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 2014-2015

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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. From April 2013 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. The laboratories carry out screening for congenital hypothyroidism (CHT), phenylketonuria (PKU), haemoglobinopathy and sickle cell disorders (SCD), medium-chain acyl-CoA dehydrogenase deficiency (MCADD) and cystic fibrosis (CF). The Willink Laboratory is one of the 6 pilot sites which participated in the expanded screening study for 5 additional metabolic conditions. The pilot study ended this year and led to acceptance of 4 out of 5 disorders tested to be incorporated to the existing screening programme. These are maple syrup urine disease (MSUD), homocystinuria (HCU), glutaric aciduria type 1 (GA1) and isovaleric acidaemia (IVA). Screening of Long chain 3-hydroxyacyl-CoA dehydrogenase deficiency (LCHADD) was discontinued from 1 September 2014. Expanded screening has been rolled out to all English screening laboratories on 5 January 2015.

Newborn screening of Inborn Errors of Metabolism now 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 that 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 2014

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) (1.0 WTE)*
- Helen Jopling 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.

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)
- Bernadette McQuade BSc FIBMS Senior Biomedical Scientist (0.67 WTE)
- Anne Walsh BSc FIBMS Senior Biomedical Scientist (1.0 WTE)
- Emma Shore MChem BSc LIBMS (0.93WTE)

Emma Shore was appointed as Biomedical Scientist in March 2015.
Bernadette McQuade left in October 2014.

Information Analyst

- Aisha Rahman BSc MSc (0.67 WTE)

Aisha Rahman was appointed in September 2014.

Medical Laboratory Assistants

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

Steve Gregson was appointed in December 2014.
Selina Keaveney left in May 2014.

Secretarial/Clerical

- Lorraine Staton — Screening Administrator (0.85 WTE)
- Neera Jones — Clerical assistant/data entry clerk (0.8 WTE)
- Patricia Richards — Clerical assistant/data entry clerk (0.56 WTE; 0.69 WTE from March 2015)

Neera Jones was appointed as Screening Administrator in January 2015 (0.85 WTE)
Lorraine Staton left in May 2014.

Willink Biochemical Genetics Laboratory

Clinical Scientists

- Claire Hart BSc MSc FRCPath, Consultant Clinical Scientist, Head of Service for Willink Biochemical Genetics (1.0 WTE) until June 2014
- *Mick Henderson PhD FRCPath, Consultant Clinical Scientist, Director of Willink Biochemical Genetics Laboratory (0.4 WTE) from Oct 2014 onwards
- Teresa Hoi-Yee Wu MSc FRCPath, Principal Clinical Scientist, Deputy Head of Service for Willink Biochemical Genetics & Head of Metabolites and Newborn Screening section (1.0 WTE)
- Alistair Horman BSc MSc PhD FRCPath, Principal Clinical Scientist, Deputy Head of Metabolites and Newborn Screening section (1.0 WTE)
- Pam Grundy BSc MSc PhD, Senior Clinical Scientist (0.6 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)
- Liz Nixon 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)
**Chief Biomedical Scientist is a new position created in 2014 as part replacement for Claire Hart
Milly Cretney, Associate Genetic Technologist (0.6 WTE) retired in Sept 2014 and was replaced by Liz Nixon

The staffing complement and structure of the screening laboratories at the end of the financial year (March 2015) 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/ Helen Jopling

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
Vacancy

*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)
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)
Liz Smith / 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 Multipuncher 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 59349 samples were received in the laboratory which included 55707 first samples, 2356 repeat samples and 1286 pre-transfusion 'day 0' samples.

This includes 412 samples (347 first samples, 36 pre-transfusion 'day 0' samples and 29 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 116 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

Blood spot samples collected on day 5-8 (where day 0 is the day of birth) are used for all tests. PKU, MCADD and expanded metabolic screening is carried out using the method of tandem mass spectrometry (Waters instrumentation). CHT and CF screening are performed using analysis of TSH (CHT) and IRT (CF) on the AutoDELFIA automated immunoassay analyser (Perkin Elmer™) with second line genetic testing for CF being undertaken within the molecular genetics laboratory (St Mary's Hospital, Manchester). SCD screening involves first line testing for Haemoglobin using a high performance liquid chromatography system (HPLC) (Biorad Variant NBS) with confirmatory testing being conducted within the Haematology Department (Manchester Royal Infirmary) using an iso-electric focussing method.

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. Individual reports are generated for incorporation in the babies' personal record (red book) and are sent by first class post.

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.
- Central Manchester Foundation Trust took part in a national pilot programme for the assessment of Antenatal and Newborn Screening Services in July 2013. An action plan was developed to address specific findings in the inspection report. These actions are now complete and have been signed off by the Trust Antenatal and Newborn Screening Board.

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

- Programme Specific Operational and Quality Groups for Cystic Fibrosis, Sickle and Metabolic screening which include all stakeholders meet on a 6-monthly basis. Matters in relation to Congenital Hypothyroid Screening are discussed as part of weekly MDT meeting with paediatric endocrinology. All groups report to the Trust Antenatal and Newborn Screening Board.

- 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 bloodspot 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). A list of audits completed in 2014/15 is provided in Appendix 1.

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.

Details of oral presentations, posters and publications in 2014/15 is 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. A Higher Specialist Trainee post specialising in paediatric and metabolic biochemistry is shared jointly between Clinical Biochemistry and 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 2014 through to March 2015.
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, 99.5% 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 9.7% to 87.7%. Overall the usage of bar-coded labels has increased slightly from 57% in 2013/14 to 64%, 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	3862	3855	**99.82%**	**86.08%**
Blackpool	1819	1811	**99.56%**	**64.71%**
Bolton	4142	4131	**99.73%**	**58.70%**
Bury	2534	2523	**99.57%**	**71.19%**
C Manc	3487	3469	**99.48%**	**70.28%**
Chorley	1979	1970	**99.55%**	**67.71%**
S Cumbria	1513	1500	**99.14%**	**10.80%**
E Lancs	3255	3248	**99.78%**	**87.76%**
Fylde & Wyre	1578	1569	**99.43%**	**66.45%**
Grt Preston	2788	2777	**99.61%**	**76.42%**
HMR	3094	3074	**99.35%**	**59.65%**
N Lancs	1788	1774	**99.22%**	**9.74%**
N Manc	2974	2959	**99.50%**	**76.37%**
Oldham	3535	3505	**99.15%**	**60.21%**
Salford	3721	3700	**99.44%**	**67.82%**
S Manc	2381	2361	**99.16%**	**70.37%**
Stockport	3511	3493	**99.49%**	**73.18%**
Tameside	3392	3378	**99.59%**	**77.94%**
Trafford	2784	2768	**99.43%**	**69.82%**
W Lancs	1018	1012	**99.41%**	**29.03%**
Wigan	3782	3755	**99.29%**	**31.68%**
Out of region	412	402	**97.57%**	**37.50%**
TOTAL	59349	59034	**99.47%**	**64.20%**

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

NOTE: Unable to provide NHS label data for quarters 1 & 2 due to an IT error in 2014. Percentages for barcode usage refer to quarters 3 & 4 only

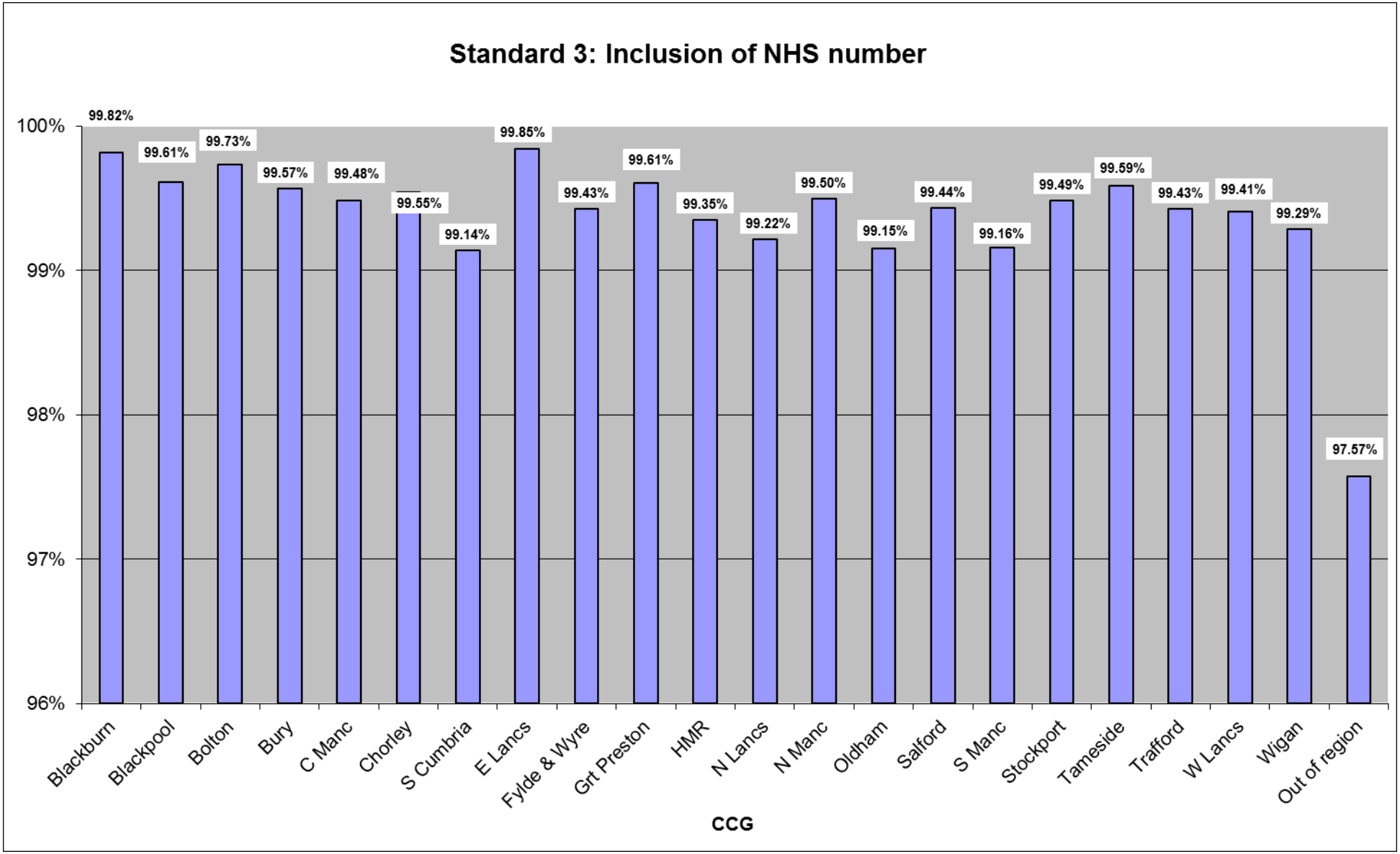

Figure 1: Graph to show percentage of cards that included NHS number for period April 2014–March 2015

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, compared with 98.1% in 2013/14. The 'achievable' threshold of 99% was met by 5 CCGs (Bury, Cumbria, HMR, Stockport and Trafford). The percentage collected on day 5 varied throughout the region ranging from 32% for Greater Preston CCG to 91% for Cumbria CCG (72% 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	1379	1310	610	149	104	0.22%	38.74%	36.80%	17.13%	4.19%	2.92%	96.85%
Blackpool	2	1017	412	219	59	29	0.12%	58.52%	23.71%	12.60%	3.39%	1.67%	98.22%
Bolton	3	2269	958	409	124	62	0.08%	59.32%	25.05%	10.69%	3.24%	1.62%	98.30%
Bury	2	1582	593	174	18	34	0.08%	65.83%	24.68%	7.24%	0.75%	1.41%	98.50%
C Manc	11	2755	275	41	18	89	0.34%	86.39%	8.62%	1.29%	0.56%	2.79%	96.86%
Chorley	6	677	921	206	25	24	0.32%	36.42%	49.54%	11.08%	1.34%	1.29%	98.39%
S Cumbria	4	1311	92	15	11	10	0.28%	90.85%	6.38%	1.04%	0.76%	0.69%	99.03%
E Lancs	10	1416	1121	299	63	60	0.34%	47.69%	37.76%	10.07%	2.12%	2.02%	97.64%
Fylde & Wyre	3	968	302	168	30	29	0.20%	64.53%	20.13%	11.20%	2.00%	1.93%	97.87%
Grt Preston	12	845	1287	351	70	59	0.46%	32.20%	49.05%	13.38%	2.67%	2.25%	97.29%
HMR	3	2677	205	26	10	34	0.10%	90.59%	6.94%	0.88%	0.34%	1.15%	98.75%
N Lancs	5	1442	169	30	14	22	0.30%	85.73%	10.05%	1.78%	0.83%	1.31%	98.39%
N Manc	4	2254	367	65	19	82	0.14%	80.76%	13.15%	2.33%	0.68%	2.94%	96.92%
Oldham	10	2958	252	48	15	62	0.30%	88.43%	7.53%	1.43%	0.45%	1.85%	97.85%
Salford	6	2793	470	73	36	55	0.17%	81.36%	13.69%	2.13%	1.05%	1.60%	98.22%
S Manc	1	1988	158	29	7	50	0.04%	89.03%	7.08%	1.30%	0.31%	2.24%	97.72%
Stockport	6	2863	353	63	17	40	0.18%	85.67%	10.56%	1.89%	0.51%	1.20%	98.62%
Tameside	15	2828	270	37	6	44	0.47%	88.38%	8.44%	1.16%	0.19%	1.38%	98.16%
Trafford	3	2357	205	33	8	28	0.11%	89.48%	7.78%	1.25%	0.30%	1.06%	98.82%
W Lancs	5	728	182	36	12	10	0.51%	74.82%	18.71%	3.70%	1.23%	1.03%	98.46%
Wigan	12	2565	626	276	49	53	0.34%	71.63%	17.48%	7.71%	1.37%	1.48%	98.18%
Out of region	2	214	88	20	5	18	0.58%	61.67%	25.36%	5.76%	1.44%	5.19%	94.24%
TOTAL	133	39886	10616	3228	765	998	0.24%	71.70%	19.08%	5.80%	1.38%	1.79%	97.97%

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

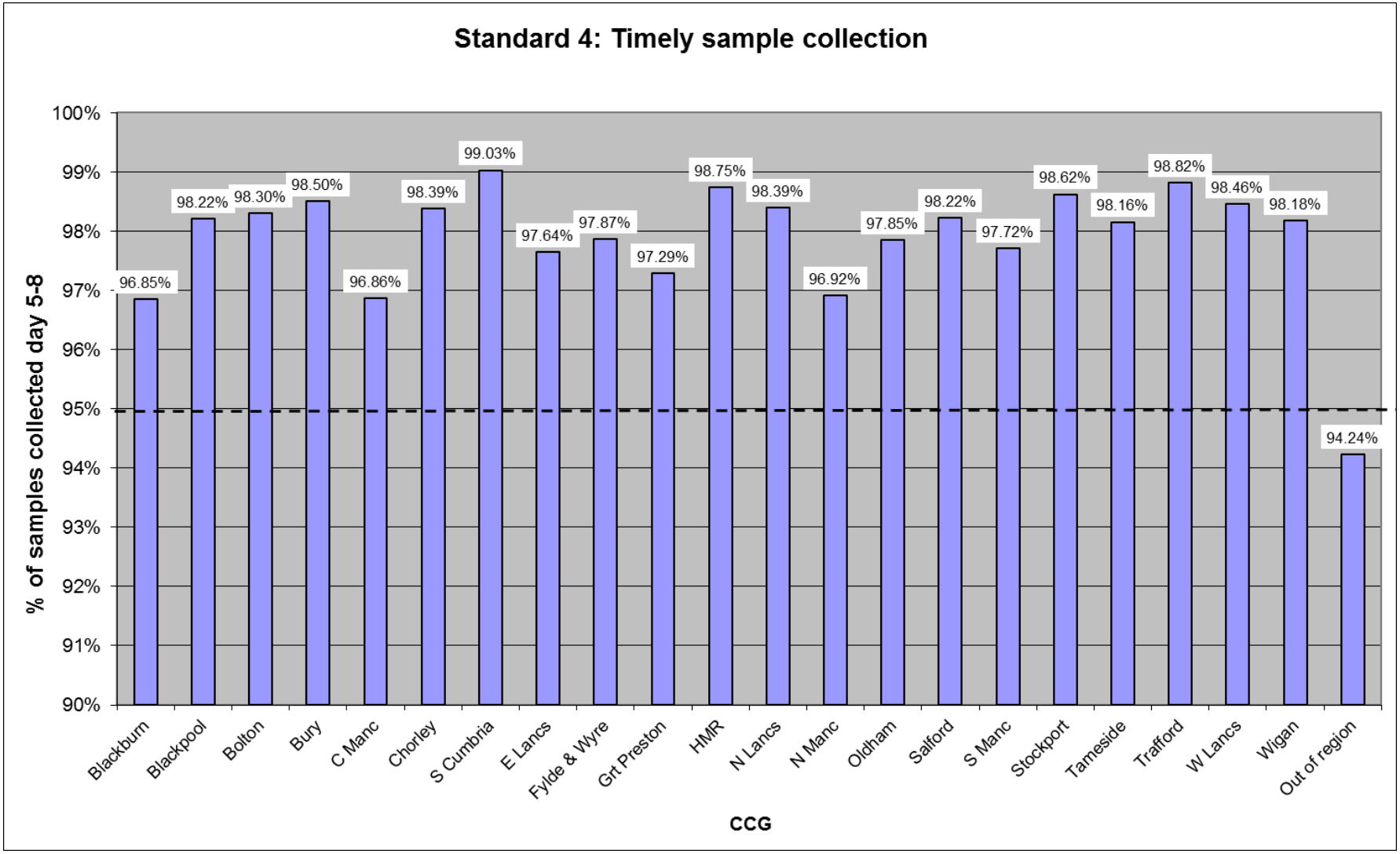

Figure 2: Graph to show percentage of samples taken 5-8 days after birth

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 92.6-99.7%). 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 71.6% for West Lancashire CCG to 99.1% for Blackburn with Darwen CCG (overall 96.1%).

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	3666	3688	12	99.08%	99.68%	0.32%
Blackpool	1661	1761	42	92.12%	97.67%	2.33%
Bolton	3893	3941	15	98.41%	99.62%	0.38%
Bury	2408	2459	17	97.25%	99.31%	0.69%
C Manc	3289	3326	22	98.24%	99.34%	0.66%
Chorley	1897	1947	16	96.64%	99.18%	0.82%
S Cumbria	1447	1484	17	96.40%	98.87%	1.13%
E Lancs	3046	3091	11	98.19%	99.65%	0.35%
Fylde & Wyre	1421	1522	42	90.86%	97.31%	2.69%
Grt Preston	2642	2738	28	95.52%	98.99%	1.01%
HMR	2975	3035	18	97.45%	99.41%	0.59%
N Lancs	1665	1755	21	93.75%	98.82%	1.18%
N Manc	2763	2855	38	95.51%	98.69%	1.31%
Oldham	3376	3459	27	96.84%	99.23%	0.77%
Salford	3495	3561	11	97.84%	99.69%	0.31%
S Manc	2296	2320	15	98.33%	99.36%	0.64%
Stockport	3258	3392	81	93.81%	97.67%	2.33%
Tameside	3245	3315	19	97.33%	99.43%	0.57%
Trafford	2649	2717	19	96.82%	99.31%	0.69%
W Lancs	725	937	75	71.64%	92.59%	7.41%
Wigan	3535	3708	42	94.27%	98.88%	1.12%
Out of region	342	365	9	91.44%	97.59%	2.41%
TOTAL	55694	57376	597	96.07%	98.97%	1.03%

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)

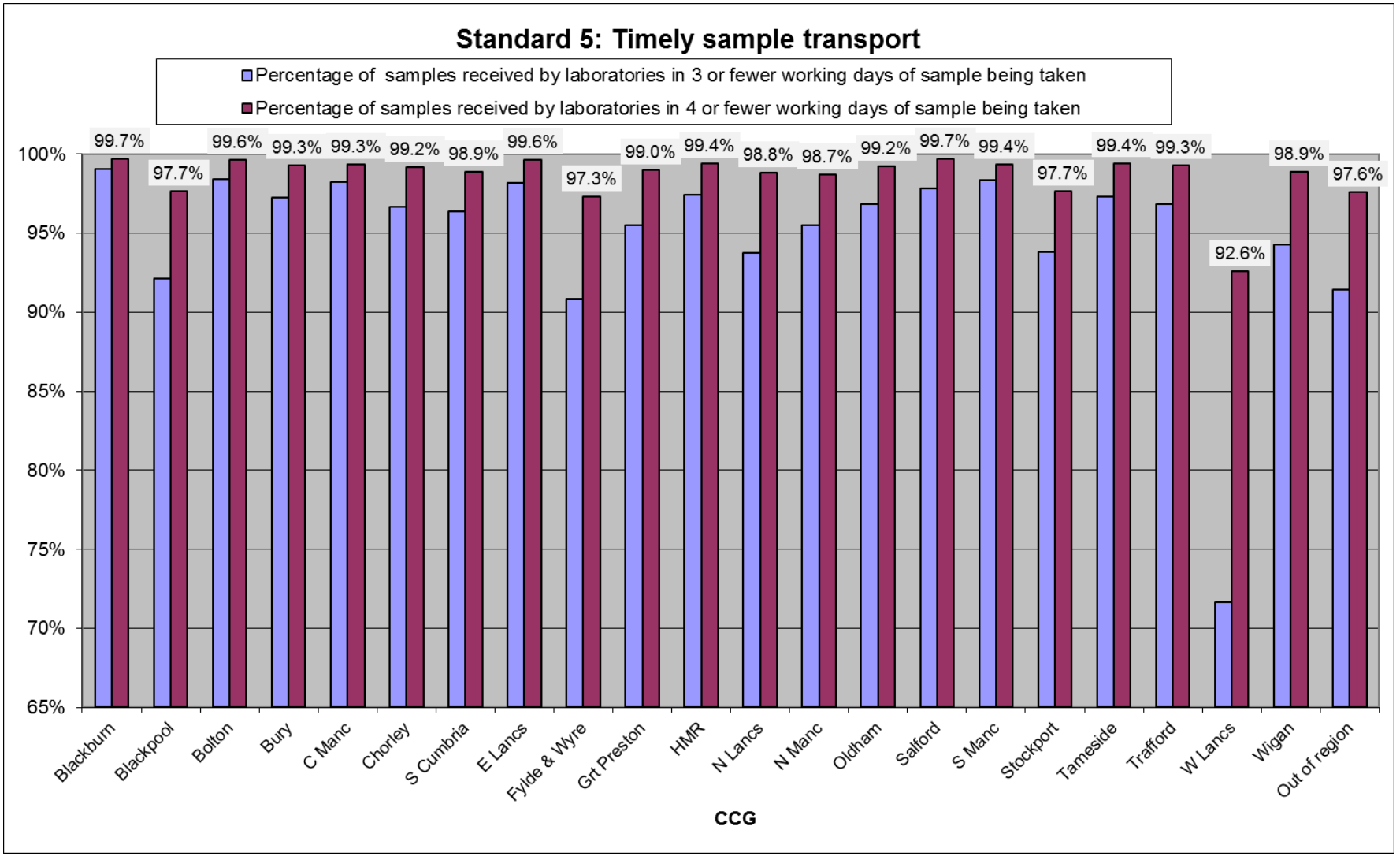

Figure 3: Graph to show percentage of samples received within 3 and 4 working days of being taken

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. In April 2015, the screening IT system was modified to allow entry of the following reasons for sample rejection: incorrect blood application, compressed/ damaged, expired card, damaged in transit. In future, this will allow a more detailed breakdown of the data for 'unsatisfactory samples'.

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 10 out of 22 CCGs achieved the standard (45% of CCGs; compared with 81% of PCTs during 2013/14). The percentage avoidable repeat rate ranged from 1.2% to 3.4% (2013/14: 0.6% to 2.7%).

The insufficient rate for samples collected from in-patients was four times higher than the rate for those collected in the community; however there has been decreasing trend in the hospital insufficient rate from 9% in 2012/13, 3.2% in 2013/14 to 2.3% this year. Table 5 shows the insufficient rate for each hospital within the area of coverage. This data is also displayed graphically in Figure 5. The rate ranges from 0% to 29%, with RMCH having the highest rate of insufficient samples as in previous years.

CCG	Number of first samples received/ babies tested	Too soon after transfusion (<72 hours)*	Too young for reliable screening (≤ 4 days)	Insufficient	Unsatisfactory sample	>14 days in transit	No NHS number	Contaminated (discrepant IRT)	Number of Avoidable Repeat Requests	Avoidable Repeat Requests Rate
Blackburn	3565	12	7	23	8	0	3	0	41	**1.2%**
Blackpool	1738	5	2	9	7	0	8	1	27	**1.6%**
Bolton	3828	14	3	24	22	1	7	6	63	**1.6%**
Bury	2403	5	1	14	8	0	9	2	34	**1.4%**
C Manc	3211	14	10	23	17	1	17	5	73	**2.3%**
Chorley	1859	7	6	11	12	0	8	1	38	**2.0%**
S Cumbria	1443	3	2	7	13	0	12	1	35	**2.4%**
E Lancs	2973	14	10	24	10	0	4	1	49	**1.6%**
Fylde & Wyre	1504	2	3	16	6	0	9	3	37	**2.5%**
Grt Preston	2629	11	10	32	19	2	11	0	74	**2.8%**
HMR	2956	3	3	3	13	1	19	2	41	**1.4%**
N Lancs	1685	3	7	24	12	0	14	0	57	**3.4%**
N Manc	2795	7	4	19	10	0	15	5	53	**1.9%**
Oldham	3346	16	8	5	14	0	24	0	51	**1.5%**
Salford	3438	17	6	23	28	0	20	6	83	**2.4%**
S Manc	2243	9	1	16	13	0	19	1	50	**2.2%**
Stockport	3345	9	7	22	36	2	17	4	88	**2.6%**
Tameside	3203	6	15	16	26	1	12	3	73	**2.3%**
Trafford	2636	10	2	17	11	0	15	4	49	**1.9%**
W Lancs	975	0	5	7	5	2	6	1	26	**2.7%**
Wigan	3583	8	9	64	12	0	27	4	116	**3.2%**
Out of region	349	9	0	15	5	1	9	1	31	**8.9%**
TOTAL	55707	184	121	414	307	11	285	51	1189	**2.1%**

Table 4: Data for Standard 6 showing avoidable repeat rate

*Not currently included in calculation of avoidable repeat rate; Unsatisfactory sample includes expired card, contaminated/ damaged card, compressed, multi-spotted, spotted both sides.

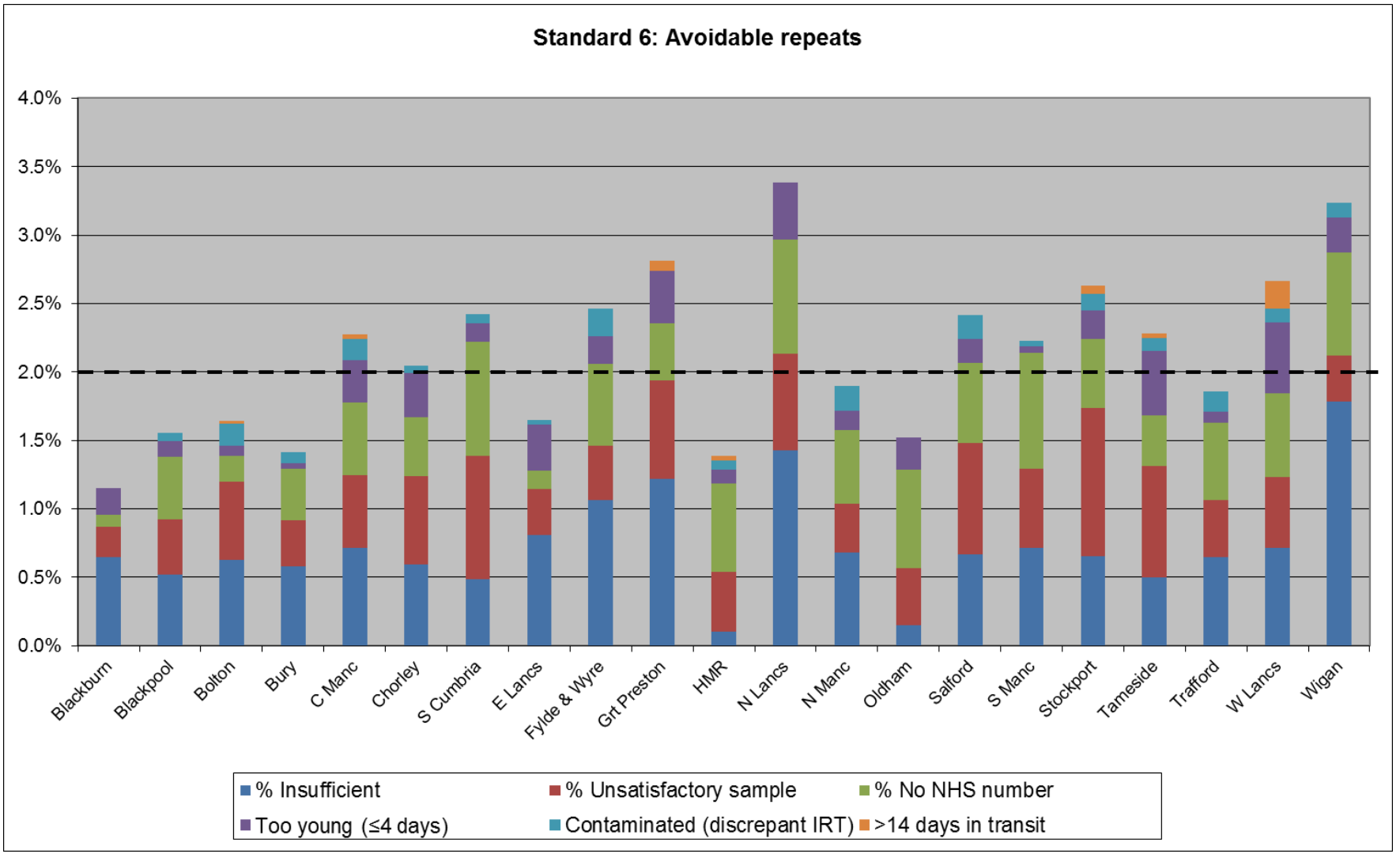

Figure 4: Graph to show avoidable repeat rate by CCG

Current Hospital	Insufficient sample from in-patients	Total number of first samples from in-patients	% Insufficient quality
Burnley General Hospital	7	703	1.0%
The Royal Bolton Hospital	4	452	0.9%
Blackpool Victoria Hospital	7	243	2.9%
Fairfield General Hospital	0	1	0.0%
Furness General Hospital	3	66	4.5%
Hope Hospital	1	0	0.0%
North Manchester General Hospital	8	391	2.0%
Ormskirk & District General Hospital	3	114	2.6%
Royal Albert Edward Infirmary	13	259	5.0%
Royal Blackburn Hospital	0	3	0.0%
Royal Lancaster Infirmary	2	246	0.8%
Royal Manchester Children's Hospital	14	49	28.6%
Royal Oldham Hospital	3	587	0.5%
Royal Preston Hospital	15	390	3.8%
Stepping Hill Hospital	9	289	3.1%
St Mary's Hospital, Manchester	25	1133	2.2%
Tameside General Hospital	3	191	1.6%
Westmorland General Hospital	0	1	0.0%
University Hospital of South Manchester	8	409	2.0%
In-patient total	**125**	**5527**	**2.3%**
Community total	**289**	**50180**	**0.6%**
Grand Total	**414**	**55707**	**0.7%**

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

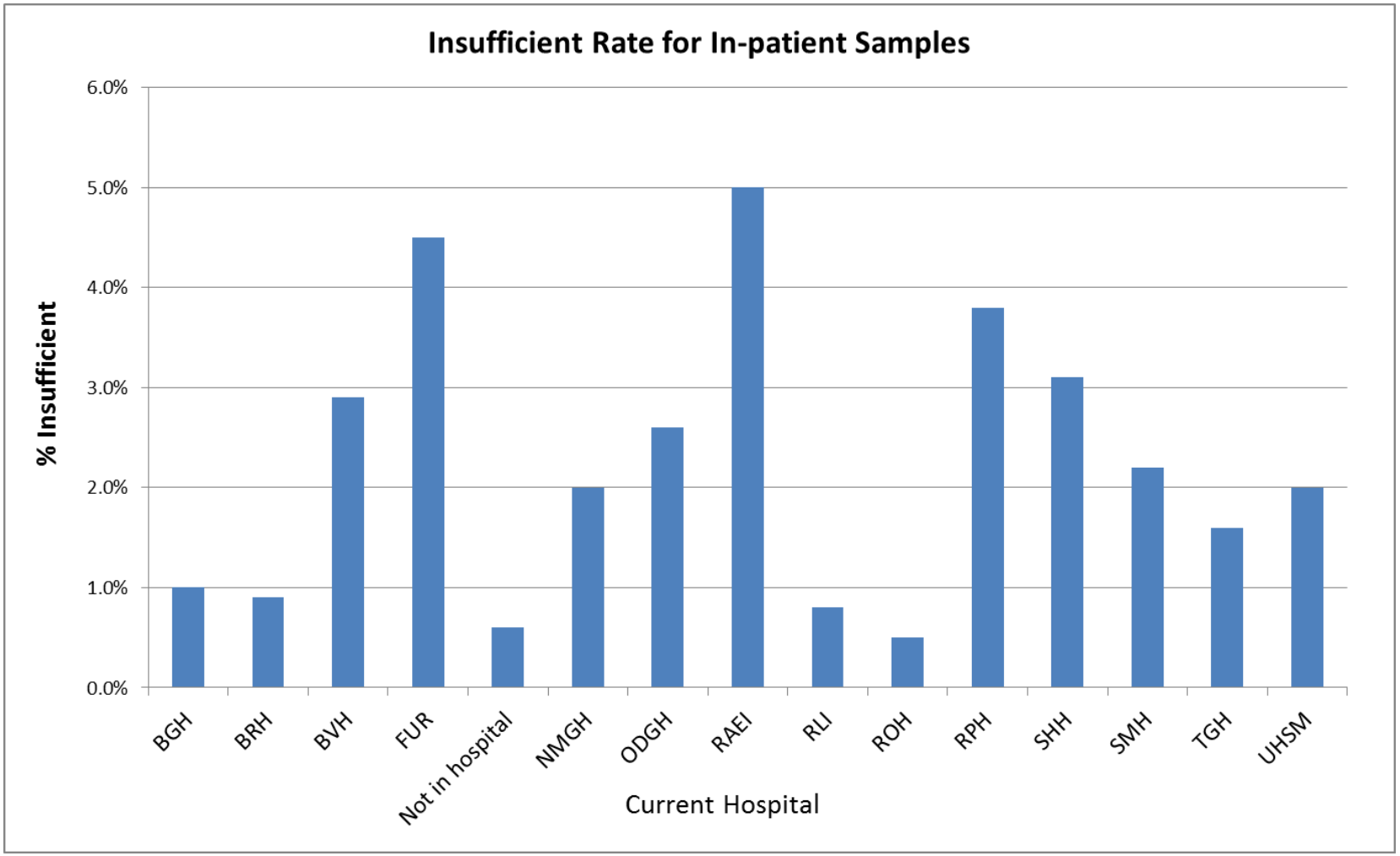

Figure 5: Graph to show percentage of insufficient samples taken within each acute Trust, whilst the baby was in hospital compared with babies in the community.

NOTE: Royal Manchester Children's Hospital excluded from graph (29%) and any hospital where the total number of samples was <5.

5. Clinical Referral Data

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

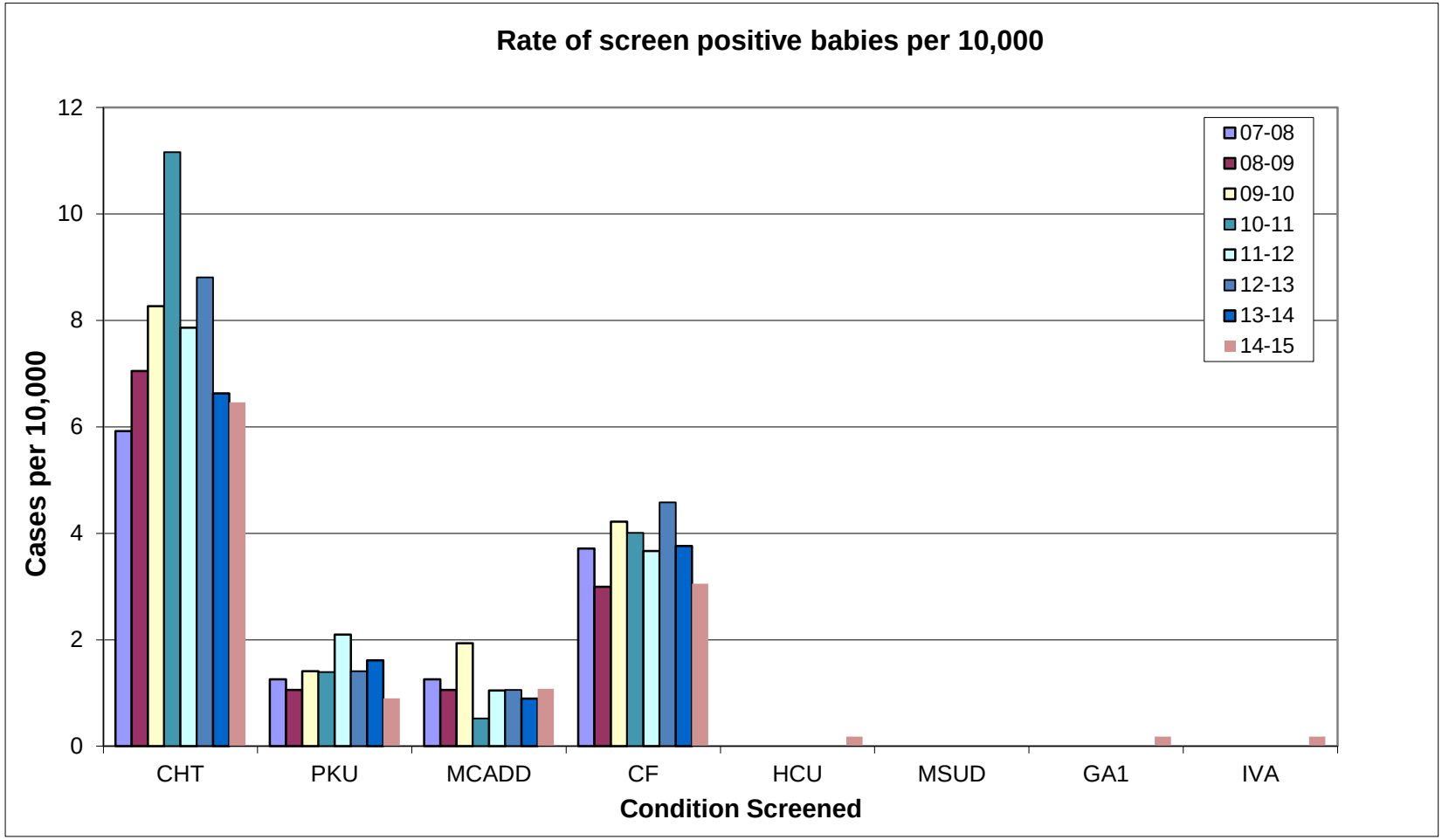

Figure 6: Rate of screen positive babies (per 10000) from 2007 onwards

Positive Cases 2014-2015

PKU Screening

Five cases of confirmed raised phenylalanine were followed up clinically by medical staff at the Willink Unit. There were two confirmed as PKU cases, giving an estimated incidence of 1: 27850. This figure was calculated based on the number of first samples received by the laboratory which may not truly reflect the birth rate. One of the confirmed cases was diagnosed on day 2 (affected sibling). Of the 3 remaining positive screens, one was confirmed as a biopterin disorder and the other two were milder elevations of phenylalanine which require follow up (hyperphenylalaninaemia). According to the clinical referral guidelines, 100% of positive screening results should be referred within four working days of sample receipt. All five cases were referred within 3 working days. The age at referral ranged from 9-11 days (excluding the baby diagnosed prior to screening). 4/4 babies had their first clinical appointment by 13 days of age (range 10-13 days).

MCADD Screening

There were six screen positives for MCADD and five were confirmed as MCADD cases, giving an estimated incidence of 1 in 11140. All screen positives were referred within 3 working days. The age at referral ranged from 9-13 days.

Expanded Screening

There was one screen positive for IVA in a premature baby (29 weeks gestation), which was referred on day 12, within 3 working days of sample receipt. This was a false positive cases as IVA was excluded on further testing. There was one screen positive for GA1 which was referred on day 11, within 3 working days. The diagnosis was confirmed and a lysine restricted diet was started on day 15. One HCU case was detected clinically, prior to screening, due to an affected sibling. The diagnosis was confirmed on day 2.

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 >287 mU/L.

There was one case of a screen positive result on a premature repeat sample, collected on day 28 (blood spot TSH concentration 113 mU/L) and referred on day 35. One baby, with an insufficient sample on day 5 (TSH 5.8 mU/L), was referred on day 28 following a TSH of 46 mU/L, collected on day 23 (clinical incident number 1036898).

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 109 initial borderline results (using a local cut off of 8 mU/L as opposed to the national cut off of 10 mU/L), 14 (13%) were treated as positive following repeat sampling with a TSH ranging from 8 to 24 mU/L on repeat.

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 14 days (range 11-19 days). The first clinic appointment was attended by day 17 in 19 cases (95%; In-patients are evaluated on the day of referral). The standard was not achieved in one case due to the Christmas bank holidays (referred on day 14, appointment day 19).

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 darker (purple) bars in figure 7. The median age at the first clinic appointment was 22 days (range 16-38; excluding the premature repeat screen positive result and the insufficient repeat described earlier). The first clinic appointment was attended by day 24 in 11 cases (79%; In-patients evaluated on the day of referral). Two babies exceeding 24 days, were the subject of clinical incidents due to delayed sample collection (aged 19 and 33 days; incident numbers 1025648 and 1028415 respectively). The standard was not achieved in one further case due to the Easter bank holidays (referred on day 20, appointment day 25).

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. Over 97% (35/36) of positive CHT cases were referred within 4 working days (one case was delayed by 1 day due an analytical problem with the TSH assay; baby aged 17 days at first appointment).

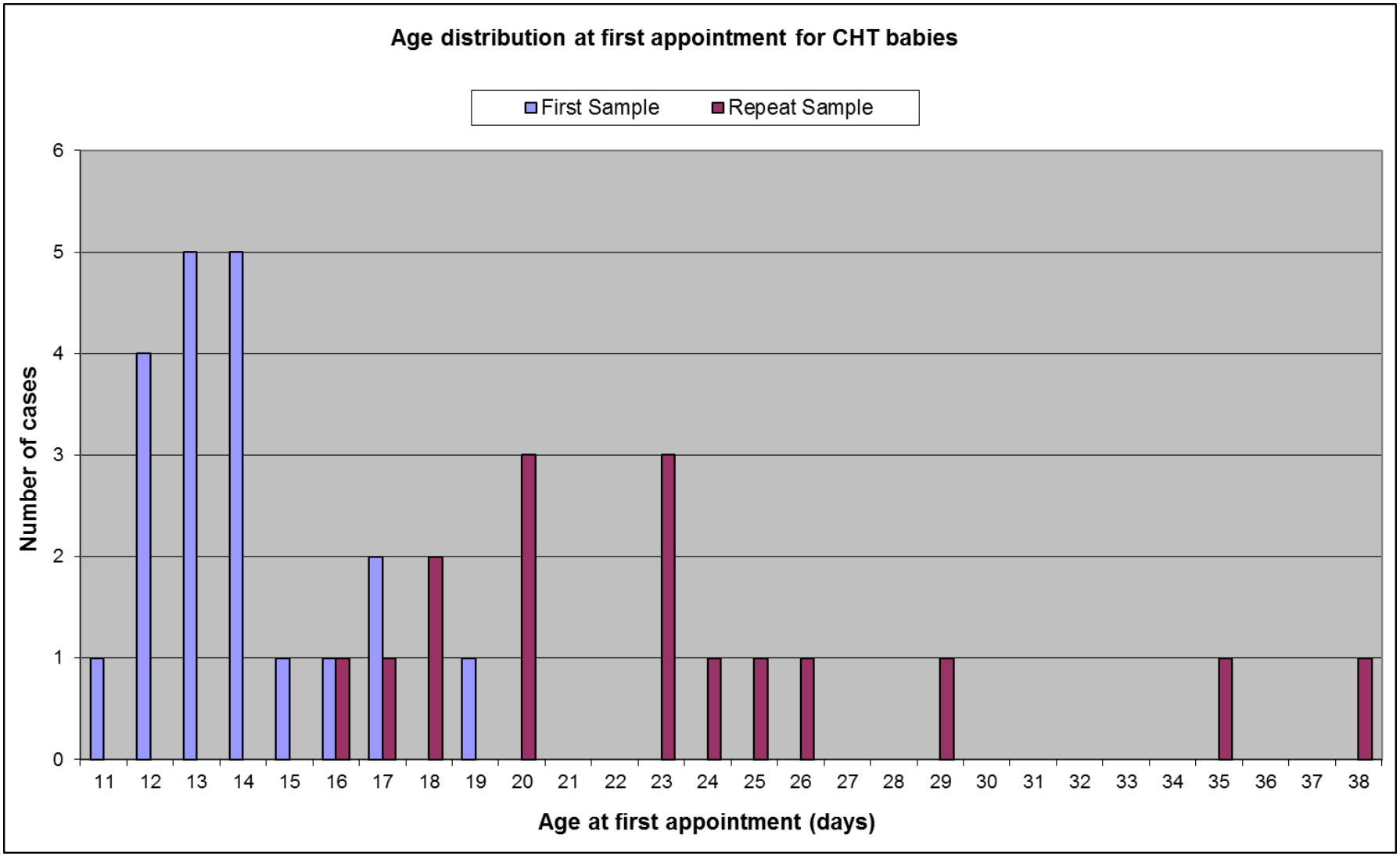

Figure 7: Graph to show age at first appointment for each positive CHT case (in days)

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)
NHS Blackburn with Darwen CCG	1	13
NHS Blackpool CCG	1	12
NHS Bolton CCG	1	14
NHS Bury CCG	1	17
NHS Central Manchester CCG	1	14
NHS Chorley and South Ribble CCG	0	
NHS Cumbria CCG	0	
NHS East Lancashire CCG	2	13, 16
NHS Fylde and Wyre CCG	1	19
NHS Greater Preston CCG	1	13
NHS Heywood, Middleton and Rochdale CCG	3	13,14, 14
NHS Lancashire North CCG	1	12
NHS North Manchester CCG	1	17
NHS Oldham CCG	0	
NHS Salford CCG	1	15
NHS South Manchester CCG	0	
NHS Tameside and Glossop CCG	3	11, 12, 13
NHS Trafford CCG	1	12
NHS Wigan Borough CCG	1	14

Table 6: Location and age at referral of positive CHT babies identified on the first sample

CCG	Number of cases	Age at referral (days)
NHS Blackburn with Darwen CCG	0	
NHS Blackpool CCG	0	
NHS Bolton CCG	1	20
NHS Bury CCG	0	
NHS Central Manchester CCG	0	
NHS Chorley and South Ribble CCG	1	18
NHS Cumbria CCG	2	23, 38
NHS East Lancashire CCG	5	18, 20, 24, 24, 35
NHS Fylde and Wyre CCG	0	
NHS Greater Preston CCG	1	23
NHS Heywood, Middleton and Rochdale CCG	0	
NHS Lancashire North CCG	2	25, 26
NHS North Manchester CCG	0	
NHS Oldham CCG	1	20
NHS Salford CCG	0	
NHS South Manchester CCG	1	29
NHS Tameside and Glossop CCG	0	
NHS Trafford CCG	1	17
NHS Wigan Borough CCG	1	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 data for CF screening is shown in tables 8, 9 and 10. Comparative data for 2013/14 is shown in table 9 and summary data since the programme was implemented in 2007 in table 10.

		2013/2014	2014/2015
Screening data (first sample)	Number of babies screened for CF	55603	55469
	Number ≥ 99.5th centile sent for mutation analysis	272	274
	Total number of second samples requested	42	28
	Number with first IRT ≥ 99.5th centile and one mutation	18	13
	Number with first IRT ≥ 99.9th centile and no mutation found	24	15
CF not suspected	Number with first IRT < 99.5th centile	55331	55195
	Number with first IRT ≥ 99.5th centile but < 99.9th, no mutations detected (2nd sample not required)	212	230
	Number with first IRT ≥ 99.9th centile, no mutations detected and second sample IRT below cut-off 2	22	14
CF suspected	Number with first IRT ≥ 99.5th centile and two mutations detected	18	16
	Number with first IRT ≥ 99.5th centile and two mutations detected on the four mutation panel	8	12
	Number with first IRT ≥ 99.5th centile and two mutations detected, with the second mutation detected on the extended mutation panel	10	4
	Number with first IRT ≥ 99.5th centile, one mutation and second sample IRT above cut-off 2	1	0
	Number with first IRT ≥ 99.9th centile, no mutations detected and second sample IRT above cut-off 2	2	1
	Total number of 'CF suspected' babies	21	17
Carrier	Number with first IRT ≥ 99.5th centile and one mutation found and second sample IRT below cut-off 2	17	13

Table 8: Summary of screening results for cystic fibrosis.

A second IRT sample is requested if no mutations were identified and the initial IRT result was greater than the 99.9th centile (120 ng/mL) OR if one mutation was identified. If the second IRT sample was greater than cut off 2 (currently 53 ng/mL) then that baby was reported as "CF suspected".

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

Table 9: CF Outcome Data for CF Since Programme Implementation
Figures in parentheses are numbers predicted from the national algorithm; A Preston baby was reported as CF suspected by Alder Hey – not included in table

The percentage of samples referred for DNA testing equalled the target of 0.5%. However this figure did fluctuate throughout the year (0.32-0.67%) due to lot to lot variation of the IRT kits. An adjustment to the IRT cut-offs was made in January 2015 following a referral rate of 0.32% in December 2014. A more robust procedure for determining IRT cut-off is being developed nationally as it is recognised that individual centres have insufficient numbers of samples to determine their own 99.5th percentile in a useful timescale.

The total number of babies who were screen positive is lower 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 10 and figure 8 detail the age of each baby at the first clinic appointment. The case that was referred following analysis of a second IRT is shown to the right of the chart, in red. The median age for referral for the double mutation cases was 19 days (range 15–27 days, excluding one baby referred on day 55). The median age at first clinic appointment for this group was 22 days (range 12-29 days, excluding the baby referred on day 55). The baby who had an appointment on day 12 was diagnosed from cord blood before the screening result was available (positive screen on day 17) due to having an echogenic bowel *in utero* and two known carrier parents.

Of the double mutation cases, 15/17 (88%) were seen by the CF team by day 28. Two babies did not have an appointment by day 28. The first was referred aged 55 days due to a delay in collection of a repeat sample (first sample collected within 72 hours of a transfusion; clinical incident number 1042758). In the second case, where the baby was seen on day 29, the standard was not achieved due to delayed sample transit (7 calendar days, 5 working days).

The CF case identified following a second raised IRT was referred on day 26 and had a clinic appointment on day 33.

CCG	Number of cases	Age at first appointment
NHS Blackburn with Darwen CCG	1	24
NHS Central Manchester CCG	1	23
NHS Chorley and South Ribble CCG	1	17
NHS East Lancashire CCG	1	25
NHS Lancashire North CCG	1	24
NHS North Manchester CCG	1	**33**
NHS Oldham CCG	2	17, 18
NHS Salford CCG	2	22, 22
NHS South Manchester CCG	1	17
NHS Stockport CCG	1	55
NHS Tameside and Glossop CCG	2	12, 15
NHS Trafford CCG	1	22
NHS Wigan Borough CCG	2	22, 29

Table 10: Location of CF cases identified by screening and age at first appointment

The age shown in bold represents the case that was identified following receipt of a second samples for IRT analysis.

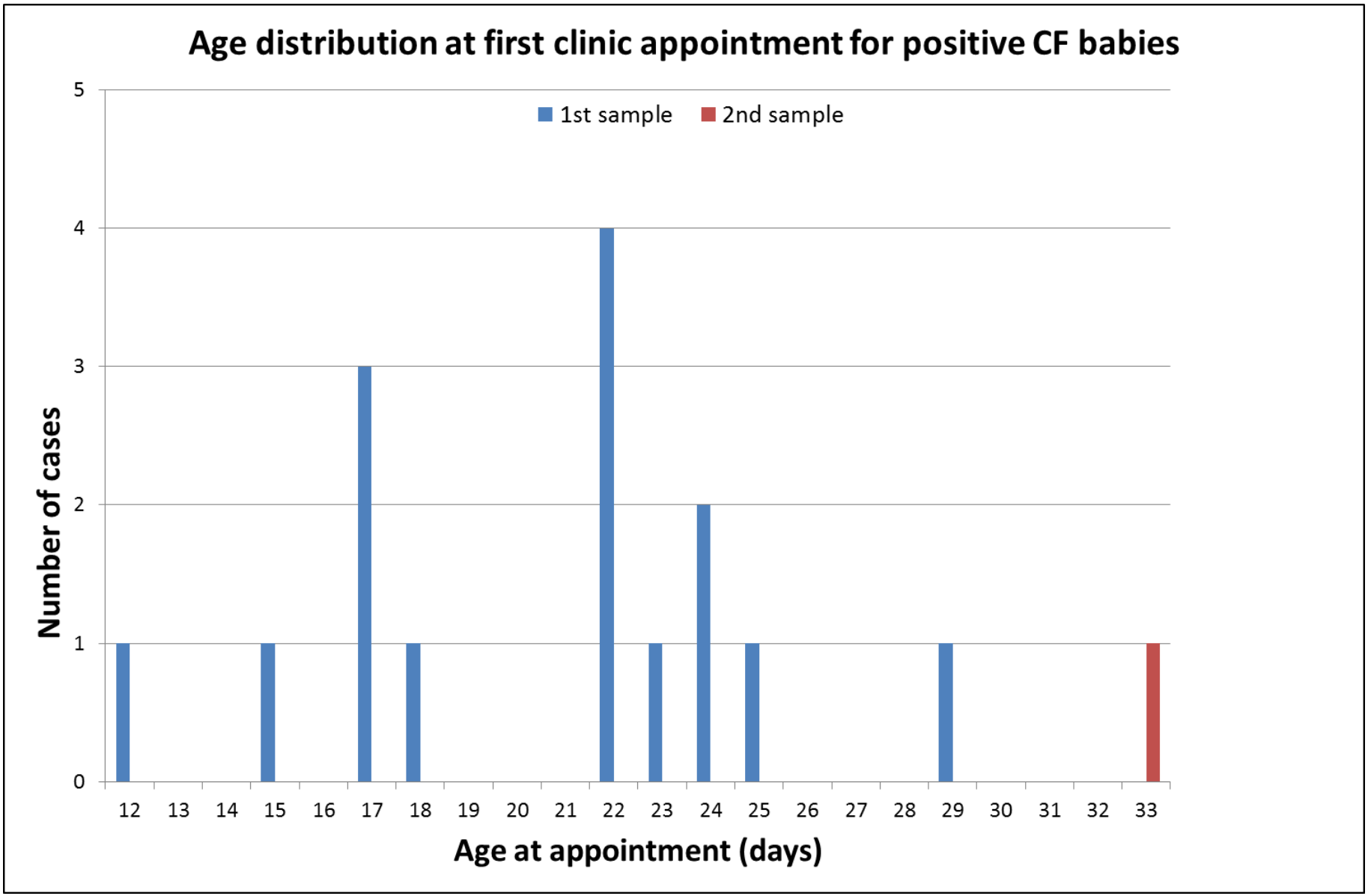

Figure 8: Graph to show the age at first clinic appointment for CF Suspected cases.
The baby referred following receipt of a second blood spot is shown to the right of the graph. One baby referred on day 55 is excluded from the chart.

In 2014/15 a total of 240 babies missed CF screening which is slightly more than the number in 2013/14 (201). 95% (227) of these babies were born outside of the UK (similar to percentage the previous year of 93%). 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 13 babies born in the UK who missed CF screening, 12 appear to have had their first sample collected at more than 8 weeks of age. One baby had two samples collected before 8 weeks of age without a valid NHS number. A 2nd repeat was declined shortly afterwards. A valid sample was finally collected on day 81. Figures 9 and 10 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.

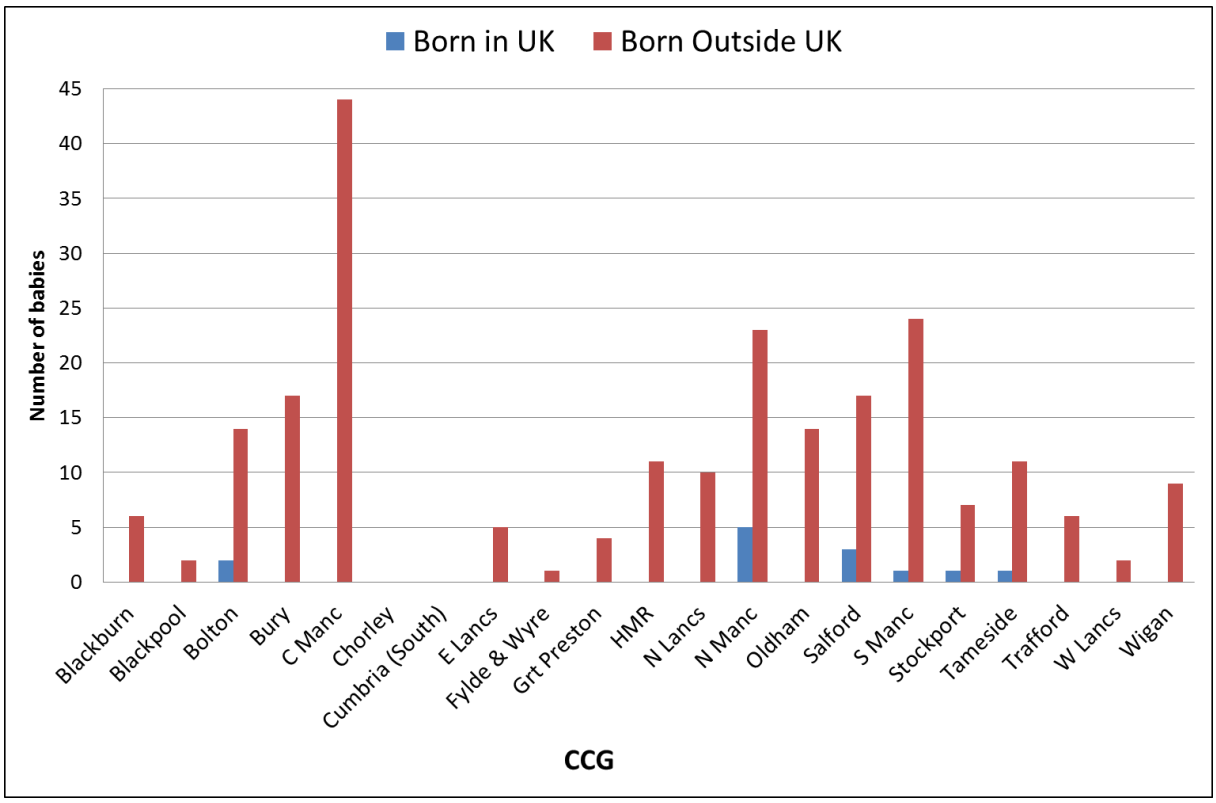

Figure 9: The number of babies who missed CF screening sorted by CCG.

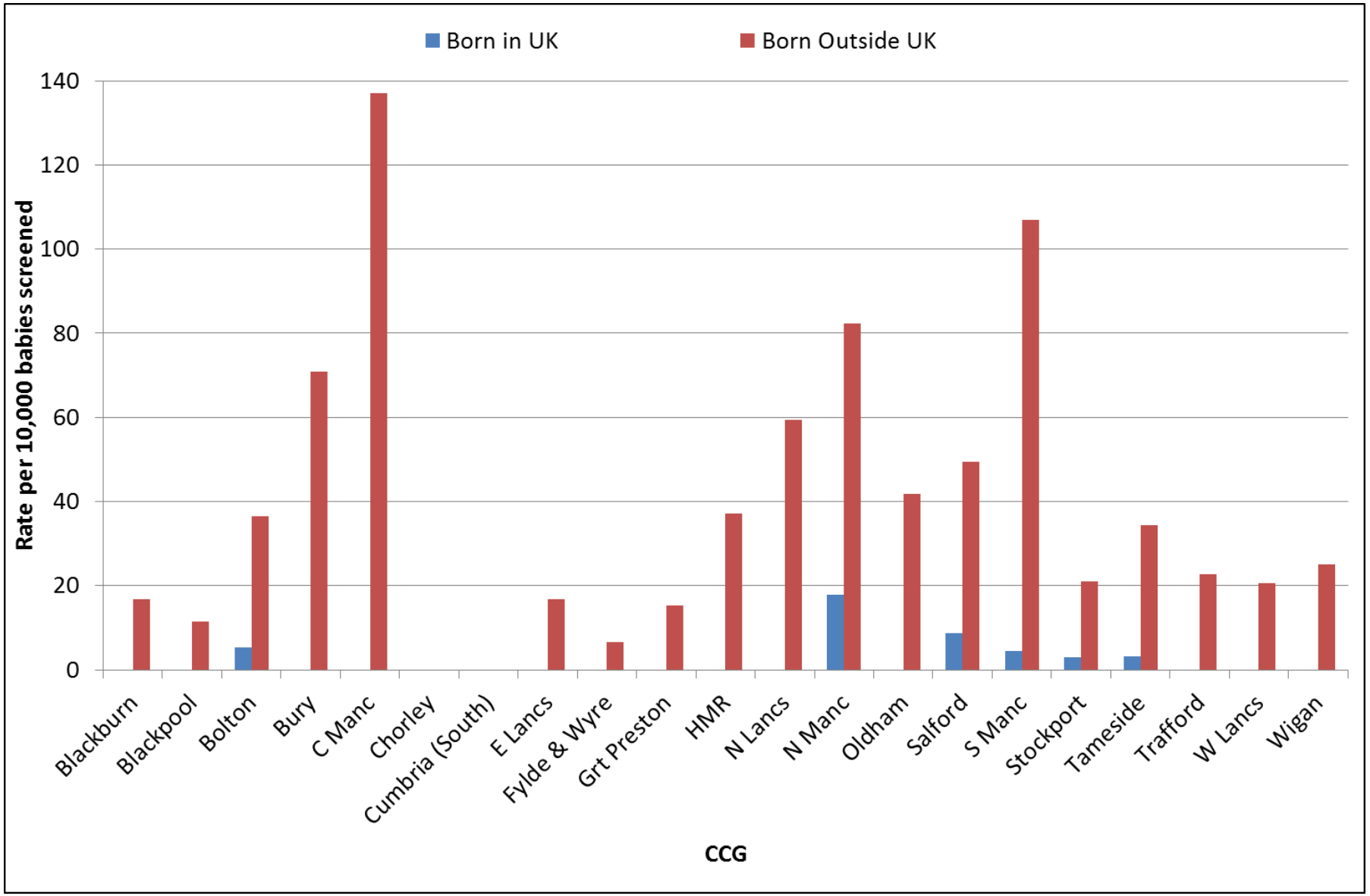

Figure 10: The number of babies who missed CF screening per 10,000 babies screened by each CCG

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 727 samples for confirmatory testing, 55 of which were subsequently reported as not suspected for Sickle Cell Disease. The 55 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 11. There were 16 babies identified as having sickle cell disease (15 FS and 1 FSC) and 1 baby identified as a thalassaemia case (HbF).

Data on the ethnic origin of babies identified with sickle cell disease or other clinically significant haemoglobinopathies is shown in table 12 and age at referral for those babies in table 13. 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 2014 and March 2015, 86% of the clinically significant disorders identified were reported by 24 days of age. In one case of sickle cell disease, the referral was delayed due to prematurity (28 weeks at birth). In another case of sickle cell disease the baby was detected on a sample collected on day 258 (movement in to the country). Finally a result of FSA was referred on day 27 on a baby who was later confirmed as a sickle cell carrier on follow up. Referral of this case was delayed due to the Christmas Bank Holidays.

CCG	Significant Diseases					Non-significant diseases		Carriers			
	FS	FSC	FSA	FE	F only	FC	FD	FAS	FAC	FAD	FAE
Blackburn	0	0	0	0	0	0	0	14	0	4	2
Blackpool	0	0	0	0	0	0	0	7	0	1	1
Bolton	2	0	1	0	0	0	0	33	3	2	3
Bury	0	0	0	0	1	0	0	5	0	3	1
C Manc	7	1	1	0	0	0	0	81	20	11	4
Chorley	0	0	0	0	0	0	0	1	1	1	0
S Cumbria	0	0	0	0	0	0	0	0	0	2	1
E Lancs	0	0	0	0	0	0	0	3	1	9	5
Fylde & Wyre	0	0	0	0	0	0	0	4	0	0	0
Grt Preston	0	0	0	0	0	0	0	13	1	3	0
HMR	0	0	0	0	0	0	0	31	3	6	4
N Lancs	0	0	0	0	0	0	0	3	1	0	2
N Manc	3	0	1	0	0	0	0	100	17	2	3
Oldham	0	0	0	1	0	0	0	15	2	5	20
Salford	1	0	1	0	0	0	0	59	7	6	1
S Manc	0	0	0	0	0	0	0	19	6	0	3
Stockport	0	0	0	0	0	0	0	16	0	4	4
Tameside	0	0	0	0	0	0	0	13	1	5	9
Trafford	2	0	0	0	0	0	0	18	1	2	4
W Lancs	0	0	0	0	0	0	0	1	0	0	0
Wigan	0	0	0	0	0	0	0	10	0	1	3
Out of region	0	0	0	0	0	0	0	2	0	0	1
Total	**15**	**1**	**4**	**1**	**1**	**0**	**0**	448	64	67	71

Table 11: Results obtained for sickle cell and haemoglobinopathy screening.

FS = sickle cell disease
FSC = SC type sickle cell disease
FSA = possible heterozygote for sickle cell/β thalassaemia
FE = HbE disease
F only = β thalassaemia major

FAS = sickle cell carrier
FAC = HbC carrier
FAD = HbD carrier
FAE = HbE 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	28	8	11	5
White Irish	0	0	0	0	0	0	0	0	0	0	0
Any other White	0	0	0	0	0	0	0	3	0	0	1
White and Black	0	0	1	0	0	0	0	26	7	1	1
White and Black African	2	0	0	0	0	0	0	39	8	0	0
White and Asian	0	0	0	0	0	0	0	1	0	1	5
Any other mixed	0	0	0	0	0	0	0	21	1	0	9
Indian	0	0	0	0	0	0	0	10	0	4	1
Pakistani	0	0	0	0	0	0	0	3	0	40	9
Bangladeshi	0	0	0	1	0	0	0	0	0	2	31
Any other Asian	0	0	0	0	0	0	0	5	0	4	3
Black Caribbean	1	0	0	0	0	0	0	13	8	0	0
Black African	10	1	2	0	0	0	0	259	30	0	0
Any other Black	2	0	0	0	0	0	0	21	2	0	0
Chinese	0	0	0	0	0	0	0	0	0	1	1
Any other ethnic	0	0	1	0	1	0	0	10	0	0	4
Not stated	0	0	0	0	0	0	0	9	0	3	1
Totals	**15**	**1**	**4**	**1**	**1**	**0**	**0**	**448**	**64**	**67**	**71**

Table 12: Distribution of babies with sickle cell disease and other clinically significant haemoglobinopathies by ethnic origin

Age in days			Screening result
Sample collection	Receipt of sample in lab	Positive result reported	
5	6	19	FS
5	9	17	FS-Other
5	8	15	FS
5	5	32	FS
9	13	20	F-only
5	8	14	FS
5	7	13	FS
5	7	14	FS
5	7	15	FS
5	6	12	FS
5	6	18	FE
5	6	14	FS
8	9	27	FS-Other
5	8	17	FS
5	7	16	FS
5	8	13	FS
5	8	15	FS-Other
5	8	15	FSC
5	7	14	FS
5	6	13	FS-Other
6	12	16	FS
258	261	274	FS

Table 13: Age at referral for babies with sickle cell disease and other clinically significant haemoglobinopathies

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 2014/15 99.5% 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 very low. Overall there has been a small increase in the usage of bar-coded labels (from 57% to 64%).
- Standard 4 - Timely sample collection: All CCGs met this standard. Overall 98.0% of first samples were collected on days 5-8, compared with 98.1% in 2013/14.
- Standard 5 - Timely sample receipt in the lab: 99.0% samples were received within 4 working days which remains unchanged from last year (target 100%).
- Standard 6 - Quality of Blood spot Sample: 10 out of 22 CCGs achieved this standard which represents deterioration in performance from last year when 81% of PCTs met the standard (target 2%). The percentage avoidable repeat rate ranged from 1.2% to 3.4% (2013/14: 0.6% to 2.7%). The insufficient rate for samples collected from in-patients was four times higher than the rate for those collected in the community; however there has been decreasing trend in the hospital insufficient rate from 9% in 2012/13, 3.2% in 2013/14 to 2.3% this year.

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 (4/4 referred by 11 days, appointment by day 13). For CHT positive babies identified on the initial screening sample 95% had their first clinic appointment by 17 days and 75% by 14 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 94% of CHT referrals were made within 3 working days (97% within 4 working days).

Cystic Fibrosis Programme

- Overall, an appropriate number of samples (0.5%) were referred for DNA testing.
- The number of babies who were screen positive is lower than the figure predicted from the national algorithm. 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, 88% were assessed by the CF team by 28 days of age (the national standard). One case missed the standard by 1 day due to delayed sample transit. The other delayed case was due to a significant delay in collection of a repeat sample following a blood transfusion.
- One baby, referred following receipt of a second sample for IRT, had an appointment on day 33 (standard day 35).
- The number of babies who missed CF screening because a satisfactory sample was not collected before 8 weeks of age increased from 201 in 2013/14 to 240. The proportion that were "movers in" (born outside of the UK) stayed the same (93%).

Sickle Programme

- In 2014/15 16 babies with sickle cell disease and 1 with β thalassaemia were identified as well as 448 carriers of the sickle gene, 202 carriers of haemoglobins C, D and E.
- Age at referral for babies screen positive for sickle cell and β thalassaemia ranged from 12–274 days (median 15 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. Results of 86% (19/22) of 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 and cards delayed in transit comprised 92% of the total incidents. 3% 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.

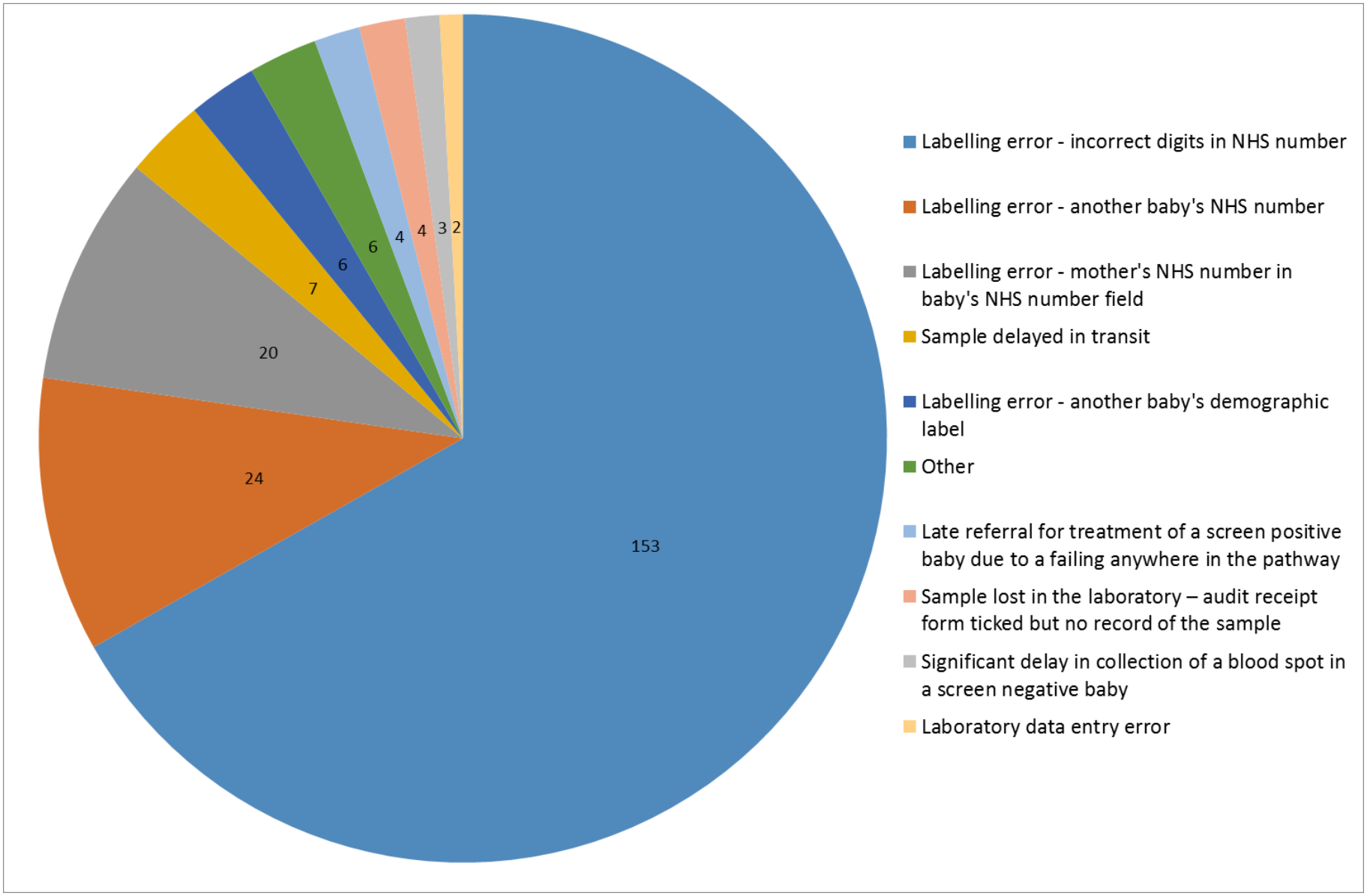

Figure 11: Newborn Blood Spot Screening Clinical Incidents by Cause

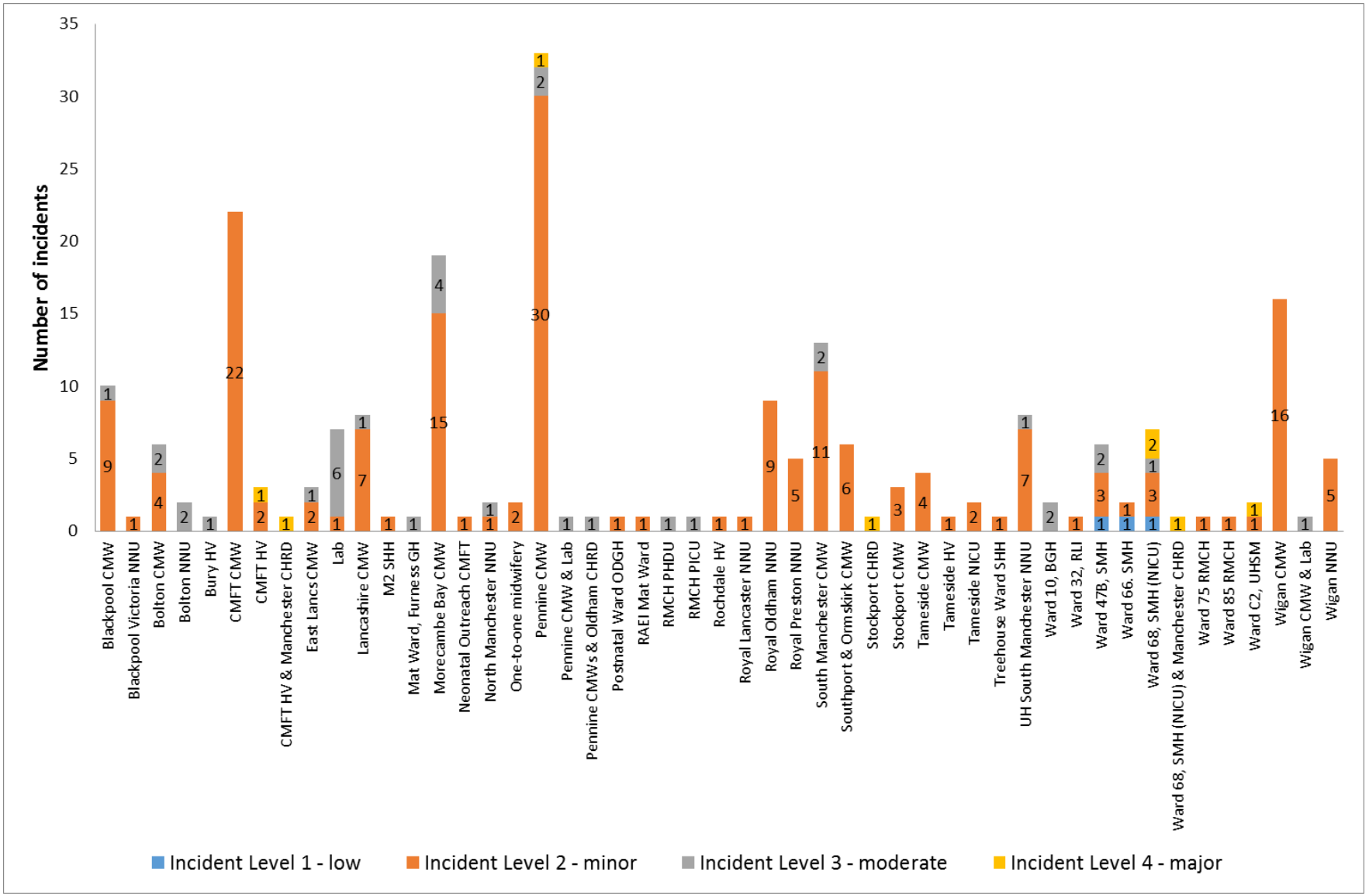

Figure 12: Newborn Blood Spot Incidents (logged by CMFT) by location of incident; Key: CMW – Community midwives, HV – Health Visitors, CHRD -Child Health Records Dept, NNU – Neonatal Unit.

7. Current and Future Developments

- Following completion of a pilot programme for expanded newborn screening for metabolic conditions, which the Willink laboratory participated in, a national consultation took place in March 2014 and a decision was made by the NSC to include four of the five additional conditions include in the pilot (maple syrup urine disease, homocystinuria, glutaric aciduria type I and isovaleric acidaemia) in the national programme. The expanded programme was rolled out nationally for all samples received from 5th January 2015.

- 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. The laboratory now uploads the 01 (sample received) code and is currently working on configuring the results file for uploading. As part of this work 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 is working with CMFT IT leads, Perkin Elmer, Northgate IS, National Screening IT leads and Manchester Child Health Records to implement electronic reporting. This work currently involves transmitting a copy of the csv file being configured for the failsafe via the Trust Integration Engine to the Manchester Child Health system (McKesson). The aim is to role this out to the other Child Health Records Departments served by the Manchester NBS laboratory. Ultimately the laboratory hopes to move to ITK messaging in line with the national strategy.

- The NBS laboratory has been involved in work locally and nationally to improve blood spot quality. Following on from collaborative work with the North West QA team focusing on blood spot collection and close monitoring of quality against national standards Laura Hamilton (Chief Biomedical Scientist) undertook a study to assess the clinical impact of multi-layering, multi-spotting and compression of blood spots. The report of this work (Blood Spot Sample Quality Project, April 2013) fed into the national blood spot quality group (led by Kate Hall, Birmingham NBS laboratory) of which Laura was a key member. Posters of the local and national work were presented at the ISNS European Neonatal Screening Meeting in October 2014. Standardised criteria for blood spot acceptance and rejection were subsequently agreed as a result of this work with a plan to implement in April 2015.

- 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 are to be presented at the annual meeting of the Royal College of Paediatrics and Child Health (RCPCH) in April 2015.

Appendix 1: Research and Development and Audit

Local Audits Completed in 2014-15

Audit of Information Provided to Parents of Carriers of Abnormal Haemoglobin Variants..
Helen Jopling and Beverly Hird
November 2014

Poster Presentations

Investigating bloodspot homogeneity and analytical bias across the spot diameter
S K Hall, F Mackenzie, L Allen, C Griffith, R George, L Hamilton, L Tetlow, C Dibden, J Bonham
9th ISNS European Neonatal Screening Meeting, Birmingham, October 2014

The Effect of Bloodspot Sample Quality on Newborn Screening Results
L Hamilton, B Hird, L Tetlow
9th ISNS European Neonatal Screening Meeting, Birmingham, October 2014

A Re-Audit of the Turnaround Time of Samples for the Sickle Cell and Thalassaemia Newborn Screening Programme in the Manchester Newborn Screening Laboratory
S Armitage, C Manfredonia, S MacDonald, S McLaughlin, V Davis, L Tetlow
9th ISNS European Neonatal Screening Meeting, Birmingham, October, 2014

An Audit to Assess the Impact of Increasing the Borderline Bloodspot TSH Cut-Off on the Detection of Cases of Congenital Hypothyroidism (CHT) Identified via Newborn Screening
L Tetlow, C Steele, B Hird, C Manfredonia, D Nice, J Scargill
42nd Annual Meeting British Society of paediatric Endocrinology (BSPED), Winchester, Nov 2014

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 baby's NHS number	Percentage of all blood spot cards including baby's' NHS number	Percentage of all blood spot cards including ISB barcoded baby's' NHS number
Blackpool Victoria Hospital	1838	1832	99.67%	66.18%
Central Manchester University Hospitals	4582	4555	99.41%	71.74%
East Lancashire Hospitals	4244	4239	99.88%	87.93%
Lancashire Teaching Hospitals	3758	3748	99.73%	73.75%
North Cumbria University Hospitals	1	1	100.00%	0.00%
NOT STATED	14059	13939	99.15%	58.31%
One-to-One Midwifery	189	186	98.41%	23.48%
Pennine Acute Hospitals	10175	10116	99.42%	67.22%
Royal Albert Edward Infirmary	3188	3167	99.34%	32.80%
Royal Bolton Hospital	5839	5828	99.81%	61.19%
Southport & Ormskirk Hospital	856	852	99.53%	32.86%
Stockport	2899	2888	99.62%	77.32%
Tameside General Hospital	2831	2823	99.72%	79.42%
University Hospitals of Morecambe Bay	1693	1674	98.88%	8.77%
University Hospitals South Manchester	3197	3186	99.66%	74.85%
Grand Total	59349	59034	99.47%	64.20%

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

NOTE: Unable to provide NHS label data for quarters 1 & 2 due to an IT error in 2014. Percentages for barcode usage refer to quarters 3 & 4 only

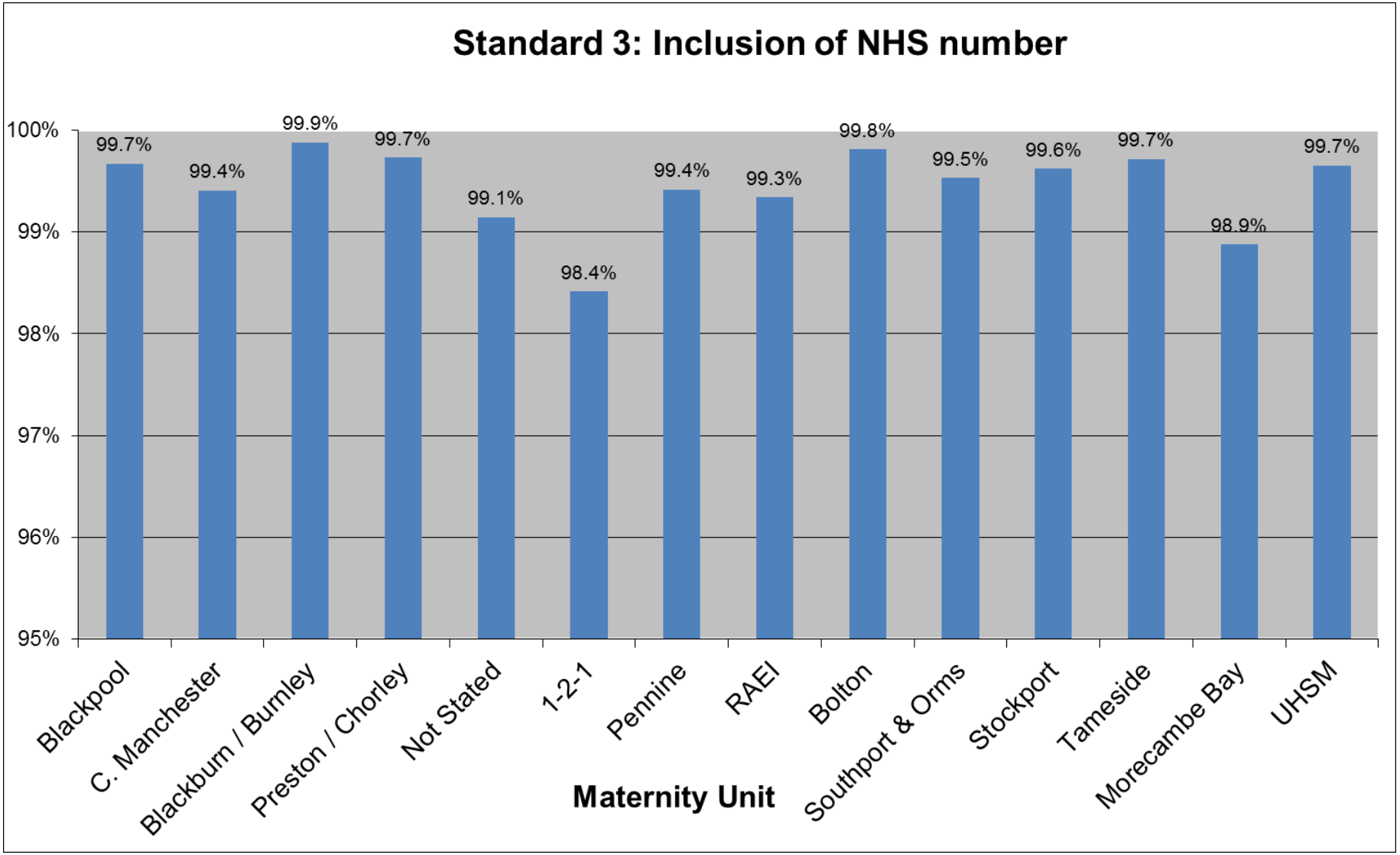

Figure 1: Graph to show percentage of cards that included NHS number for period April 2014 – March 2015

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	1	1723	30	**0.06%**	**98.23%**	**1.71%**
Central Manchester University Hospitals	11	3916	75	**0.27%**	**97.85%**	**1.87%**
East Lancashire Hospitals	7	3929	86	**0.17%**	**97.69%**	**2.14%**
Lancashire Teaching Hospitals	15	3533	55	**0.42%**	**98.06%**	**1.53%**
North Cumbria University Hospitals	0	1	0	**0.00%**	**100.00%**	**0.00%**
Not Stated	49	12103	489	**0.39%**	**95.74%**	**3.87%**
One-to-One Midwifery	0	171	1	**0.00%**	**99.42%**	**0.58%**
Pennine Acute Hospitals	14	9727	99	**0.14%**	**98.85%**	**1.01%**
Royal Albert Edward Infirmary	7	3007	35	**0.23%**	**98.62%**	**1.15%**
Royal Bolton Hospital	4	5388	51	**0.07%**	**98.99%**	**0.94%**
Southport & Ormskirk Hospital	4	829	2	**0.48%**	**99.28%**	**0.24%**
Stockport	3	2767	26	**0.11%**	**98.96%**	**0.93%**
Tameside General Hospital	12	2686	22	**0.44%**	**98.75%**	**0.81%**
University Hospitals of Morecambe Bay	4	1596	13	**0.25%**	**98.95%**	**0.81%**
University Hospitals South Manchester	2	3119	14	**0.06%**	**99.49%**	**0.45%**
Grand Total	133	54495	998	**0.24%**	**97.97%**	**1.79%**

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

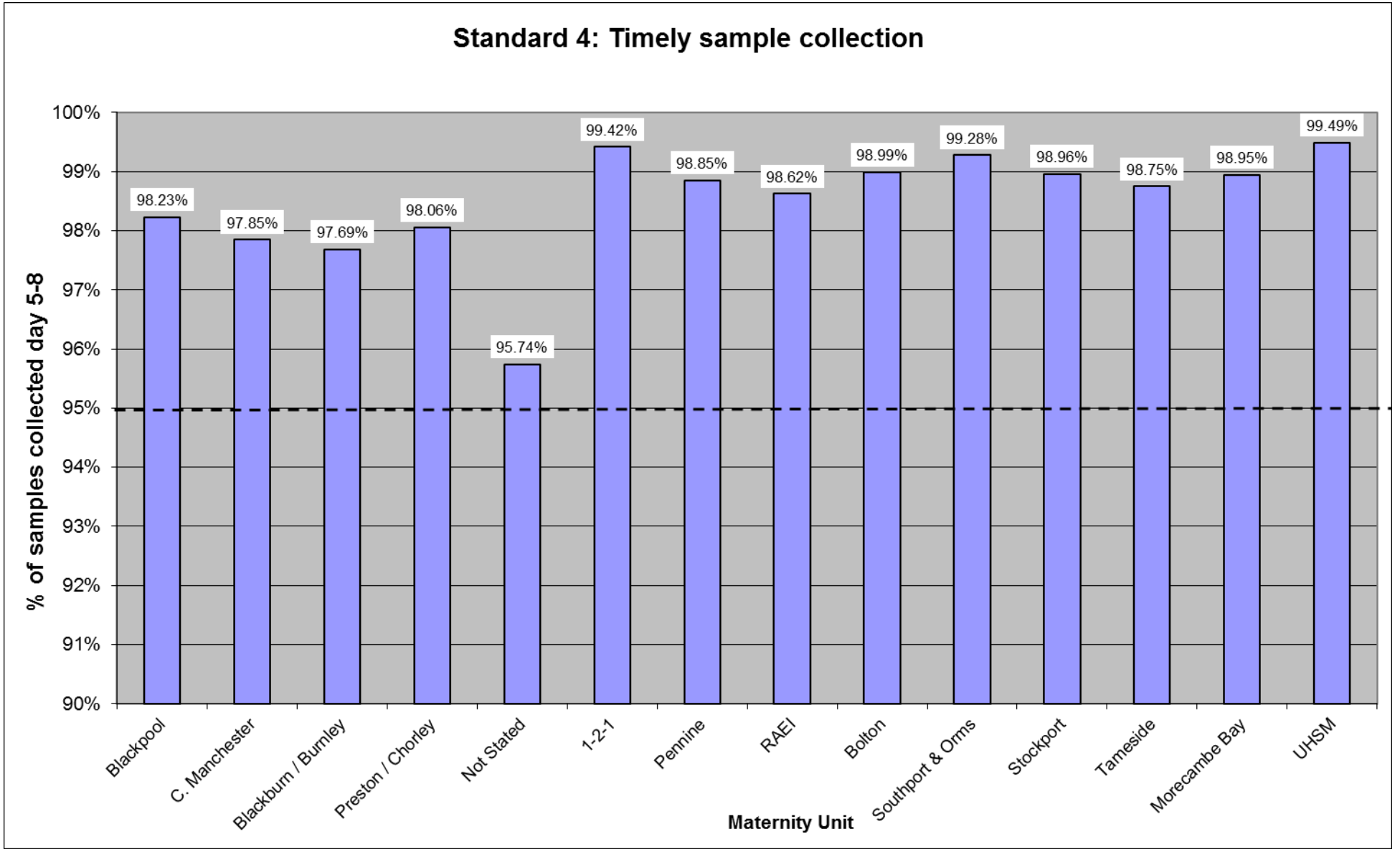

Figure 2: Graph to show percentage of samples taken 5-8 days after birth

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	1692	1793	34	92.61%	98.14%	1.86%
Central Manchester University Hospitals	4200	4224	12	99.15%	99.72%	0.28%
East Lancashire Hospitals	4099	4129	11	99.01%	99.73%	0.27%
Lancashire Teaching Hospitals	3612	3717	32	96.35%	99.15%	0.85%
Not Stated	12854	13296	194	95.29%	98.56%	1.44%
One-to-One Midwifery	167	176	10	89.78%	94.62%	5.38%
Pennine Acute Hospitals	9742	10026	87	96.33%	99.14%	0.86%
Royal Albert Edward Infirmary	3023	3158	28	94.88%	99.12%	0.88%
Royal Bolton Hospital	5561	5605	8	99.07%	99.86%	0.14%
Southport & Ormskirk Hospital	595	792	64	69.51%	92.52%	7.48%
Stockport	2704	2825	68	93.47%	97.65%	2.35%
Tameside General Hospital	2729	2791	11	97.39%	99.61%	0.39%
University Hospitals of Morecambe Bay	1602	1668	21	94.85%	98.76%	1.24%
University Hospitals South Manchester	3114	3176	17	97.53%	99.47%	0.53%
Grand Total	55694	57376	597	96.07%	98.97%	1.03%

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

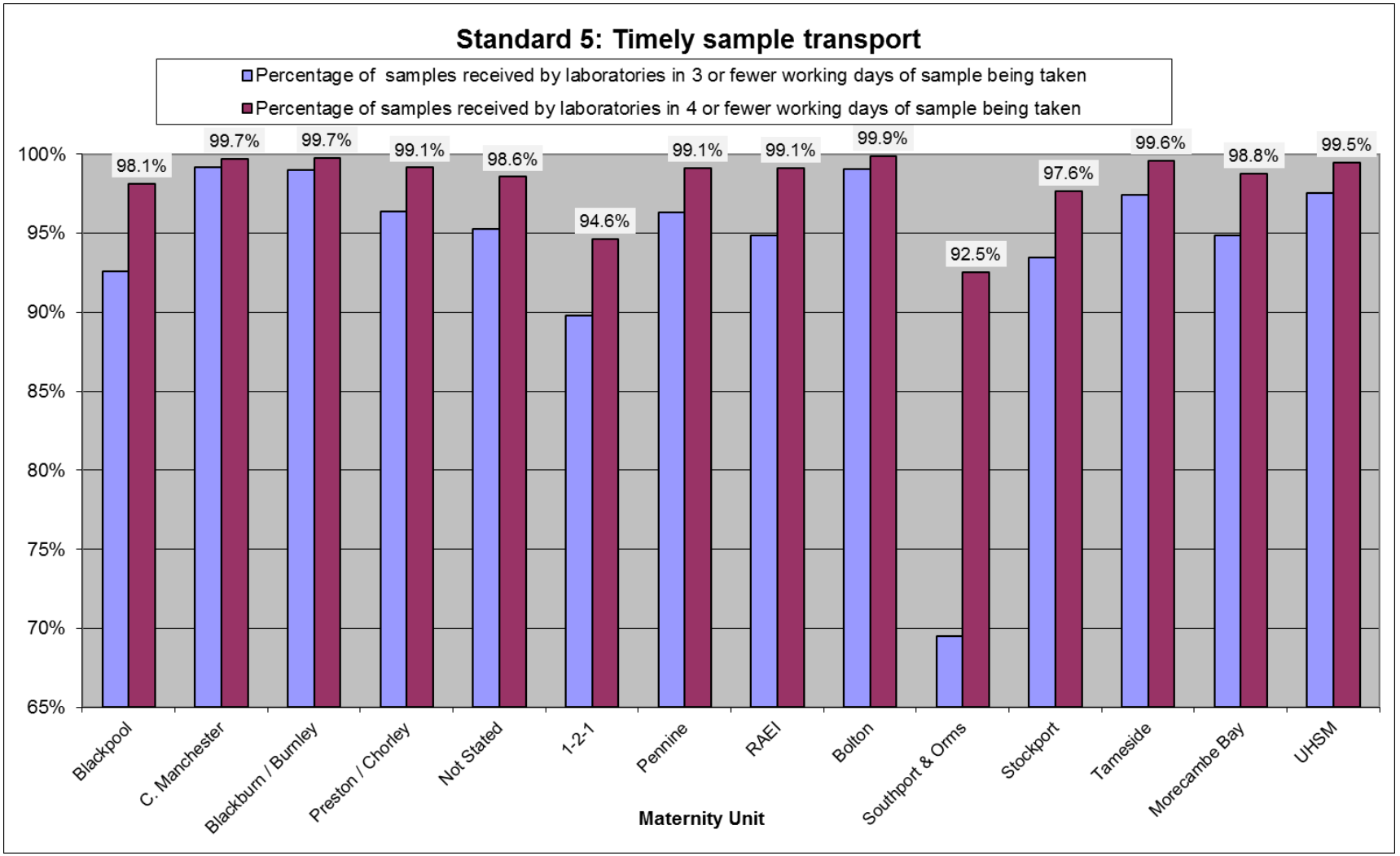

Figure 3: Graph to show percentage of samples received within 3 and 4 working days of being taken, by maternity unit

Maternity Unit	Number of first samples received/ babies tested	Too soon After Transfusion (<72 hours)*	Too young for reliable screening (≤ 4 days)	Insufficient/ multi-layered sample	Unsatisfactory sample	>14 days in transit	No NHS number	Contaminated (discrepant IRT)	Number of Avoidable Repeat Requests	Avoidable Repeat Requests Rate
Blackpool	1754	1	1	20	8	0	6	4	39	**2.2%**
C. Manchester	4010	46	7	26	31	0	25	7	96	**2.4%**
Blackburn / Burnley	4022	13	7	30	9	0	3	0	49	**1.2%**
Preston / Chorley	3605	6	15	26	23	2	10	2	78	**2.2%**
Not Stated	12701	63	43	164	100	7	102	16	432	**3.4%**
1-2-1	175	0	0	9	2	0	3	2	16	**9.2%**
Pennine	9842	22	12	22	36	0	57	5	132	**1.3%**
RAEI	3051	1	6	48	7	0	21	2	84	**2.8%**
Bolton	5443	23	4	22	22	0	6	7	61	**1.1%**
Southport & Orms	835	0	4	1	5	2	4	0	16	**1.9%**
Stockport	2798	2	4	14	21	0	11	3	53	**1.9%**
Tameside	2721	3	12	9	23	0	7	1	52	**1.9%**
Morecambe Bay	1613	1	4	14	7	0	19	0	44	**2.7%**
UHSM	3138	3	2	9	13	0	11	2	37	**1.2%**
Grand Total	55707	184	121	414	307	11	285	51	1189	**2.1%**

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

*Not currently included in calculation of avoidable repeat rate

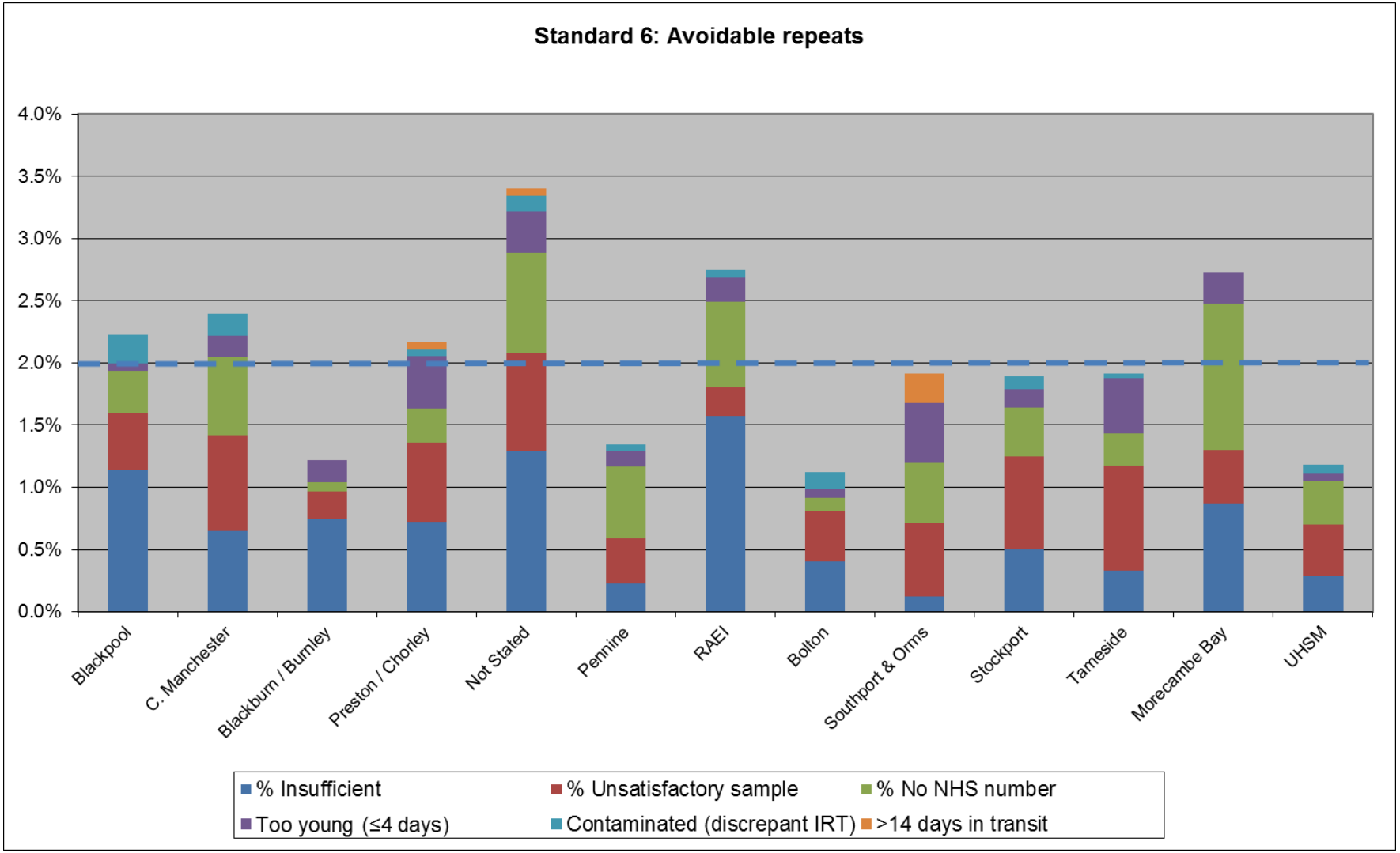

Figure 4: Graph to show avoidable repeat rate by maternity unit
1-2-1 midwives excluded from chart (avoidable repeat rate 9.2%)

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
1022248	24/03/14	3	Near miss	Blood spot sample labelled with another baby's bar-coded demographic sticker	Ward 10B, Burnley General Hospital
1025058	03/04/14	3	Near miss	Laboratory data entry error - incorrect recording of dates/GA leading to incorrect reporting of results. Incorrect GA entered. Not detected at reporting. No premature repeat for CHT requested.	Lab
1025648	13/05/14	3	Near miss	Late referral for treatment of a screen positive baby due to a failing anywhere in the pathway. Baby in whom CHT suspected on a repeat sample referred on day 26 (National Std day 24). Due to delay in collecting repeat (7 days)	Morecambe Bay Community Midwives
1026737	09/05/14	3	Actual harm (level 2)	Sample lost in the laboratory – audit receipt form ticked but no record of the sample	Lab
1026791	23/05/14	3	Actual harm (level 2)	Blood spot sample manually labelled with another baby's demographic details	Bolton Community Midwives
1027266	03/06/14	3	Actual harm (level 2)	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct)	Bolton NNU
1027272	03/06/14	3	Actual harm (level 2)	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct)	RMCH PHDU
1027943	30/05/14	3	Actual harm (level 2)	Blood spot sample labelled with another baby's bar-coded demographic sticker. Detected by lab prior to reporting (handwritten mother's details didn't match sticker)	Lancashire (Preston/ Chorley) Community Midwives
1028193	27/05/14	3	Actual harm (level 2)	Sample lost in the laboratory – audit receipt form ticked but no record of the sample	Lab
1028195	05/06/14	3	Actual harm (level 2)	Blood spot sample labelled with another baby's bar-coded demographic sticker. Detected by lab prior to reporting (handwritten mother's details didn't match sticker)	Ward 10 Lancashire Women's & Newborn Centre
1028415	16/06/14	4	Actual harm	Late referral for treatment of a screen positive baby due to a failing anywhere in the pathway. Delayed collection of borderline CHT repeat sample. CHT positive. Referrred day 36 instead of by day 24.	Ward 68, SMH (NICU)
1031535	08/07/14	3	Actual harm (level 2)	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct)	Morecambe Bay Community Midwives

Incident Number	Incident Date	Incident Level	Near miss or actual harm	Summary of incident	Lab/ Ward/ Maternity Unit
1031767	16/07/14	4	Near miss	Blood spot sample labelled with a NHS number belonging to another person (other demographic details correct) & results entered onto CHRD system against wrong person	CMFT Health Visitors & Manchester Child Health
1032341	29/07/14	3	Actual harm (level 2)	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct). Led to incorrect demographics downloaded by lab. Discrepancy with other details noticed before reporting.	Wigan Community Midwives & Lab
1032343	04/07/14	3	Actual harm (level 2)	Sample lost in the laboratory – audit receipt form ticked but no record of the sample	Lab
1032344	25/07/14	3	Actual harm (level 2)	Sample lost in the laboratory – audit receipt form ticked but no record of the sample	Lab
1032387	08/08/14	3	Actual harm (level 2)	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct)	Blackpool Community Midwives
1032645	05/08/14	3	Actual harm (level 2)	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct)	Bury Health Visitors
1033429	14/08/14	3	Near miss	Blood spot screening result incorrectly reported by laboratory but does not result in harm. Results reported as not suspected (04) instead of repeat (03). Suspected contamination on IVA screen. Error detected before entering onto CHRD system.	Lab
1034282	27/08/14	3	Actual harm (level 2)	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct)	East Lancs Community Midwives
1034477	29/08/14	4	Near miss	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct)	CMFT Health Visitors
1034956	02/09/14	3	Near miss	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct). Number belonged to deceased twin	Bolton Community Midwives
1034976	27/08/14	3	Actual harm (level 2)	Blood spot sample labelled with a handwritten NHS number belonging to baby's mother & entered against mother's record on CHRD system. Also mother's forename instead of baby's.	Pennine Community Midwives & Oldham Child Health
1036035	19/09/14	4	Actual harm (level 2)	Blood spot sample labelled with another baby's bar-coded demographic sticker. Sample positive for CHT. Error detected by lab as DOB, GA & weight mismatch (handwritten).	Ward 68, SMH (NICU)

Incident Number	Incident Date	Incident Level	Near miss or actual harm	Summary of incident	Lab/ Ward/ Maternity Unit
1036268	21/09/14	3	Actual harm (level 2)	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct)	Morecambe Bay Community Midwives
1036272	20/09/14	3	Actual harm (level 2)	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct)	Ward 47B, SMH
1036279	22/09/14	3	Actual harm (level 2)	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct)	Pennine Community Midwives
1036898	22/09/14	3	Actual harm	Late referral for treatment of a screen positive baby due to a failing anywhere in the pathway. Delay in collection of repeat sample. Repeat requested when baby aged 11 days (first sample insufficient). Repeat sample collected aged 23 days. Baby screened positive for CHT. Referred aged 28 days.	South Manchester Community Midwives
1037304	03/10/14	4	Actual harm (level 2)	Blood spot sample labelled with another baby's bar-coded demographic sticker, reported against wrong baby, missed CF screen due to delay in identifying issue	Ward 68, SMH (NICU) & Manchester Child Health
1037570	09/10/14	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). Twin 2's sticker contained twin 1's NHS number	North Manchester NNU
1037806	08/10/14	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 the baby's twin	UH South Manchester NNU
1038803	22/10/14	3	Actual harm (level 2)	Sample(s) delayed in transit resulting in retesting of baby. Found in midwives notes trolley	Ward 47B, SMH
1039445	29/10/14	3	Actual harm (level 2)	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct). Twins.	South Manchester Community Midwives
1041283	21/11/14	3	Near miss	Significant delay in collection of a blood spot in a screen negative baby. Noted on Failsafe that sample not collected for 20 day old baby.	Ward 68, SMH (NICU)
1042086	05/10/14	3	Near miss	Significant delay in collection of a blood spot in a screen negative baby	RMCH PICU
1042224	26/11/14	3	Actual harm (level 2)	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct)	Morecambe Bay Community Midwives

Incident Number	Incident Date	Incident Level	Near miss or actual harm	Summary of incident	Lab/ Ward/ Maternity Unit
1042758	08/12/14	4	Actual harm	Late referral for treatment of a screen positive baby due to a failing anywhere in the pathway	Stockport Child Health
1044574	21/12/14	4	Actual harm (level 2)	Blood spot sample labelled with another baby's bar-coded demographic sticker. Detected before reported.	Pennine Community Midwives
1045993	13/01/15	3	Actual harm (level 2)	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct)	Bolton NNU
1047121	24/04/14	3	Actual harm (level 2)	Incorrect barcodes on discharge information due to IT error. 25 blood spot samples included incorrect NHS number (last 4 digits wrong). Of these 2 required a repeat due to incorrect DoB in one case and due to an NHS number belonging to another baby in the other case.	Pennine Community Midwives
1047802	29/01/15	3	Actual harm (level 2)	Blood spot sample labelled with a handwritten NHS number belonging to another person (other demographic details correct)	Mat Ward, Furness General Hospital
1049870	23/02/15	3	Actual harm (level 2)	Blood spot sample labelled with a NHS number belonging to another person (other demographic details correct) & results reported to CHRD against wrong person. Detected by CHRD before entered on their system.	Pennine Community Midwives & Lab
1050485	11/02/15	4	Actual harm (level 2)	Blood spot sample manually labelled with another baby's demographic details. Baby A: NHS number, name & address; Baby B: DoB, GA, BW, Mum's details.	Ward C2, UHSM