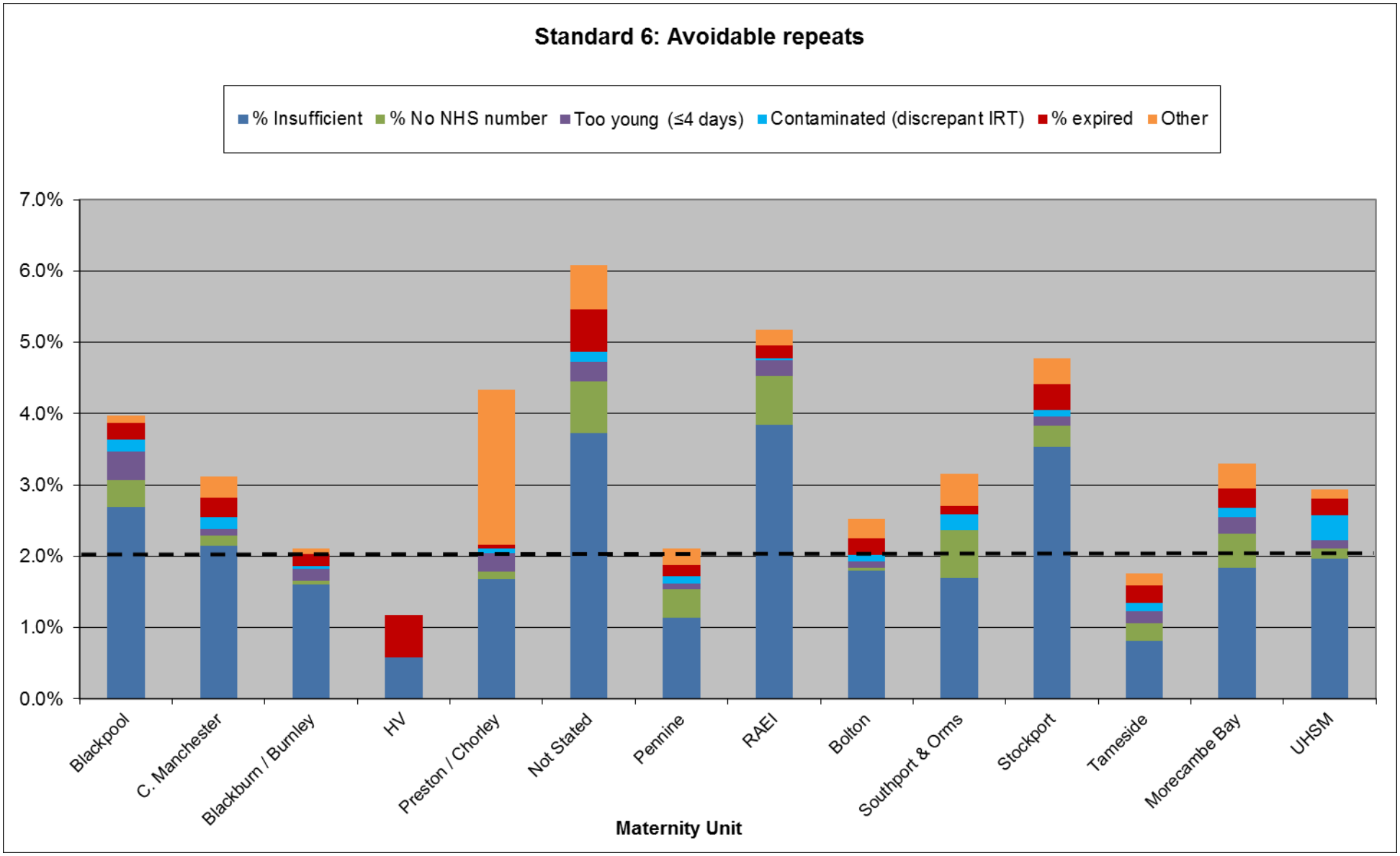

Figure 4: Graph to show avoidable repeat rate by maternity unit (1-2-1 excluded from the chart)

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	Lab/ Ward/ Maternity Unit
1052705	25/03/15	3	Actual harm (level 2)	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct)	South Manchester Community Midwives
1053444	31/03/15	3	Actual harm (level 2)	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct)	UH South Manchester NNU
1054989	23/04/15	4	Actual harm (level 2)	HbD carrier incorrectly reported as "Not suspected" by CHRD	Manchester CHRD
1055972	15/04/15	4	Actual harm (level 2)	Failure to collect a repeat blood spot sample following a transfusion. Failure to follow-up by CHRD	Ward 68, SMH (NICU) & B'pool Community midwives and/or B'pool CHRD
1056456	30/04/15	3	Actual harm (level 2)	Delayed referral of Screen Positive	Blackpool Community Midwives
1058322	27/05/15	3	Actual harm (level 2)	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct)	Wigan Community Midwives
1058433	01/06/15	3	Actual harm (level 2)	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct)	Ward 66. SMH
1059738	12/06/15	3	Error did not reach the patient (level 1b)	Laboratory data entry error - sample matched to incorrect baby in IT system and reported to CHRD (both babies had the same name and DoB. There was no match for the NHS number).	Lab

Incident Number	Incident Date	Incident Level	Near miss or actual harm	Summary of incident	Lab/ Ward/ Maternity Unit
1059739	21/05/15	3	Actual harm (level 2)	Blood spot screening result incorrectly reported by the laboratory as 'not suspected' instead of carrier for CF (due to error in Specimen Gate system, following modifications in April 2015, to allow reporting of substatus codes to CHRD).	Lab
1064194	11/08/15	3	Actual harm (level 2)	Blood spot sample labelled with a handwritten NHS number belonging to baby's twin	RAEI Maternity Ward
1064331	31/07/15	3	No harm	Laboratory data entry error - sample matched to incorrect baby in IT system and reported to CHRD (both babies had the same name and DoB. There was no match for the NHS number).	Lab
1066493	03/09/15	3	1 (no harm)	Blood spot sample labelled with a NHS number belonging to another person (other demographic details correct) & results reported to CHRD against wrong person (NHS number belonged to still-born twin).	?Wigan Maternity Unit/NNU; Sample collected on Bolton NNU
1066945	14/09/15	3	1 (no harm)	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct; no harm as this sample was an unnecessary repeat anyway)	CMFT Community Midwives
1067374	16/09/15	3	Actual harm (level 2)	Blood spot sample labelled with a demographic sticker containing errors e.g. another baby's NHS number (some details correct). Wrong address & NHS number (belonging to a baby with same surname and date of birth). Other details correct.	Morecambe Bay Maternity Unit
1067482	14/09/15	4	Actual harm (level 2)	Blood spot sample labelled with another baby's bar-coded demographic sticker and results reported to CHRD against the wrong baby	Pennine Community Midwives
1068235	25/09/15	3	Actual harm (level 2)	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct)	Ward 77, RMCH

Incident Number	Incident Date	Incident Level	Near miss or actual harm	Summary of incident	Lab/ Ward/ Maternity Unit
1070281	22/10/15	3	Actual harm (level 2)	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct). NHS number belonged to twin.	Lancashire (Preston/Chorley) Community Midwives
1070392	22/10/15	4	Actual harm (level 2)	Blood spot sample labelled with another baby's bar-coded demographic sticker and reported to CHRD against wrong baby	East Lancs Community Midwives
1073606	11/11/15	4	Actual harm (level 2)	Blood spot sample labelled with another baby's bar-coded demographic sticker	Pennine Community Midwives
1073769	21/09/15	3	1 (no harm)	Missed CF screening due to failure to collect a satisfactory sample before 8 weeks of age	CMFT Community Midwives
1076823	03/01/16	4	Actual harm (level 2)	Blood spot sample labelled with another baby's bar-coded demographic sticker. Different sticker on white copy to those on pink and yellow copy. No handwritten details for mother.	Pennine Community Midwives
1079992	19/02/16	3	Actual harm (level 2)	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct). NHS number belonged to twin.	Tameside Community Midwives
1080581	19/01/16	3	1 (no harm)	Blood spot sample labelled with an incorrect handwritten NHS number (incorrect digit(s)). In absence of a correct NHS number, the lab IT system matched sample to twin' s record using surname and date of birth. Details not adequately checked by data entry clerk. Results reported to CHRD against other twin.	Lancashire (Preston/Chorley) Community Midwives & Lab
1081183	01/03/16	3	1 (no harm)	Laboratory data entry error - sample matched to incorrect baby in IT system and reported to CHRD (Both babies had the same name and DoB. There was no match for the NHS number).	Lab

Incident Number	Incident Date	Incident Level	Near miss or actual harm	Summary of incident	Lab/ Ward/ Maternity Unit
1082332	24/03/16	4	Actual harm (level 2)	Two twins sent home with stickers from one twin. Community midwife attached stickers to sample cards from both twins. Blood spot cards therefore appeared to be from the same baby.	Stockport Community Midwives