NHS

Screening Programmes

Newborn Blood Spot

Data Collection and Performance Analysis Report

Newborn Blood Spot Screening in the UK 2013-14

Version 1.0 / August 2015

About the NHS Newborn Blood Spot Screening Programme

The NHS Newborn Blood Spot (NBS) Screening Programme screens newborn babies for a number of rare but serious conditions: sickle cell disease (SCD), cystic fibrosis (CF), congenital hypothyroidism (CHT) and six inherited metabolic diseases: phenylketonuria (PKU), medium-chain acyl-CoA dehydrogenase deficiency (MCADD), maple syrup urine disease (MSUD), isovaleric acidaemia (IVA), glutaric aciduria type 1 (GA1) and homocystinuria (pyridoxine unresponsive) (HCU).

Public Health England (PHE) is responsible for the NHS Screening Programmes. PHE is an executive agency of the Department of Health and works to protect and improve the nation's health and wellbeing, and reduce health inequalities.

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Contents

Abbreviations

CCG	clinical commissioning group
CF	cystic fibrosis
CF SPID	cystic fibrosis screen positive, inconclusive diagnosis (equivocal)
CFTR	cystic fibrosis transmembrane conductance regulator
CHIS	child health information system
CHRD	child health records department
CHS	child health service
CHT	congenital hypothyroidism
CPA	Clinical Pathology Accreditation
DAQA	Data Analyst and Quality Assurance
GA1	glutaric aciduria type 1
GOSH	Great Ormond Street Hospital
HB	health board
HCU	homocystinuria
IVA	isovaleric acidaemia
KPI	key performance indicator
MCADD	medium-chain acyl-CoA dehydrogenase deficiency
MSUD	maple syrup urine disease
NHS	National Health Service
PKU	phenylketonuria
RRTG	Routine Reporting Task Group
SCD	sickle cell disease
SE Thames	South East Thames (St. Thomas' Hospital)
SW Thames	South West Thames (St Helier Hospital)
SQAS	Screening Quality Assurance Service
TSH	thyroid stimulating hormone
UK NSC	UK National Screening Committee

Executive summary

This is the tenth annual data report for the UK's newborn blood spot screening programmes. The aim of this report is to feedback performance against the national standards.

Coverage
The Office of National Statistics reported a drop in the birth rate of 4.3% in 2013. This is reflected in the decrease in the number of babies tested 2013-14 compared to previous years.

Every region reached the acceptable level (95%) for completeness of coverage (CCG responsibility at birth). However, when timeliness of coverage is measured at 17 days, not all regions met the achievable level.

Standard 1b introduces an effective timeframe of 21 calendar days for movers in and this data collection was piloted during 2013-14. Although many areas were unable to report due to IT system limitations, this data will be collected from 2014-15.

Declined screening
Decline rates for newborn blood spot screening vary between local areas. Overall, there has been a rise in the rate of declines per 10,000 babies from 5.12 in 2010-11 to 7.93 in 2013-14 (CCG responsibility at birth population).

If a child moves into an area in England with no record of being tested they are offered screening up to one year of age. Babies may have been screened in another country but have no evidence of the results. This accounts for a higher decline rate among movers in.

The blood spot screening programme aims to investigate the root cause for higher levels of declines in 2015-16.

NHS number and barcoded label
Data show an overall increase in the use of the NHS number from 2007 to 2014. Overall, the percentage of samples including a barcoded NHS number label has increased year on year since 2010-11; however, no laboratory reported reaching the achievable standard (95% of blood spot cards received by a laboratory have the baby's NHS number included on a barcoded label).

Timeliness of sample taking and despatch
Maternity services sending their samples to English laboratories met the core standard of 95% or more for first samples taken on days 5-8. Although the percentage of samples received in the laboratory after five working days of blood samples being taken has decreased over the last eight years, there are still some local issues reported where transport is a concern.

Blood spot quality

It has been recognised that there is regional variation in laboratory definitions of an unsuitable sample, causing inequality in rejection of samples. New evidence-based blood spot quality guidelines for the English screening laboratories were implemented in April 2015 with the aim of improving quality of samples and, in turn, the efficiency of the screening pathway.

Failsafe

Stage 1 of the Newborn Blood Spot Failsafe Solution (NBSFS) is now fully implemented across all English providers of maternity services. This means all babies born in England will be identified if they have not been screened. In future, the NBSFS will capture timely taking of a repeat blood spot sample; therefore data on standard 7 (timely taking of a repeat blood spot sample) will be available.

Conditions

The maximum age at appointment for PKU was 22 days for England and 10 days for Northern Ireland (excluding two babies who moved into the country after birth and were tested late).

Variation persists in compliance with the national borderline cut off level for CHT. In England, an additional 828 babies had a borderline result on the first sample due to lower cut off levels in six laboratories.

Incomplete outcome data for MCADD made it difficult to populate the screening and diagnostic algorithm (Figure 24). Data on age at first appointment is outstanding for some babies in England, and there are still babies not meeting the 17 day appointment standard in England and Scotland.

The CF screening protocols are performing appropriately and numbers of babies with CF suspected and CF carrier results have been consistent over the last five years.

Data on SCD is available in the NHS Sickle Cell and Thalassaemia Screening Programme's annual report at www.gov.uk/government/publications/sickle-cell-and-thalassaemia-screening-data-trends-and-performance-analysis.

1. Introduction

One of the objectives of the NHS Newborn Blood Spot Screening Programme (previously the UK Newborn Screening Programme Centre) is to set national standards for newborn blood spot screening. National standards are important to support the delivery and quality assurance of a high quality screening programme and are used by local commissioners and quality improvement groups. The aims of this report are to feedback the performance against the national standards, to share lessons learned from incidents, and to highlight:

- Completeness and accuracy of data returns
- Where improvements have been made
- Where standards are not being achieved and where there is variability in practice
- Risks to the newborn blood spot screening programme
- Key recommendations for quality improvements in newborn blood spot screening
- Progress on quality improvement projects

Providers, commissioners and the Screening Quality Assurance Service (SQAS) are encouraged to review this document to identify areas for improvement locally.

1.1 Background

The UK National Screening Committee (UK NSC) recommends that all babies in the UK are offered screening for nine rare disorders: sickle cell disease (SCD), cystic fibrosis (CF), congenital hypothyroidism (CHT), phenylketonuria (PKU), medium-chain acyl-CoA dehydrogenase deficiency (MCADD), maple syrup urine disease (MSUD), isovaleric acidaemia (IVA), glutaric aciduria type 1 (GA1) and homocystinuria (pyridoxine unresponsive) (HCU).

All four UK countries screen for SCD, CF, CHT, PKU and MCADD, and England and Wales began screening for MSUD, IVA, GA1 and HCU in January 2015. This update presents 2013-14 data on SCD, CF, CHT, PKU and MCADD only.

Table 1. Incidence of each condition in the UK

Conditions	Incidence based on research prior to the introduction of the national screening programmes	Incidence of screen positive cases based on 5 years of UK screening data 2008-14
Sickle cell disease (SCD)	1:2,000	1:2,000
Cystic fibrosis (CF)	1:2,500	1:2,500
Congenital hypothyroidism (CHT)	1:3,000	1:1,500
Phenylketonuria (PKU)	1:10,000	1:8,000
Medium-chain acyl-CoA dehydrogenase deficiency (MCADD)	1:10,000	1:9,800

The overall goal is to prevent ill health, disability and death through early diagnosis and effective intervention. Population coverage is a key objective of the programme.

Note that a significant proportion of screen positive cases will not be confirmed cases.

1.2 The screening standards (2013)

Standard	Reporting responsibility
Standard 1a: Completeness of coverage (CCG responsibility at birth)	Reported by child health records department (CHRD)
Standard 1b: Completeness of coverage (movers in)	Reported by CHRD
Standard 2: Timely identification of babies with a null or incomplete result recorded on the child health information system	Reported by CHRD
Standard 3: Baby's NHS number (or UK equivalent) is included on the blood spot card	Reported by newborn screening laboratory
Standard 4: Timely sample collection	Reported by newborn screening laboratory
Standard 5: Timely receipt of a sample in the newborn screening laboratory	Reported by newborn screening laboratory
Standard 6: Quality of the blood spot sample	Reported by newborn screening laboratory
Standard 7: Timely taking of a repeat blood spot sample	Not currently collected
Standard 8: CPA (screening)	Not included
Standard 9: Timely processing of all PKU, CHT and MCADD screen positive samples	Reported by newborn screening laboratory
Standard 10: CPA (diagnosis)	Not included
Standard 11: Timely receipt into clinical care	Reported by newborn screening laboratory
Standard 12: Timeliness of results to parents	Currently reported through key performance indicators (KPIs) to the UK NSC. Will be included from 2015-16

For more information on these standards please see: www.gov.uk/government/collections/newborn-blood-spot-screening-programme-standards-and-data.

1.3 Methodology

The data collection and performance analysis dictionary is the definitive tool to guide data collection and provides definitions of the terms used and of data to be collected. Data are collected using Microsoft Excel spreadsheets; these documents are accessible from www.gov.uk/government/collections/newborn-blood-spot-screening-programme-standards-and-data. The spreadsheets must be downloaded, completed and returned to the NHS Newborn Blood Spot Screening Programme by email.

With the intention of improving clarity of definitions, completeness and accuracy of data, and to keep up to date with changes in the programme, the definitions, methods and tools are reviewed annually and amended if required. This review is undertaken in collaboration with our stakeholders and was part of the UK NSC Routine Reporting Task Group (RRTG). The RRTG has now been replaced with the Data Analyst and Quality Assurance (DAQA) group which meets monthly to monitor all data-related issues for the screening programmes.

Data are collected annually for the previous fiscal year. Aggregate data are collected to measure performance against the standards; data is grouped by CCG/CHS/HB or laboratory catchment area.

Diagnostic outcome data are also returned by the laboratories. These data are collected at individual baby level and are anonymous. Newborn screening laboratories inform the designated paediatrician directly when a baby is suspected of having one of the conditions and request diagnostic outcome data on each baby. The laboratories hold the information on screen positive babies within their catchment area and are the logical place to capture follow-up and outcome data. Laboratories experience various difficulties in collecting this data, and as a result information is not always complete. This gap in the data means that the newborn blood spot programme cannot be evaluated fully.

2. Analysis and report of screening performance

2.1 Laboratory denominator statistics

Table 2. Conditions tested during 2013-14 or date of implementation

Country	PKU, CHT and CF	SCD	MCADD
England	✓	✓	✓
Northern Ireland	✓	✓	✓
Scotland	✓	✓	✓
Wales	✓	June 2013	✓

2.1.1 Number of babies tested for each condition

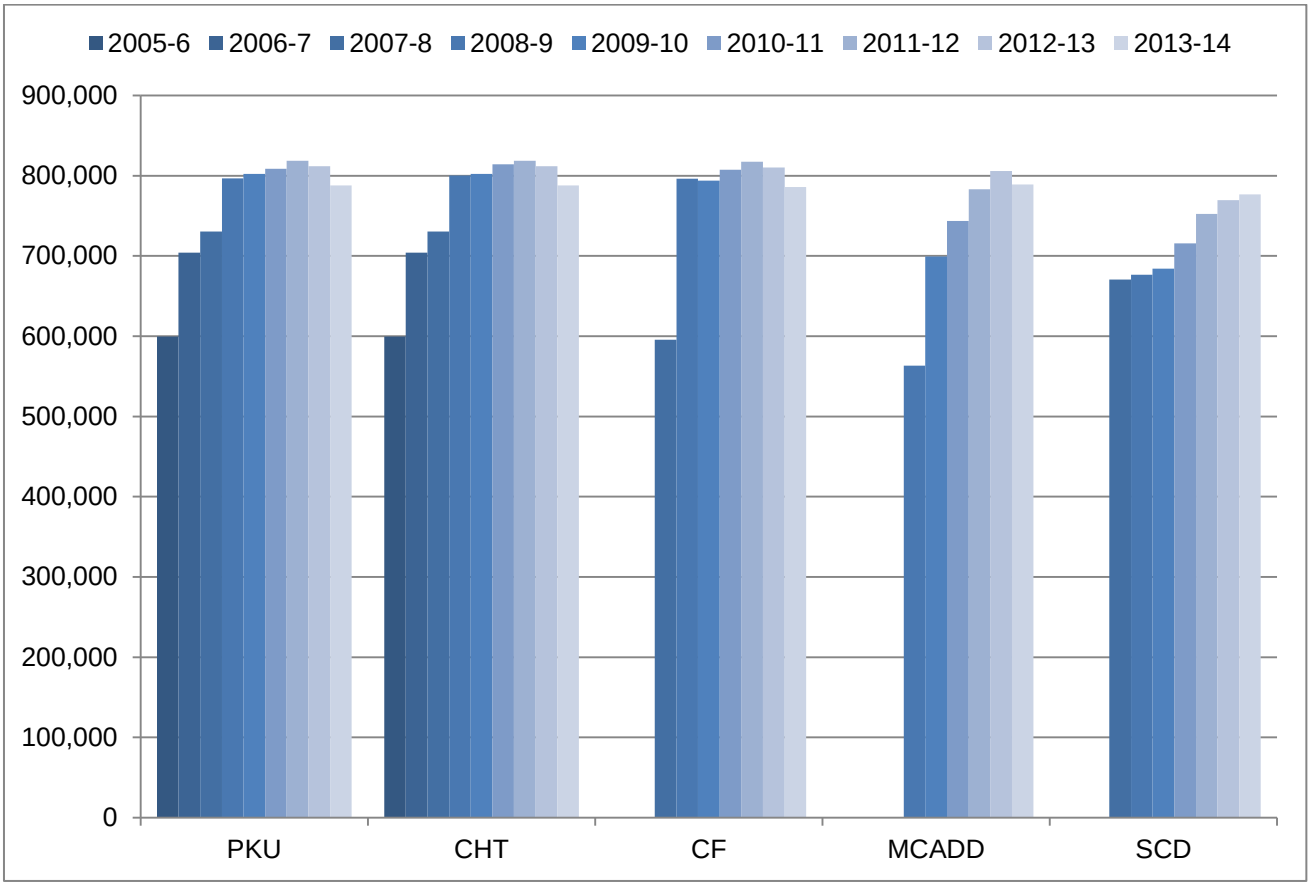
Table 3. Number of babies tested and number of screen positive results for each condition 2013-14

Laboratory	Number of babies tested for PKU	Number of screen positives for PKU	Number of babies tested for CHT	Number of screen positives for CHT	Number of babies tested for CF	Number of screen positives for CF	Number of babies tested for MCADD	Number of screen positives for MCADD	Number of babies tested for SCD	Number of screen positives for SCD
Bristol	41,041	5	41,041	18	41,041	20	41,041	3	41,009	4
Cambridge	27,675	3	27,675	16	27,675	13	27,675	5	27,675	0
GOSH	122,157	5	122,157	153	122,157	32	122,157	10	119,911	99
Leeds	44,582	2	44,582	35	44,582	16	44,582	9	42,885	9
Liverpool	29,370	3	29,370	31	28,148	18	28,148	4	27,827	6
Manchester	55,800	9	55,800	37	55,603	21	55,800	5	55,640	13
Newcastle	33,801	3	33,801	28	33,801	18	33,801	5	34,067	2
Oxford	28,470	2	28,470	18	28,324	8	28,470	4	28,257	17
Portsmouth	37,845	2	37,750	26	37,190	13	37,846	3	37,189	5
SE Thames	56,706	5	56,706	33	56,728	10	56,706	3	56,706	86
Sheffield	72,807	7	72,807	44	72,797	26	72,807	9	72,807	20
SW Thames	51,922	3	51,922	17	51,922	18	51,922	4	52,992	38

West Midlands	71,152	5	71,152	60	71,152	25	71,152	5	71,152	20
England	673,328	54	673,233	516	671,120	238	672,107	69	668,117	319
Northern Ireland	24,345	7	24,345	21	24,241	15	24,345	5	24,322	1
Scotland	56,261	9	56,260	26	56,722	23	58,850	2	56,256	14
Wales	33,859	2	33,859	24	33,663	3	33,859	5	27,828	3
UK Total	787,793	72	787,697	587	785,746	279	789,161	81	776,523	337

We would normally expect to see a lower number of babies tested for CF as samples taken when a baby is aged 8 weeks or more should not be tested for this condition.

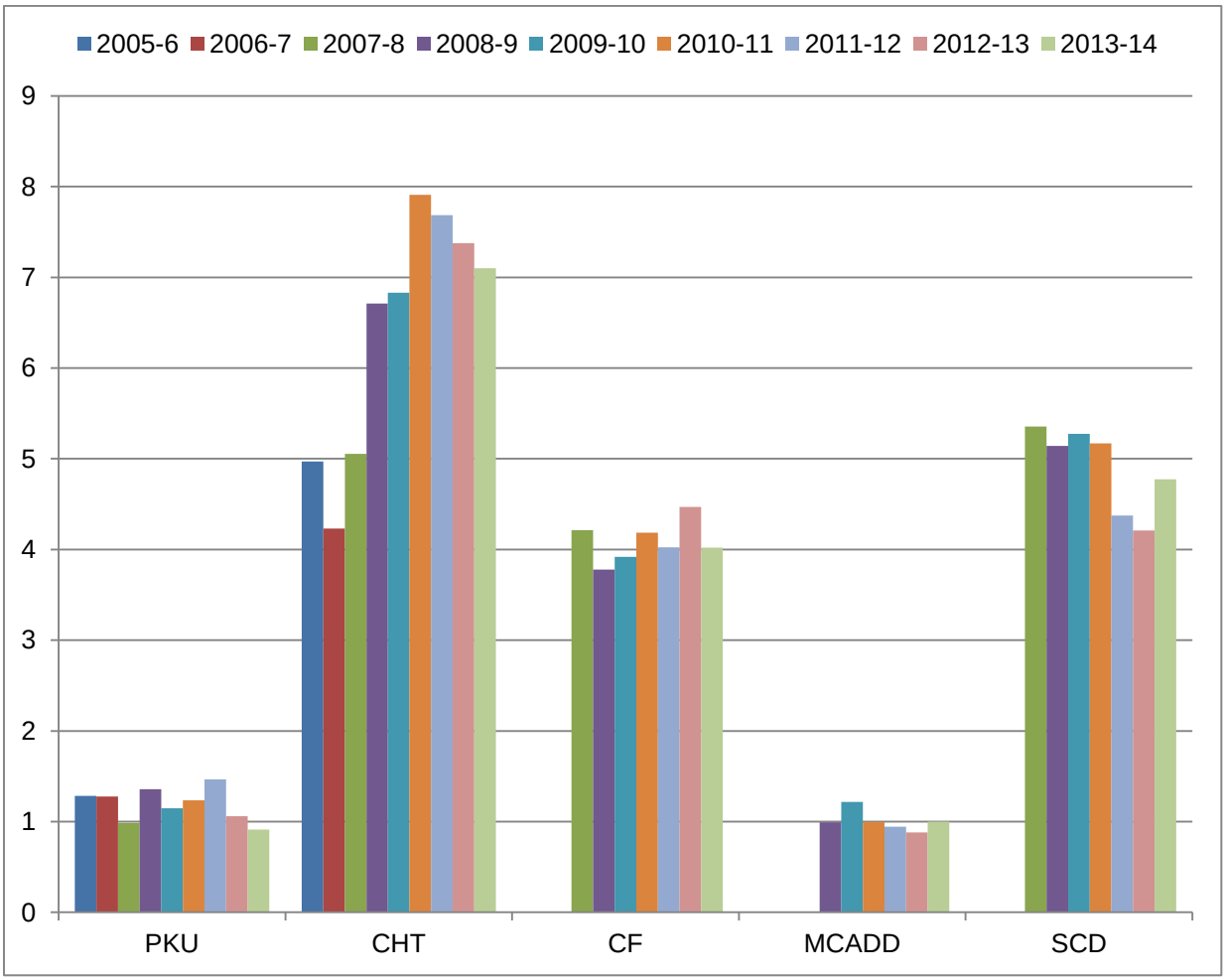
Figure 1. Number of UK babies reported as screened for each condition 2005-14



Prior to 2007-8 only England, Northern Ireland and Wales returned data on numbers of babies screened for each condition. Scotland first returned data in 2008-9 and full UK data for all laboratories has been returned since 2008-9. This accounts for the large increase in numbers tested between 2005 and 2008. In addition, the staggered implementation and rollout of new screening tests described in Table 2 affect the rates shown in Figure 2.

The Office of National Statistics reported a drop in birth rate of 4.3% in 2013 which is reflected in the decrease in number of babies tested 2013-14 compared to previous years.

Figure 2. Rate of UK babies screened positive for each condition 2005-14 (per ten thousand)



2.2 Standard 1a: Completeness of coverage (CCG responsibility at birth)

Description

The proportion of babies for whom the CCG/CHS area is responsible, at birth and at the time of the report, who are eligible for newborn blood spot screening and have a conclusive test result recorded on the CHIS for PKU, CHT, SCD, CF and MCADD by 17 days of age.

Acceptable level: ≥ 95.0% all tests
Achievable level: ≥ 99.9% PKU, MCADD, SCD
Achievable level: ≥ 98% CF, CHT

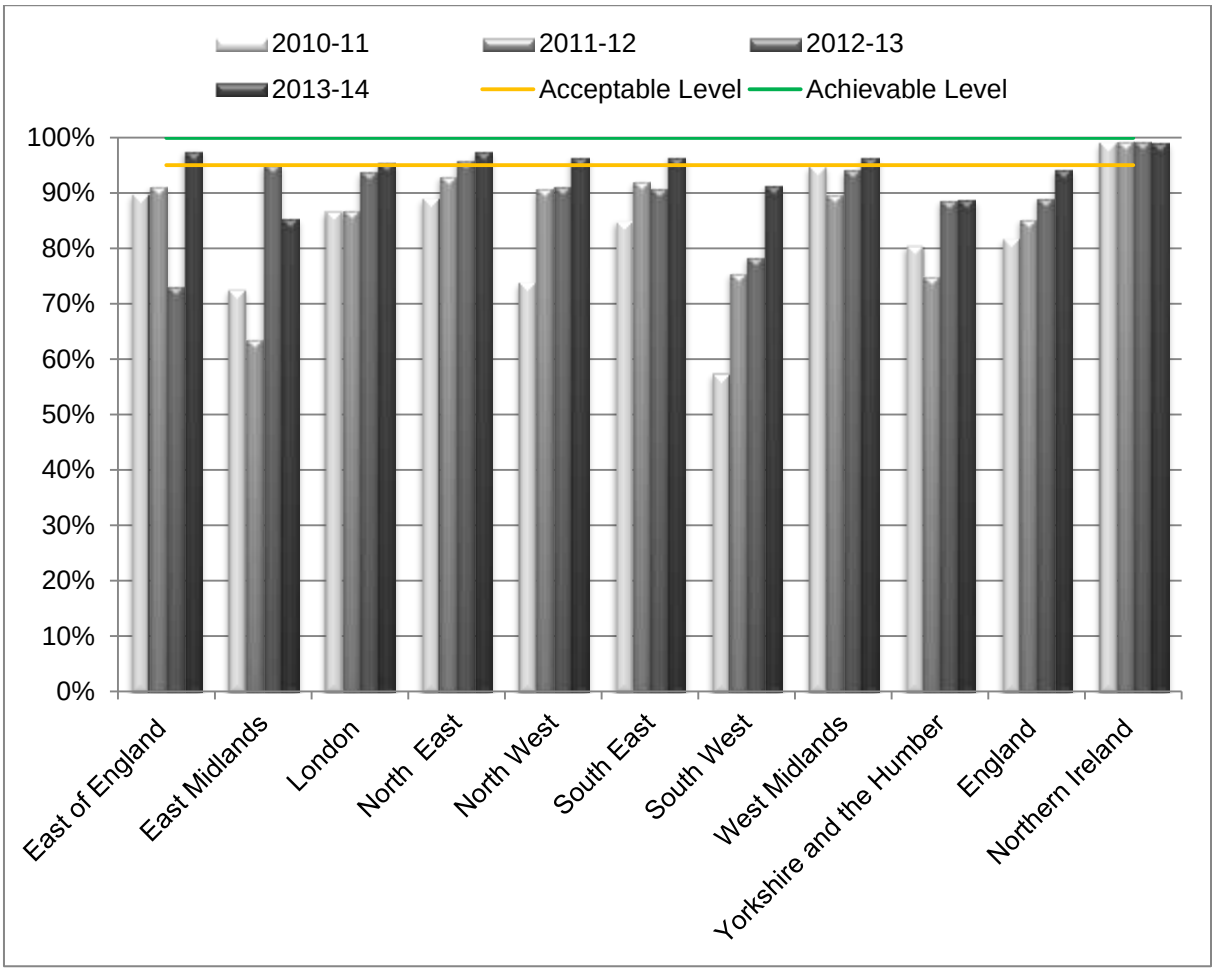
Coverage is measured at the time of the report (there is a two month period allowed for data return) and at 17 days of age. CCGs that did not return data on percentage tested by 17 days are excluded.

Table 4. Completeness of coverage for PKU, in babies for whom the CCG/CHS area was responsible for at birth and at the time of the report 2013-14

Region/ country	Regional total number of babies the CCG/country is responsible for at birth and remain responsible for on the last day of the reporting period	Number of babies tested (status codes 04,05,06,07,08, 10)	Number of babies tested and recorded on the child health system at 17 days	% of babies tested (status codes 04,05,06,07,08,10)	% of babies tested and recorded on the child health system at 17 days
East of England	57,796	56,979	56,408	98.60%	97.60%
East Midlands	47,461	47,246	40,497	99.50%	85.30%
London	98,291	96,413	93,874	98.10%	95.50%
North East	26,967	26,960	26,293	97.97%	97.50%
North West	62,772	62,622	60,588	99.80%	96.50%
South East	97,205	96,641	93,803	99.40%	96.50%
South West	53,688	53,357	49,017	99.40%	91.30%
West Midlands	62,701	61,736	60,436	98.50%	96.40%
Yorkshire and Humber	58,388	58,338	51,871	99.90%	88.80%
England	565,269	560,292	532,787	99.12%	94.25%
Northern Ireland	23,708	23,695	23,503	99.90%	99.10%

Data for the South East region have previously been split into South Central and South East Coast. The data for 2013-14 are the total of these two regions added together.

Figure 3. Completeness of coverage for PKU, in babies for whom the CCG/CHS area was responsible for at birth and at the time of report 2010-14 (measured at 17 days)



2.3 Standard 1b: Completeness of coverage (movers in)

Description

The proportion of babies who 'move in' and become the responsibility of the CCG during the reporting period and for whom the CCG/CHS remains responsible on the last day of the reporting period, who are eligible for newborn blood spot screening and have a conclusive test result recorded on the CHIS for PKU, CHT, SCD, CF and MCADD equal to or less than 21 calendar days of movement in being recorded on the child health information system

Acceptable level: ≥ 95% of eligible babies are tested for PKU
Achievable level: ≥ 99.9% of eligible babies are tested for PKU

From 2010-2014 data has been collected to measure the number of 'mover in' babies tested, without applying an effective timeframe. Standard 1b introduces an effective timeframe of 21 calendar days and this data collection was piloted during 2013-14. Although many areas were unable to report due to IT system limitations, the data will be collected from 2014-15.

Table 5. Completeness of coverage for PKU, in babies who moved into the CCG/CHS area under one year of age and who were the responsibility of the CCG/CHS area on the day of the report 2013-14

Region/ country	Regional total number of 'movers in' up to one year of age for whom the CCG/country is responsible for on the last day of the reporting period	Number of babies tested (status codes 04,05,06,07,08,10)	% of babies tested (status codes 04,05,06,07,08,10)
East of England	3,940	3,639	92.4%
East Midlands	1,463	1,323	90.4%
London	8,310	7,506	90.3%
North East	1,305	1,222	93.6%
North West	2,311	2,005	86.8%
South East	4,208	3,737	88.8%
South West	1,482	1,183	79.8%
West Midlands	2,196	1,521	92.0%
Yorkshire and Humber	4,051	3,866	95.4%
England	5,403	4,962	91.8%
Northern Ireland	356	292	82.0%

Data for the South East region have previously been split into South Central and South East Coast. The data for 2013-14 are the total of these two regions added together.

Figure 4. Completeness of coverage for PKU, in babies who moved into the CCG/CHS area under one year of age and who were the responsibility of the CCG/CHS area on the day of the report 2010-2014

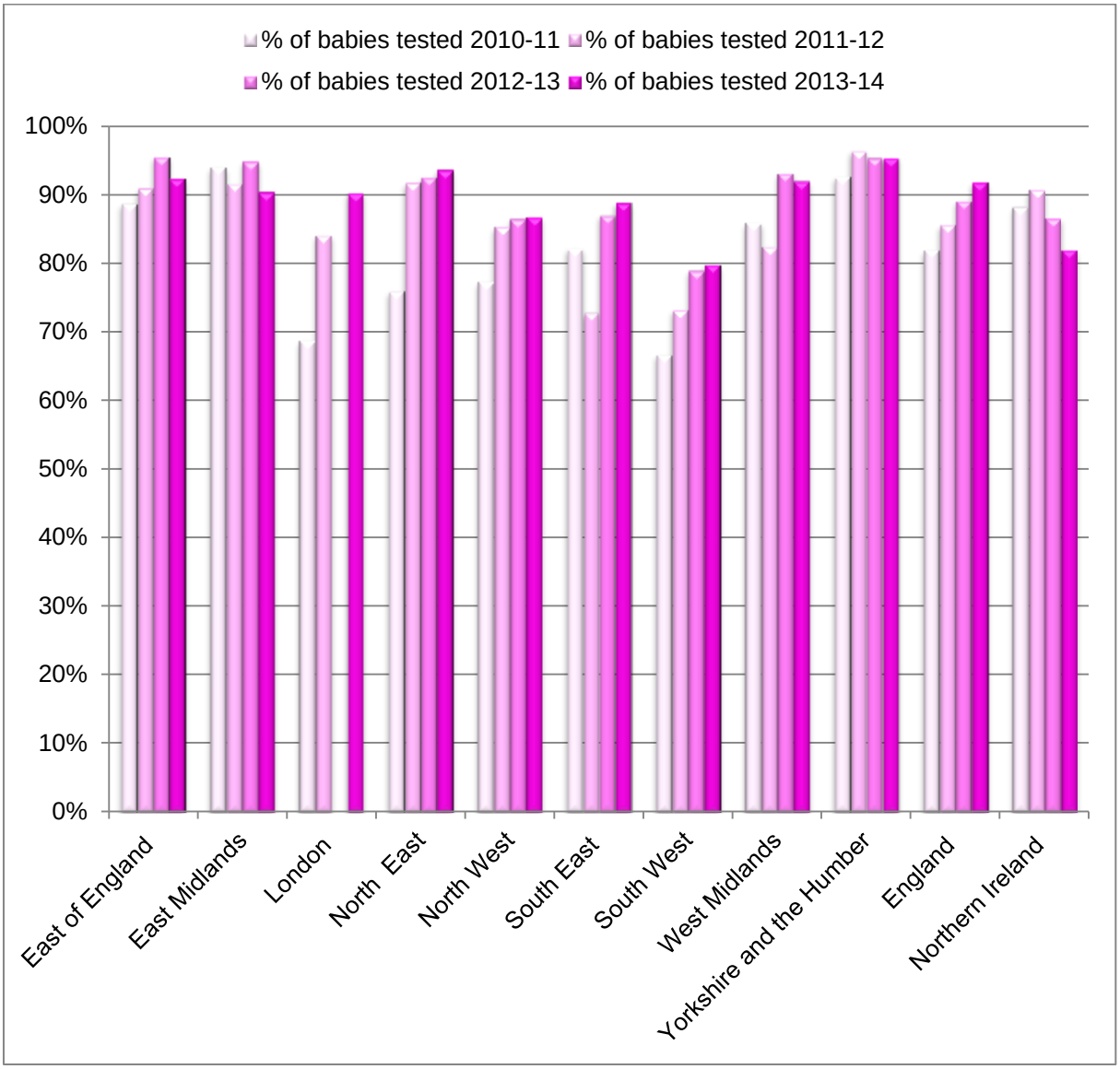


Table 6. CHRD process data

Region	Number of CHRDs that receive newborn screening results with the screening status codes	Number of CHRDs who record results using status codes	Number of CHRDs who receive results by hard copy	Number of CHRDs who receive results by email	Number of CHRDs who receive results by electronic messaging	Number of CHRDs who send letters direct to parents when 04 is reported on all 5 conditions	Total responses
East Midlands	20	20	10	10	11	7	20
East of England	6	7	6	6	1	6	8
London	26	26	10	24	2	19	26
North East	12	12	12	0	0	12	12
North West	21	20	20	21	3	7	21
South East	32	32	27	28	13	8	32
South West	12	12	12	10	1	9	12
West Midlands	20	20	3	0	20	15	20
Yorkshire and Humber	21	21	6	10	13	19	21
England	170	170	106	109	64	102	172
Northern Ireland	4	4	4	0	0	0	4

Figure 5. Percentage of CHRDs who received results by hard copy, email and electronic messaging

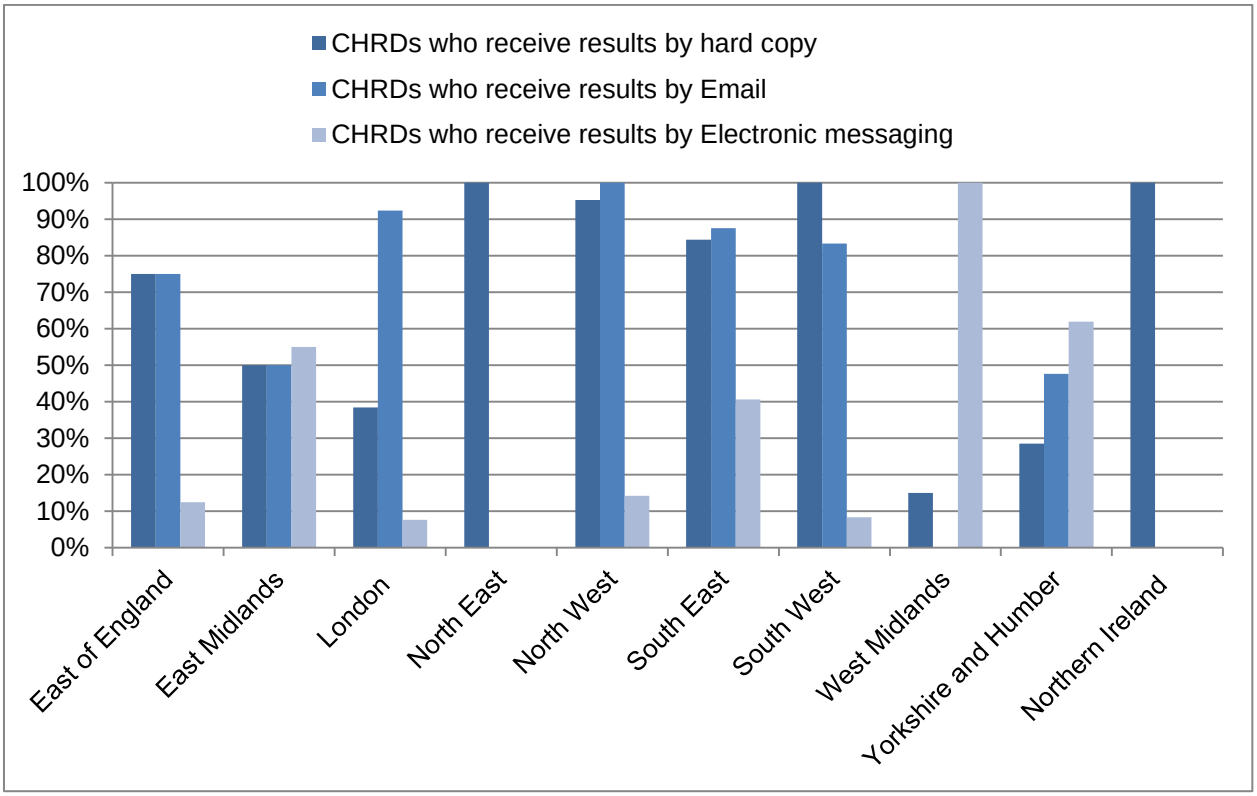


Table 7. Number and rate of declines using PKU as a close approximation for all conditions 2013-14 (CCG responsibility at birth)

Region/country	Regional total number of babies the CCG/ country is responsible for at birth and remains responsible for on the last day of the reporting period	Number of babies declined (status code 02)	Rate of decline per 10,000 babies PKU 2013-14
East Midlands	47,461	39	8.22
East of England	57,796	45	7.79
London	98,291	145	14.75
North East	26,967	2	0.74
North West	62,772	41	6.53
South East	97,205	71	7.30
South West	53,688	54	10.06
West Midlands	62,701	26	4.15
Yorkshire and Humber	58,388	25	4.28
England	565,269	448	7.93
Northern Ireland	23,708	12	5.06
Scotland	56,261	38	6.75
Wales	33,910	19	5.60

Decline rates vary between local areas. The blood spot screening programme aims to investigate the root cause for higher levels of declines in 2015-16.

Figure 6. Rate of declines per 10,000 babies using PKU as a close approximation for all conditions 2010- 2014 (CCG responsibility at birth)

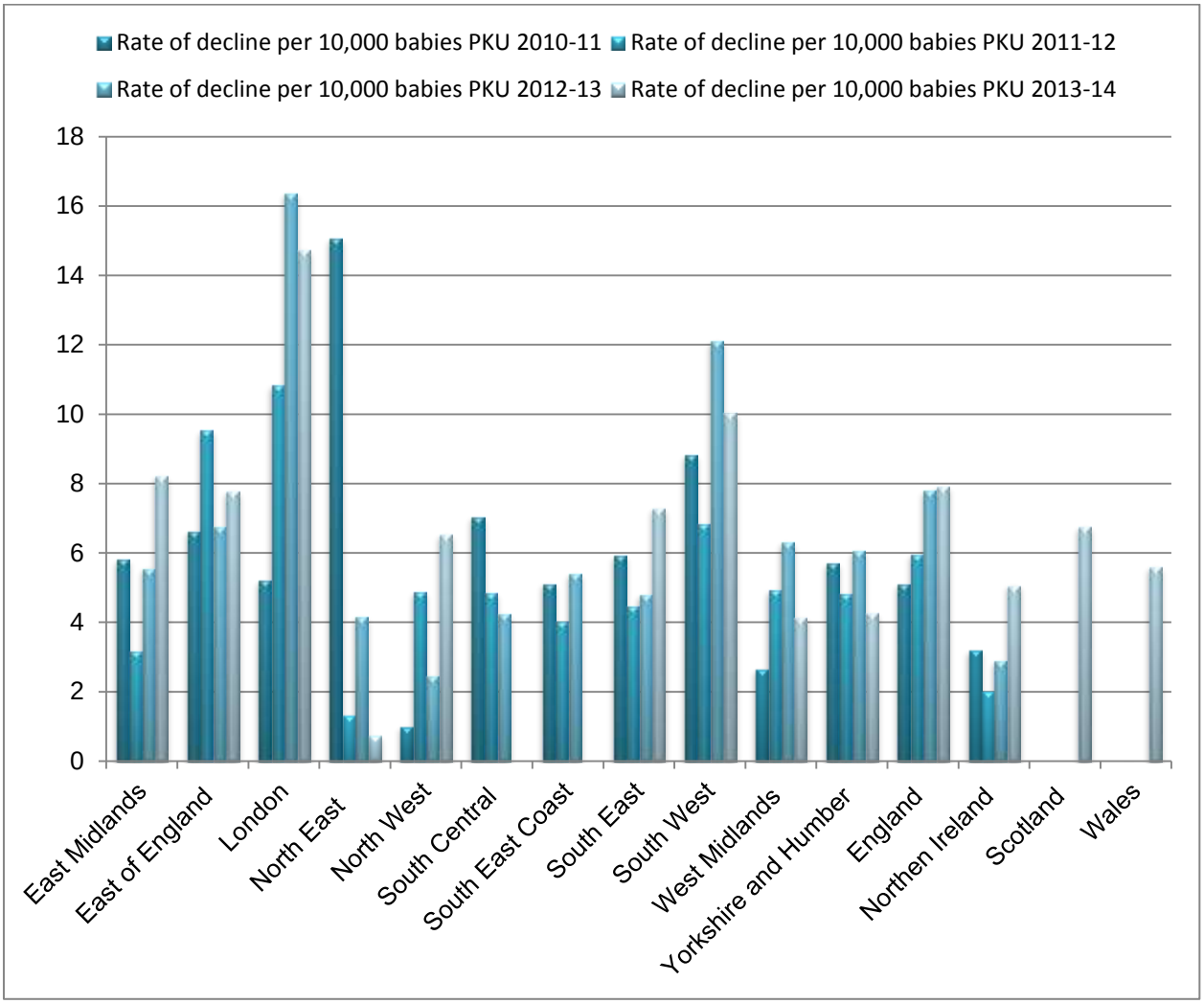
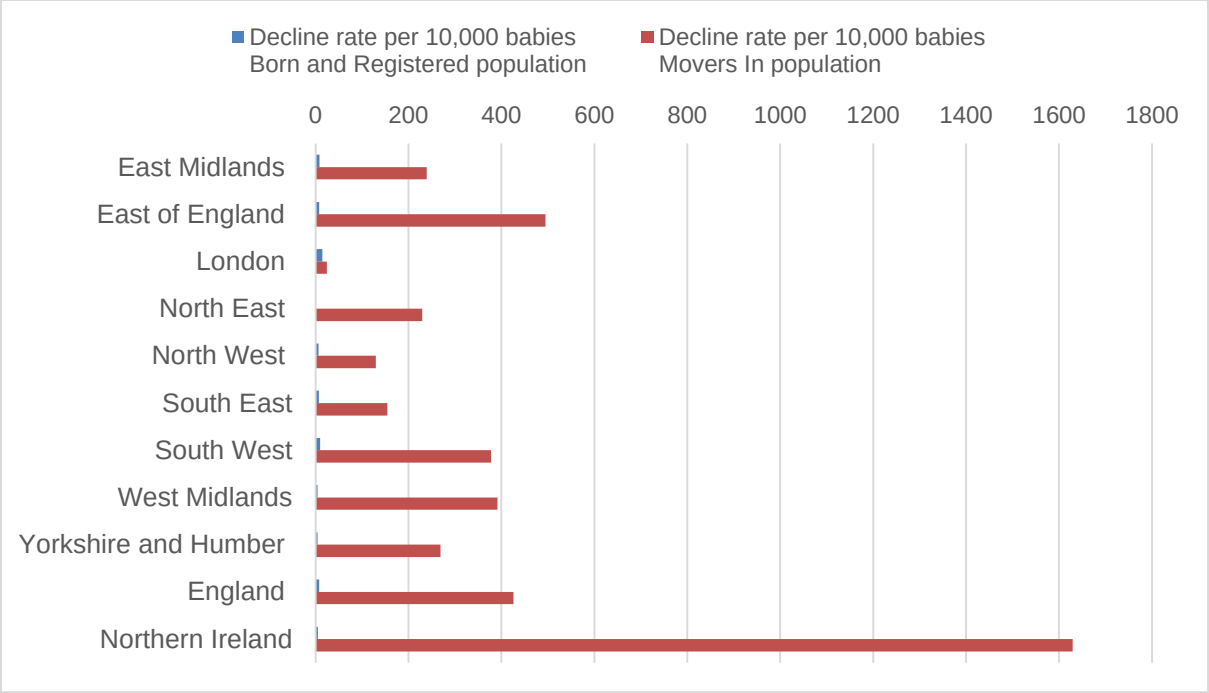


Figure 7. Rate of declines per 10,000 babies using PKU as a close approximation for all conditions, 2013-14, split between 'Born and Registered' and 'Mover In' populations



Northern Ireland has a failsafe which identifies movers in under 1 year of age and offers screening to all movers in from outside the UK and also those who move in from other UK countries, where there is no documented evidence of completed screening. Similarly in England if a child moves into an area with no record of being tested they are offered screening up to one year of age. This accounts for a higher decline rate among movers in.

2.4 Standard 2: Timely identification of babies with a null or incomplete result recorded on the child health information system

Description

CHRDs perform regular checks for a null or incomplete result and initiate fast track, follow-up arrangements.

Acceptable level

100% of child health records departments perform regular checks (ideally daily, minimum weekly) to identify babies with null values or status codes 01 specimen received in laboratory or 03 repeat/further sample required, for any of the five conditions, for all babies equal to or more than 17 days and equal to or less than 364 days.

Achievable level

100% of child health records departments perform regular checks (ideally daily, minimum weekly) to identify babies with null values or status codes 01 specimen received in laboratory or 03 repeat/further sample required, for any of the five conditions, for all babies equal to or more than 14 days and equal to or less than 364 days.

CHRDs are relied upon to provide a failsafe to ensure all eligible babies are offered screening and that those whose parents accept screening are actually tested and have a conclusive result. To achieve this, CHRDs must maintain a list of the eligible babies and check their CHIS for a null or inconclusive result for any of the five tests. If screening is found to be incomplete CHRDs initiate follow-up arrangements to ensure parents are offered the screening test and babies are tested and have a conclusive result as soon as possible.

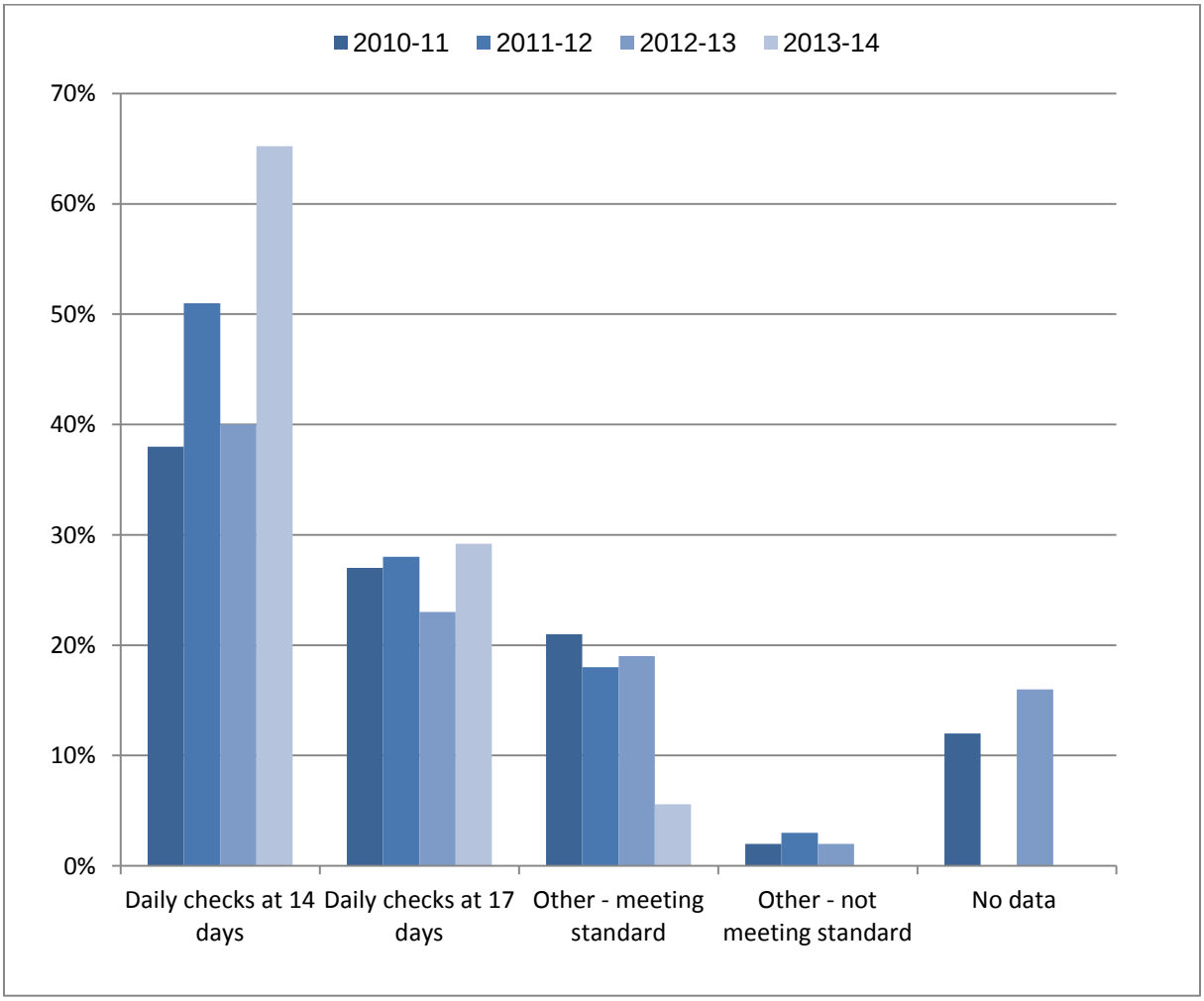
CHRDs were asked if they performed daily checks at 17 days and 14 days. Table 8 shows by region the number of data returns, the proportion of these CHRDs that perform checks and whether the checks meet the standard.

Table 8. Number of CHRDs that search for missing results on day 17, day 14 and 'other' 2013-14

Region/country	CHRDs/CHS areas that responded	Daily check at 14 days	Daily check at 17 days	Other - meeting standard
East of England	26	19	7	
East Midlands	7	3	4	
London	20	12	7	1
North East	13	11		2
North West	20	9	11	

South East	30	27		3
South West	12	8		4
West Midlands	20	5	15	
Yorkshire and the Humber	13	11		2
England	161	105	44	12
Northern Ireland	4			4

Figure 8. Percentage of CHRDs that search for missing results on day 17, day 14 and 'other' 2010-14



2.5 Standard 3: Baby's NHS number (or UK equivalent) is included on the blood spot card

Description

This standard is intended to ensure use of the baby's NHS number (or UK equivalent) throughout the newborn screening process. The NHS number is a unique identifier that will aid the identification and tracking of babies as they progress through the screening pathway. Since April 2010 it has been mandatory for the NHS number to be used in England, ideally in a bar-coded label with an eye-readable NHS number.

Acceptable level

100% of blood spot cards received by a laboratory include the baby's NHS number.

Achievable level

95% of blood spot cards received by a laboratory have the baby's NHS number included on a bar-coded label.

A breakdown of performance for each laboratory catchment area is shown in Table 9 and Figure 9 shows an overall increase in the use of the NHS number from 2007 to 2014.

Table 9. Number of blood spot cards including the baby's NHS number (or UK country equivalent) 2013-14

Laboratory	Number of all samples (including repeats)	Number of blood spot cards including babies' NHS number (or UK country equivalent)	Percentage of all blood spot cards including babies' NHS number or (UK country equivalent)
Bristol	45,473	45,446	99.9%
Cambridge	27,685	27,644	99.9%
GOSH	128,179	127,690	99.6%
Leeds	46,876	45,287	96.6%
Liverpool	25,222	25,094	99.5%
Manchester	58,965	58,684	99.5%
Newcastle	35,872	35,740	99.6%
Oxford	30,528	30,506	99.9%
Portsmouth	38,998	38,321	98.3%
SE Thames	60,285	59,991	99.5%
Sheffield	77,021	76,680	99.6%
SW Thames	52,918	52,818	99.8%
West Midlands	76,809	76,596	99.7%
England	704,831	700,497	99.4%
Scotland	59,413	58,370	98.2%
Wales	33,910	33,316	98.2%

The Health + Care number (Northern Ireland equivalent to NHS number) is currently recorded on blood spot cards and plans are underway for the regional screening laboratory to routinely capture and report on the use of the number.

Figure 9. Percentage of all blood spot cards including the baby's NHS number (or UK country equivalent) 2007-14 (please note the Y axis does not begin at zero)

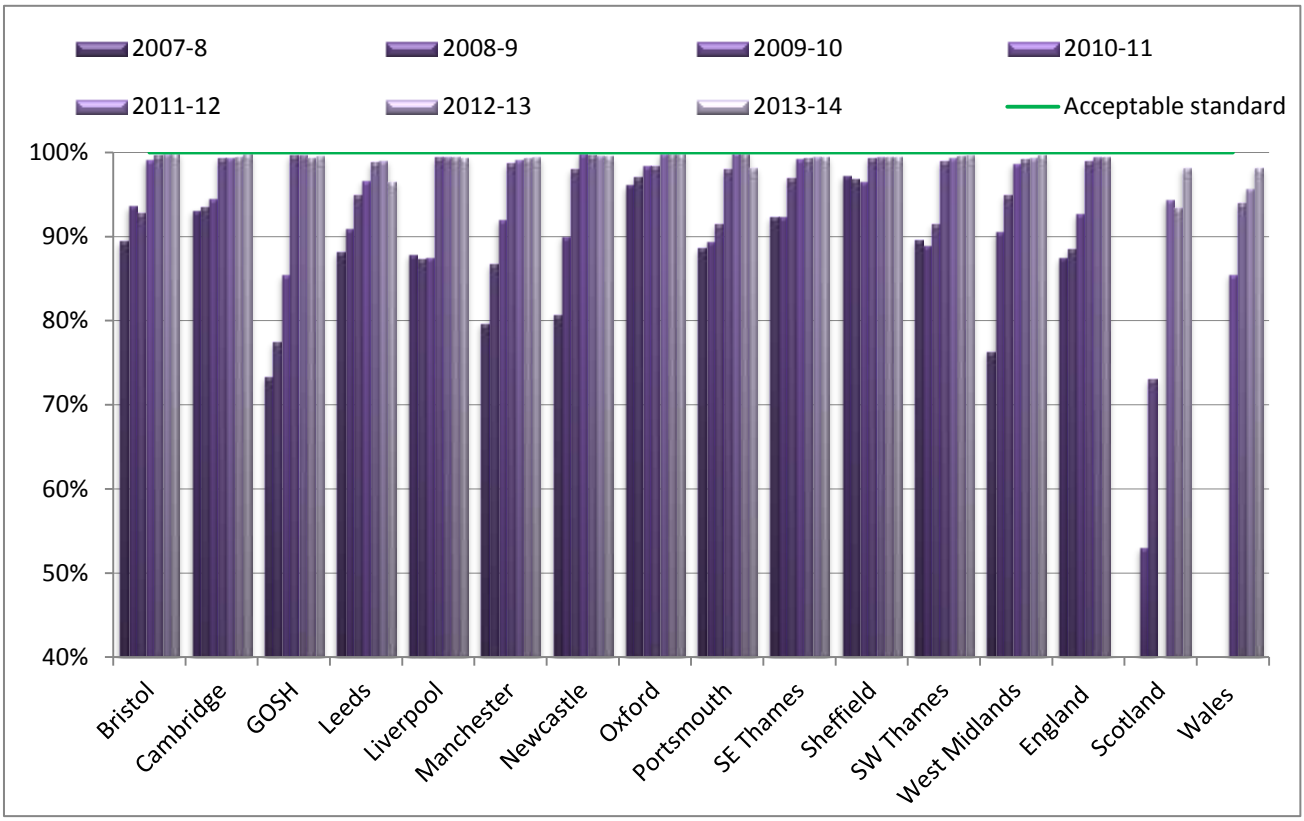


Figure 10. CCG/CHS area returning the lowest, average and highest percentage of samples including NHS number (or UK country equivalent) 2013-14 (please note the Y axis does not begin at zero)

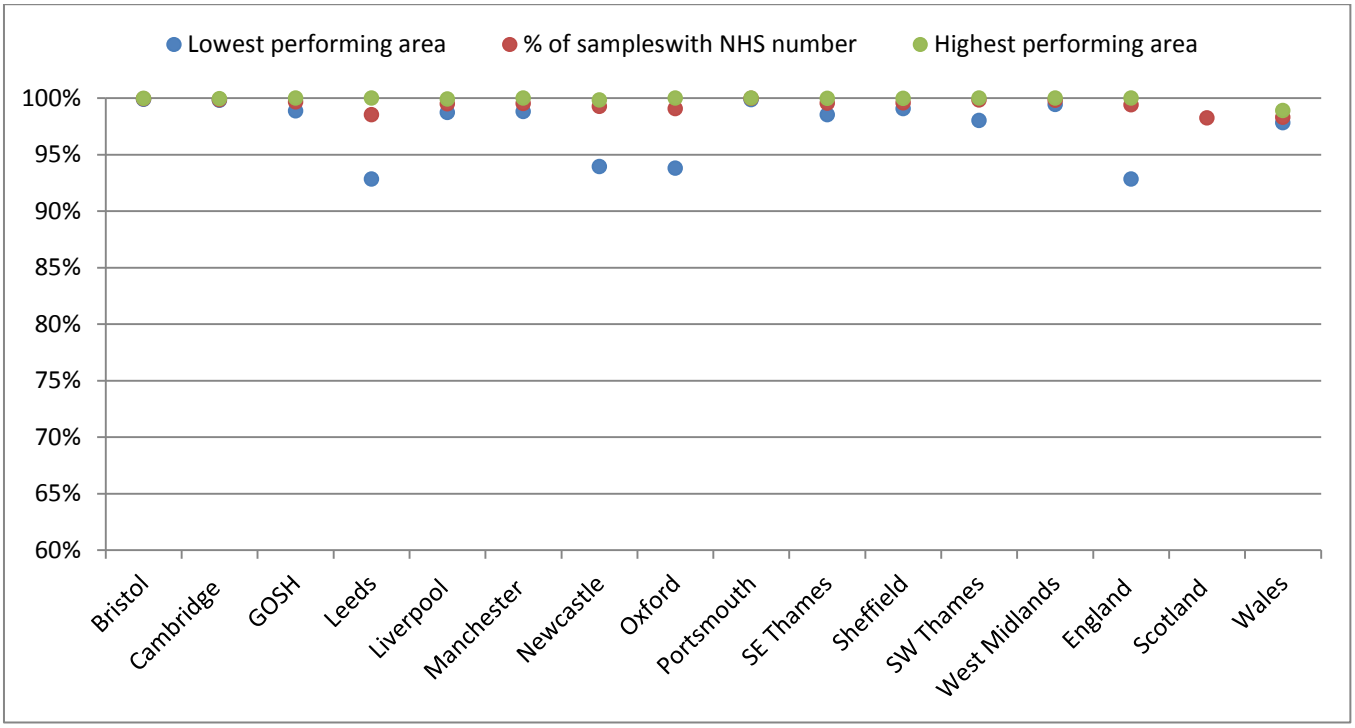
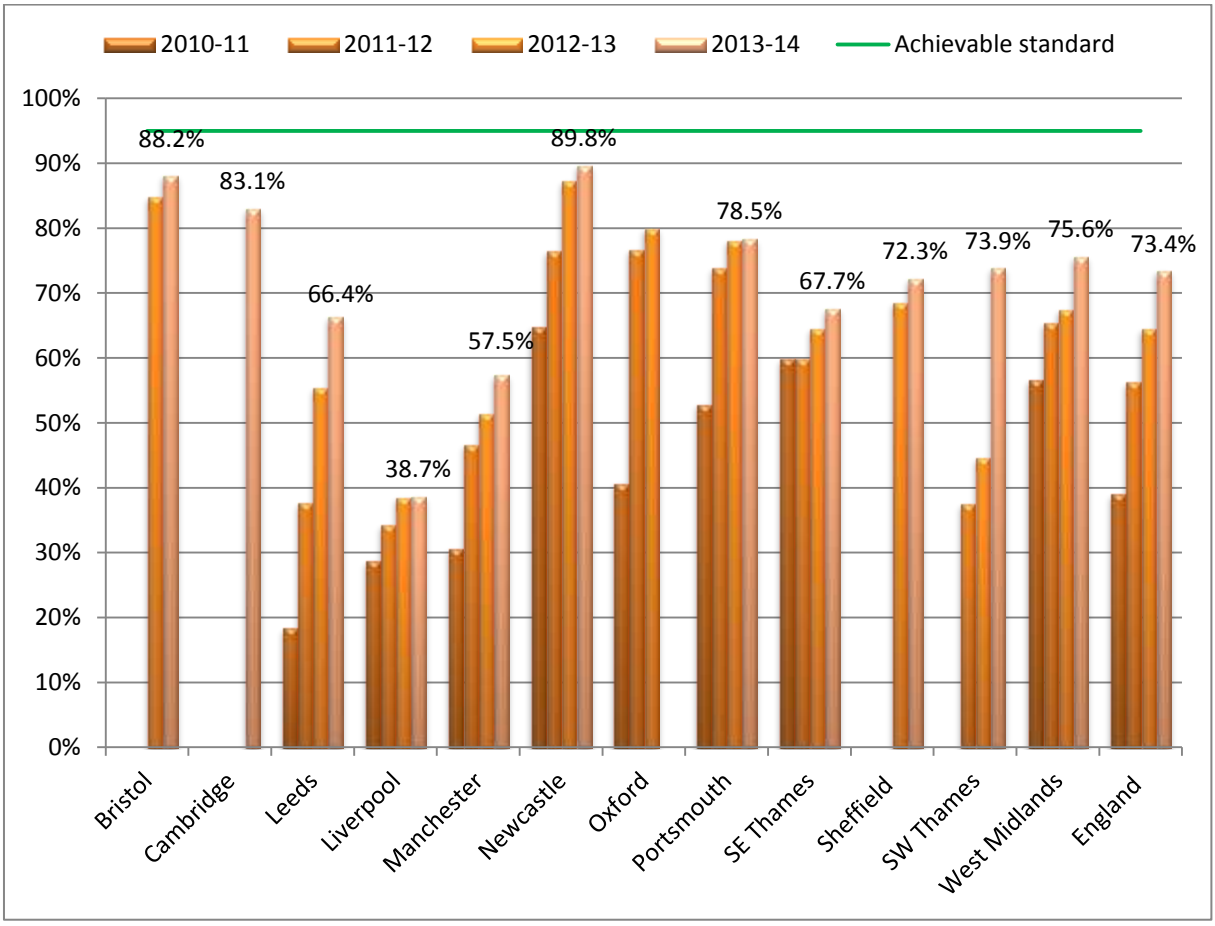


Figure 11. Percentage of samples including a barcoded NHS number label 2010-14



Overall percentage of samples including a barcoded NHS number label has increased year on year since 2010-11; however, no laboratory reported reaching the achievable standard. GOSH and Oxford are currently unable to report usage of the barcoded label due to IT limitations.

For more information see www.gov.uk/government/publications/barcode-labels-quality-assurance-in-newborn-blood-spot-screening.

2.6 Standard 4: Timely sample collection

Description

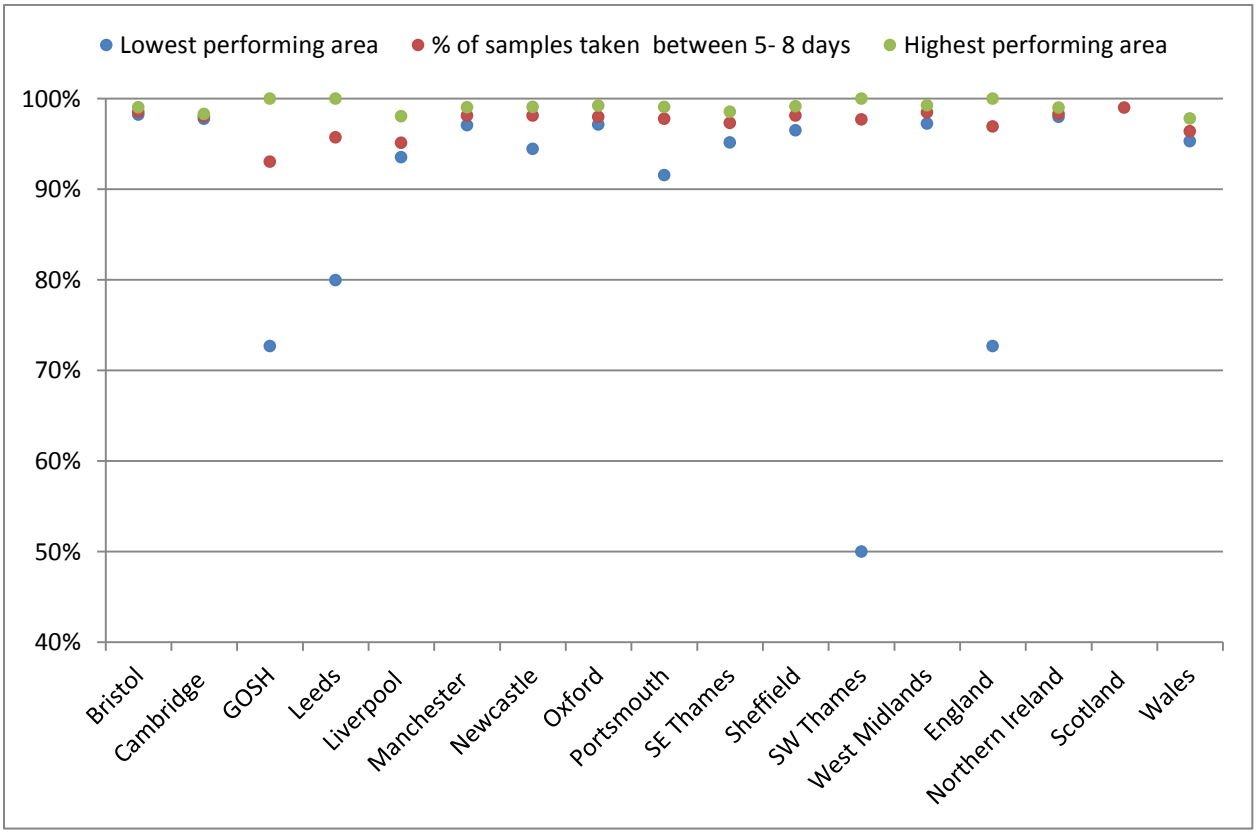
It is essential to take the blood spot sample promptly to give each screen positive baby the best possible chance of receiving early treatment. The health professional responsible for taking the blood sample should adhere to the guidelines for newborn blood spot sampling to ensure a valid sample is taken.

Acceptable level: Equal to or greater than 95% of first samples taken on days 5-8 (ideally on day 5).

Achievable level: Equal to or greater than 99% of first samples taken on days 5-8 (ideally on day 5).

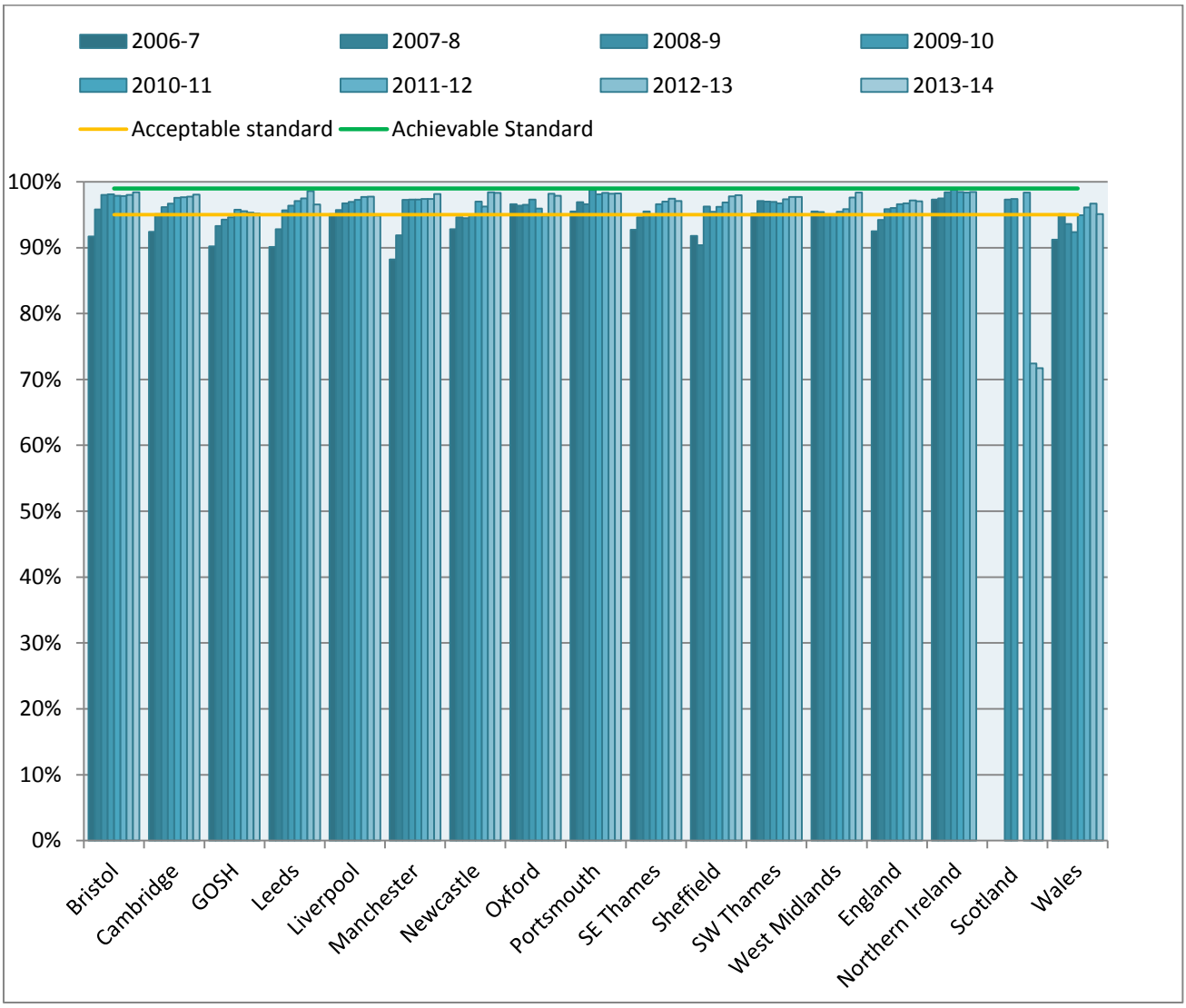
The maternity services sending their samples to all English laboratories met the core standard of 95% or more first samples taken on days 5-8. 96.9% (range 72.6-100%) of samples in England were taken on days 5-8. 98.3% (range 98-99%) of samples were taken on days 5-8 in Northern Ireland, and Wales achieved 96.4% (range 95.3-97.8%). Scotland reported 71.7% of samples were taken on days 5-8; Scotland no longer counts day 4 as too early for screening and 27.3% of samples were taken on day 4.

Figure 12. CCG/CHS/HB area returning the lowest, average and highest percentage of samples taken on days 5-8 2013-14



The figure for Scotland includes samples taken on day 4. The lowest performance for SW Thames represents a small number of samples taken in Barking and Dagenham.

Figure 13. Percentage of samples taken on days 5-8, 2006-14



2.7 Standard 5: Timely receipt of a sample in the newborn screening laboratory

Description

To maximise accuracy of screening test. All samples must arrive within the screening laboratory as soon as possible after the sample has been taken. This enables the laboratory to analyse the sample at the earliest opportunity and also reduces the risk of sample deterioration due to prolonged despatch.

Acceptable level: Equal to or greater than 99% of all samples received within 4 working days.
Achievable level: Equal to or greater than 99% of all samples received within 3 working days.

In England, 96.8% (range 88.2-99.5%) of samples were received in the screening laboratory within four working days of the sample being taken (Figure 14). Northern Ireland achieved 99.6% (range 99.3-99.8%). Wales reported 82.9% (range 78.5-86.3%) and Scotland reported 90.3% of samples received within 4 working days.

Figure 14. Percentage of samples received by laboratories within three and four working days of blood sample being taken 2013-14

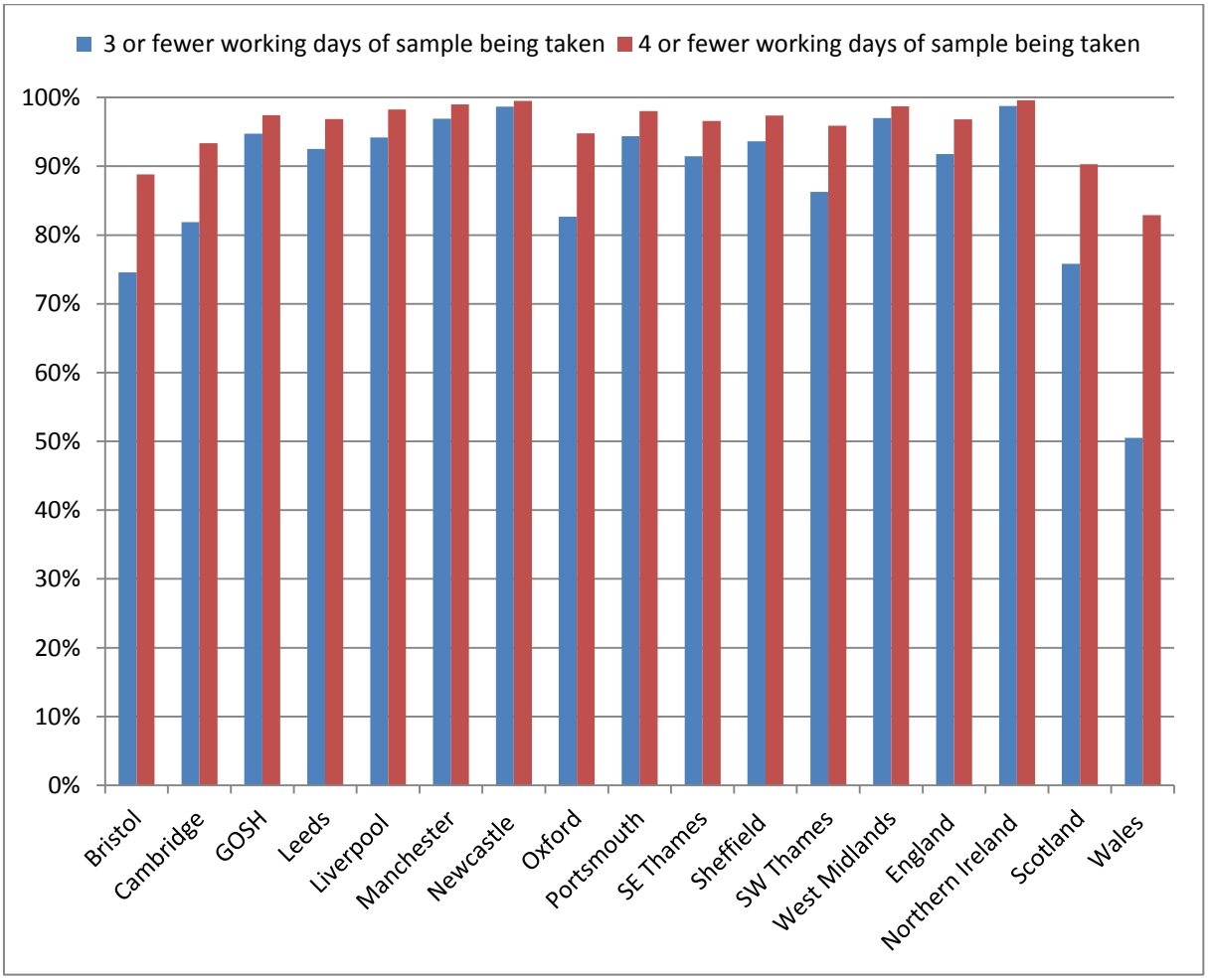
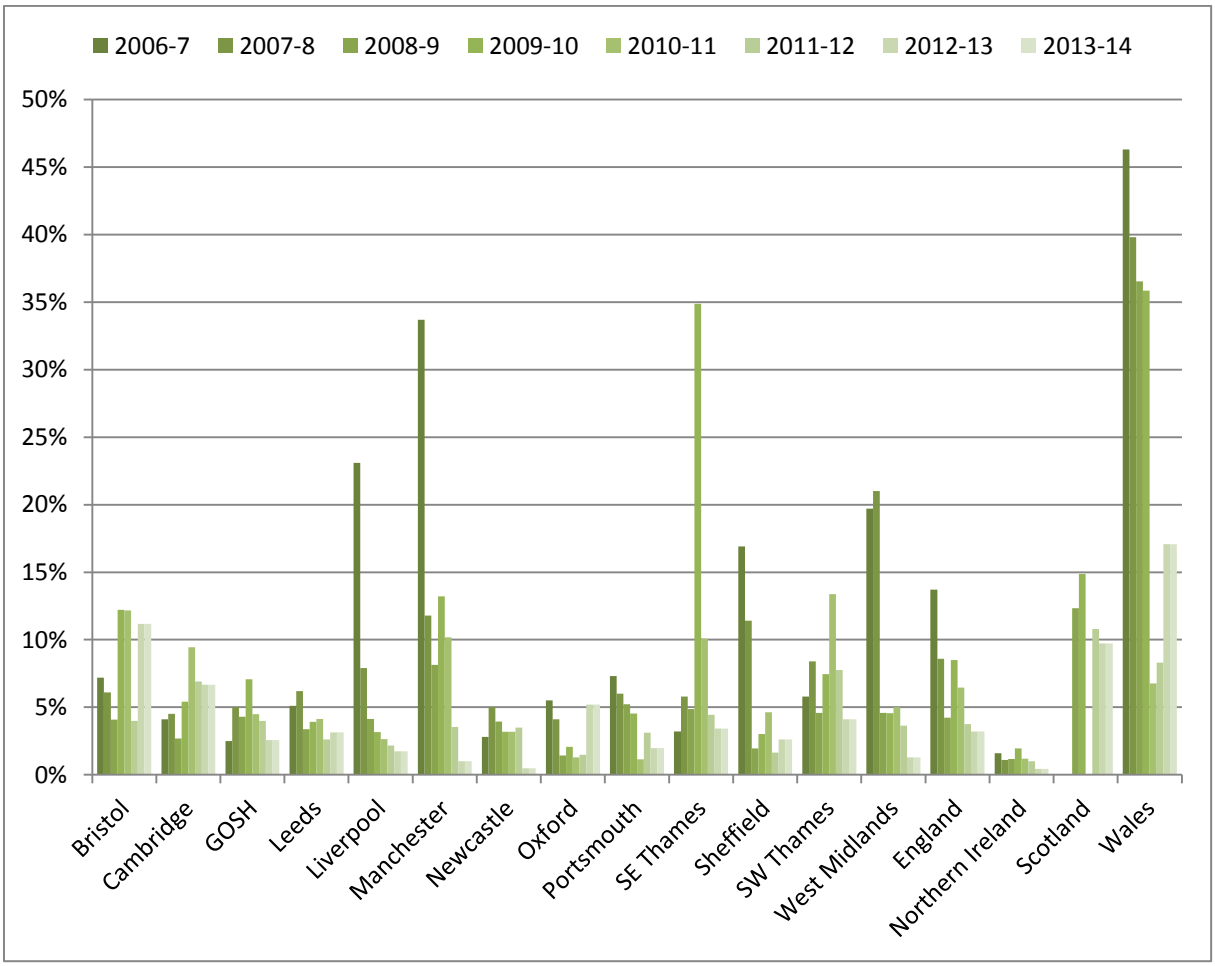


Figure 15. Percentage of samples received in the laboratory after five working days or more of blood sample being taken 2006-14



2.8 Standard 6: Quality of the blood spot sample

Description

A good quality blood spot sample is one that: is taken at the right time; has all data fields completed on the blood spot card; contains sufficient blood to perform all tests; has not been contaminated; and arrives in the laboratory in a timely manner.

Avoidable repeat requests (numerator) is the total number of repeat (second or subsequent) samples requested by the laboratory during the reporting period because the previous sample was:

- Taken when the baby was too young (on or before day 4, where day of birth is day 0) (excluding pre-transfusion admission samples)
- Insufficient blood
- Unsuitable sample/card (eg on an expired blood spot card, contaminated, in transit for more than 14 days, anti-coagulated sample, baby's NHS number and/or other details not accurately recorded on the blood spot card)

Acceptable level: The avoidable rate is less than or equal to 2%
Achievable level: The avoidable rate is less than or equal to 0.5%

It has been recognised that there is regional variation in laboratory definitions of an unsuitable sample, causing inequality in rejections of samples.

The Welsh newborn screening laboratory implemented more stringent blood spot quality standards in 2014. A high avoidable repeat rate was expected for the period 2013-2014. The new standards include requesting a repeat if the NHS number is missing or if the blood spots contain a very low volume of blood. The laboratory has indicated that the overall quality of the samples has improved recently.

New evidence-based blood spot quality guidelines for the English screening laboratories were implemented in April 2015 with the aim of improving quality of samples and, in turn, the efficiency of the screening pathway. The new quality guidelines will standardise the rejection and acceptance criteria used by English screening laboratories. Some areas experienced an initial rise in the avoidable repeat rate but have reported subsequent improvements. The programme will continue to monitor this data and update the screening advisory boards. Additional educational and information resources have been developed to support training for samples takers (cpd.screening.nhs.uk/bloodspot-elearning).

Figure 16. Avoidable repeat rates (insufficient and unsuitable sample) 2006-14

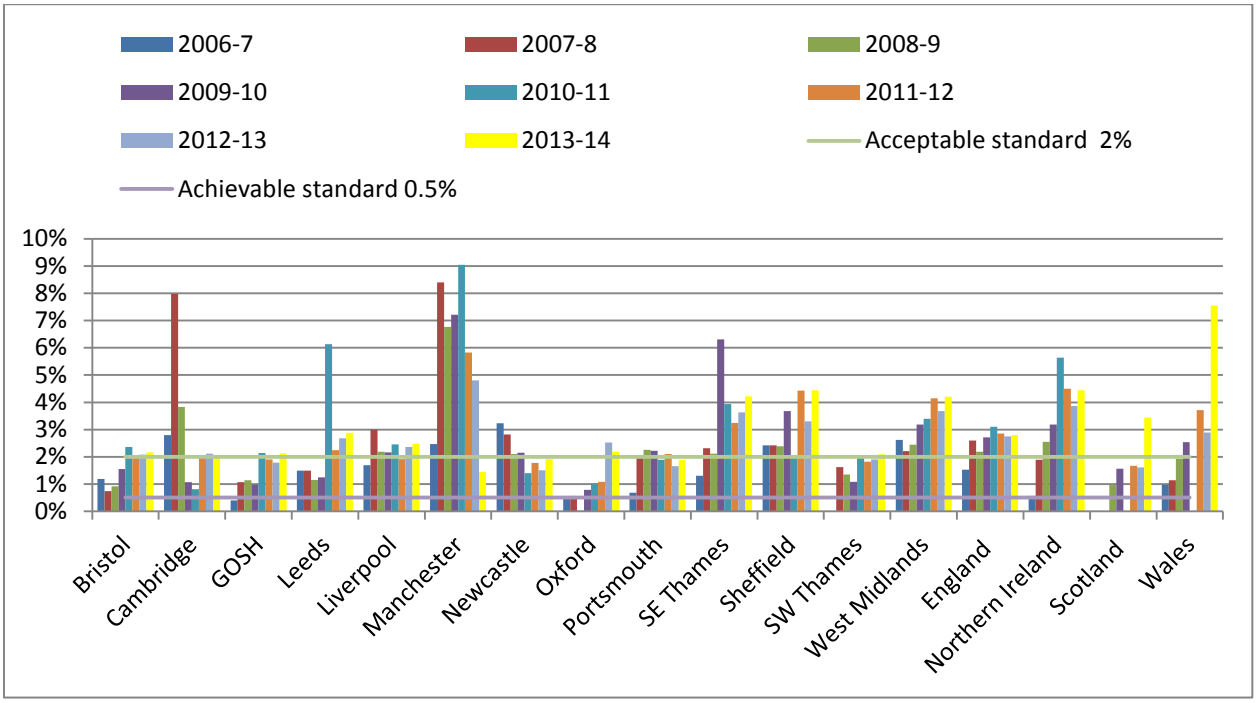
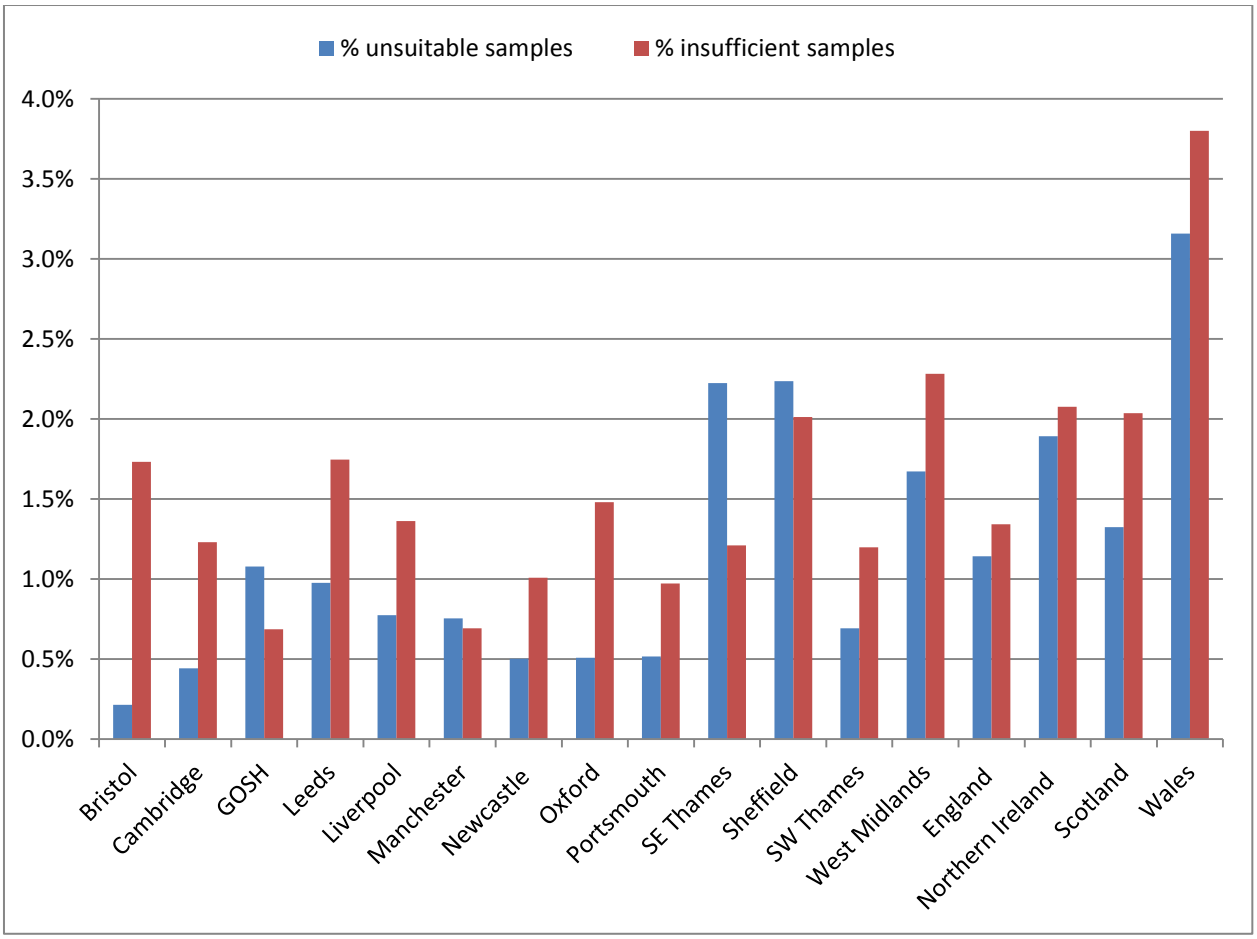


Figure 17. Percentage of samples repeated due to insufficient and unsuitable sample 2013-14



2.9 Standard 7: Timely taking of a repeat blood spot sample

Description

This standard covers repeat/second samples requested by the laboratory because the first sample was of poor quality, not valid for testing or required by the UK protocol for the specific condition. In order that treatment and clinical referral targets are met, the timely receipt of a repeat/second blood spot sample is imperative.

Laboratory information systems do not support collection of data for this standard, so performance cannot be measured. However, Northgate Information Solutions UK Ltd was awarded the contract in January 2013 to provide the Newborn Blood Spot Screening Failsafe Solution (NBSFS). This is a web-based solution that identifies babies who have not had blood spot screening. Stage 1 of the NBSFS is now fully implemented across all English providers of maternity services. This means all babies born in England will be identified if they have not been screened. The NBSFS is also linked to the Welsh blood spot screening failsafe system. In future the NBSFS will store all the screening results that will include identifying babies that need a repeat sample. Where applicable, the screening results will have subcategories; this will be particularly beneficial for repeat samples as the subcategories will provide the reason the repeat sample is required. Timeliness of repeat samples being taken and received will also be available from the NBSFS.

2.10 Standard 9: Timely processing of all PKU, CHT and MCADD screen positive samples

Description

This standard relates to PKU, CHT and MCADD and subsequent action on positive screening results. It is intended to measure the timeliness of screening laboratory processing and clinical referral. The purpose is to facilitate high quality and timely intervention in those who wish to participate.

Acceptable level: 100% of babies with a positive screening result have a clinical referral initiated within four working days of sample receipt by screening laboratory.

Achievable level: 100% of babies with a positive screening result have a clinical referral initiated within three working days of sample receipt by screening laboratory.

Table 10. Numbers of samples processed within the standard in the UK

Condition	Number of screen positive samples	Number (%) of babies with a positive screening result have a clinical referral initiated within four working days of sample receipt by screening laboratory	Number (%) of babies with a positive screening result have a clinical referral initiated within three working days of sample receipt by screening laboratory
PKU	72	72 (100%)	72 (100%)
CHT	587* (*586 referrals)	586 (100%)	573 (97.8%)
MCADD	83	82 (98.8%)	79 (95.2%)

2.11 Standard 11: Timely receipt into clinical care

Description
A baby in whom PKU, CHT (on first sample) or MCADD is suspected should attend their first clinical appointment by:

Acceptable level: 100% by 17 days of age
Achievable level: 100% by 14 days of age

2.11.1 Phenylketonuria (PKU)

Table 11. Appointment timeliness and outcome for PKU screen positive babies

PKU	England	Northern Ireland	Scotland	Wales
Babies screened positive for PKU	54	7	9	2
Babies with age at appointment reported	49	7	6	2
Number seen ≤ 14 days	44	6	6	2
Number seen ≤ 17 days	45	6	6	2
All babies median age at appointment:	11	9	8	12
Range *	7-329 days	7-306 days	7-9 days	10-14 days
Babies with age at appointment unknown:	4	0	3	0
Deceased	1	0		0
Not reported	3	0	3	0
Outcome:				
PKU confirmed treatment required	33	5	6	2
Non PKU eg biopterin disorders	1	0	1	0
No persistent abnormalities - false positive (PKU excluded)	10	1	2	0
PKU monitoring required	4	1	0	0
Not reported	6	0	0	0

*One baby in England and one baby in Northern Ireland moved into the country after birth and were tested late (329 and 306 days respectively) and therefore had their first appointment very late. Without these exceptions the maximum age at appointment would be 22 days for England and 10 days for Northern Ireland.

Figure 18. Age in days of PKU screen positive babies, in the UK, at time of first appointment 2013-14

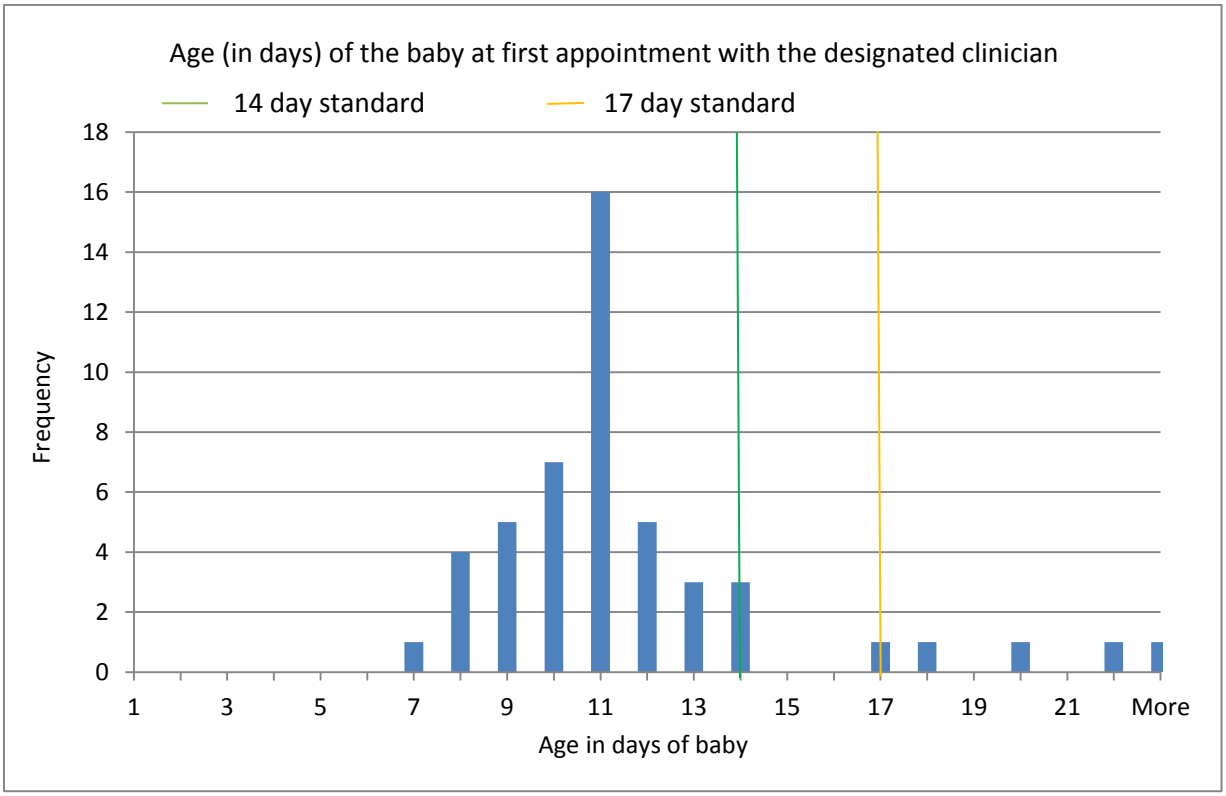
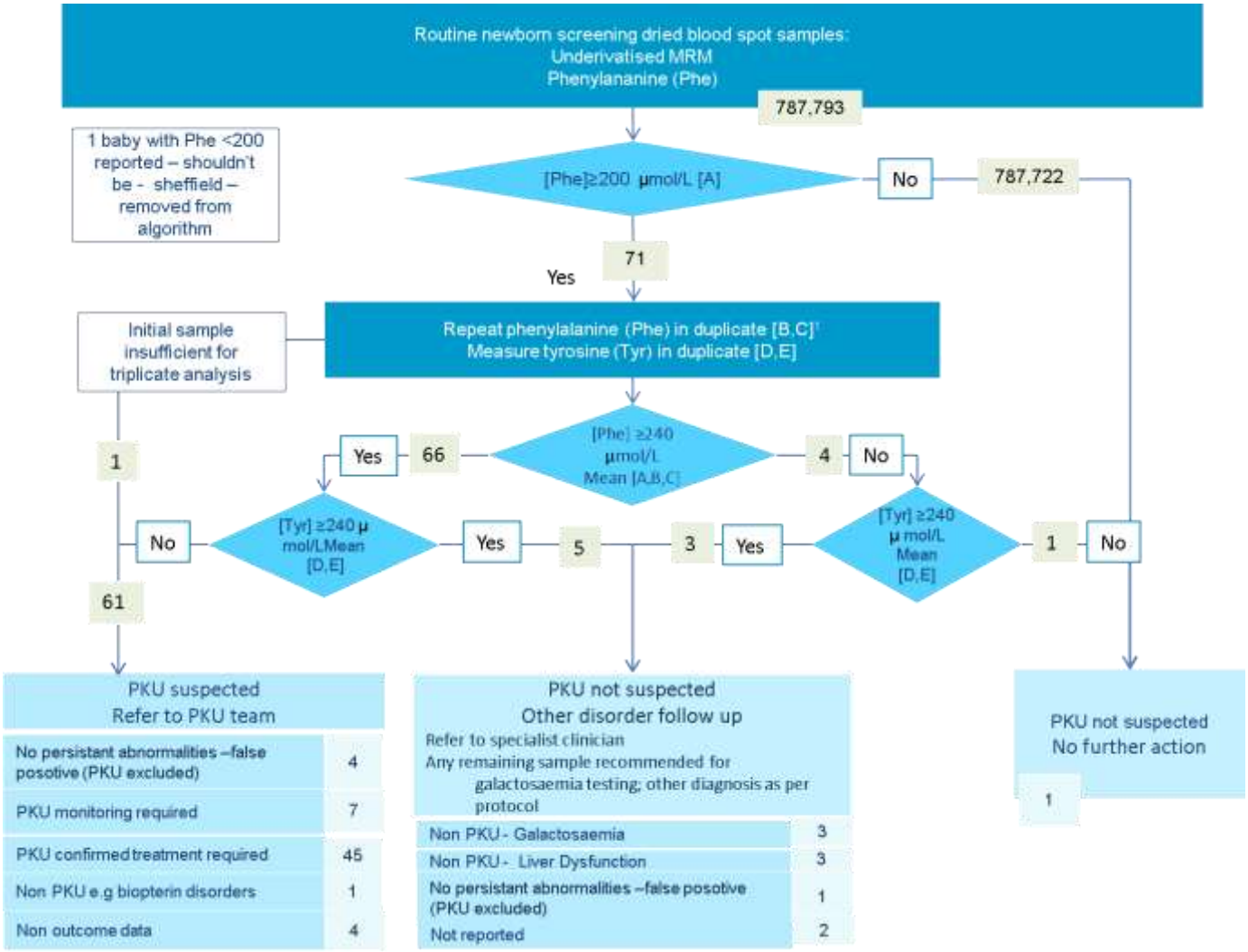


Table 12. Incidence of screen positive PKU results 2005-14

Laboratory	Number of babies tested for PKU 2005-14	Total number of screen positives 2005-14	Rate of PKU screen positives per 10,000
Bristol	365,707	28	0.77
Cambridge	245,096	41	1.67
GOSH	1,090,663	107	0.98
Leeds	402,183	50	1.24
Liverpool	261,510	31	1.19
Manchester	451,375	65	1.44
Newcastle	309,667	39	1.26
Oxford	265,843	20	0.75
Portsmouth	317,089	20	0.63
SE Thames	509,356	55	1.08
Sheffield	658,489	92	1.40
SW Thames	459,678	36	0.78
West Midlands	637,688	74	1.16
England	5,974,371	666	1.11
Northern Ireland	221,691	52	2.35
Wales	351,994	52	1.48
Scotland *	311,946	47	1.51
UK total	6,860,002	817	1.19

*Scotland incidence data is based upon figures from 2008 to 2014

Figure 19. UK PKU screening and diagnostic algorithm 2013-14



2.11.2 Congenital hypothyroidism (CHT)

The time by which a baby in whom a diagnosis of CHT has been made should commence treatment with oral levothyroxine depends on whether this follows an initial or second sample:

a) CHT suspected on initial screening sample

Acceptable level: 17 days of age (100% of infants)
Achievable level: 14 days of age (100% of infants)

b) CHT suspected on a repeat blood spot sample that follows a borderline TSH

Acceptable level: 24 days of age (100% of infants)
Achievable level: 21 days of age (100% of infants)

Table 13. Appointment timeliness and treatment for CHT screen positive babies detected on first sample 2013-14

CHT – detected on first sample	England	Northern Ireland	Scotland	Wales
Babies detected on first sample	298	15	19	19
Babies with age at appointment reported	262	15	18	0
Number seen ≤ 14 days standard (of known data)	225	15	18	
Number seen ≤ 17 days standard (of known data)	248	15	18	
Median age at appointment:	12	10	10	
Range	7-244 days	7-13 days	7-13 days	
Babies with age at appointment unknown:	36	0	1	19
Inpatient	5			
Baby died	1			
Not reported	30			19
Has baby started on thyroxine at the first appointment?				
Yes	222	14	17	
No	7			
Not reported	43		2	19
Thyroxine not given but follow up required	15	1		
Thyroxine not given and baby discharged	11			

Table 14. Appointment timeliness and treatment for CHT screen positive babies detected on second sample 2013-14

CHT – detected on second sample	England	Northern Ireland	Scotland	Wales
Babies detected on second sample	219	5	7	5
Babies with age at appointment reported	181	5	7	0
Number seen ≤ 21 days standard	116	4	3	
Number seen ≤ 24 days standard	138	5	5	
All babies median age at appointment:	20	18	18	
Range	11-59 days	14-23 days	14-32 days	
Babies with age at appointment unknown:	38	0	0	5
Inpatient	14			
Baby died	1			
Not reported	23		4	5
Has baby started on thyroxine at the first appointment?				
Yes	104	5	4	
No	5			
Not reported	33		1	5
Thyroxine not given but follow up required	50		1	
Thyroxine not given and baby discharged	27		1	

One further baby, born at 25 weeks gestational age, had an “03/L” result (requires pre-term CHT test) on the day 5 sample and an “08” (CHT suspected) result on the preterm CHT sample, taken at 32 days. This baby had its first clinical appointment aged 33 days.

Figure 20. Age of CHT screen positive babies in the UK, detected on first sample, at time of first appointment 2013-14

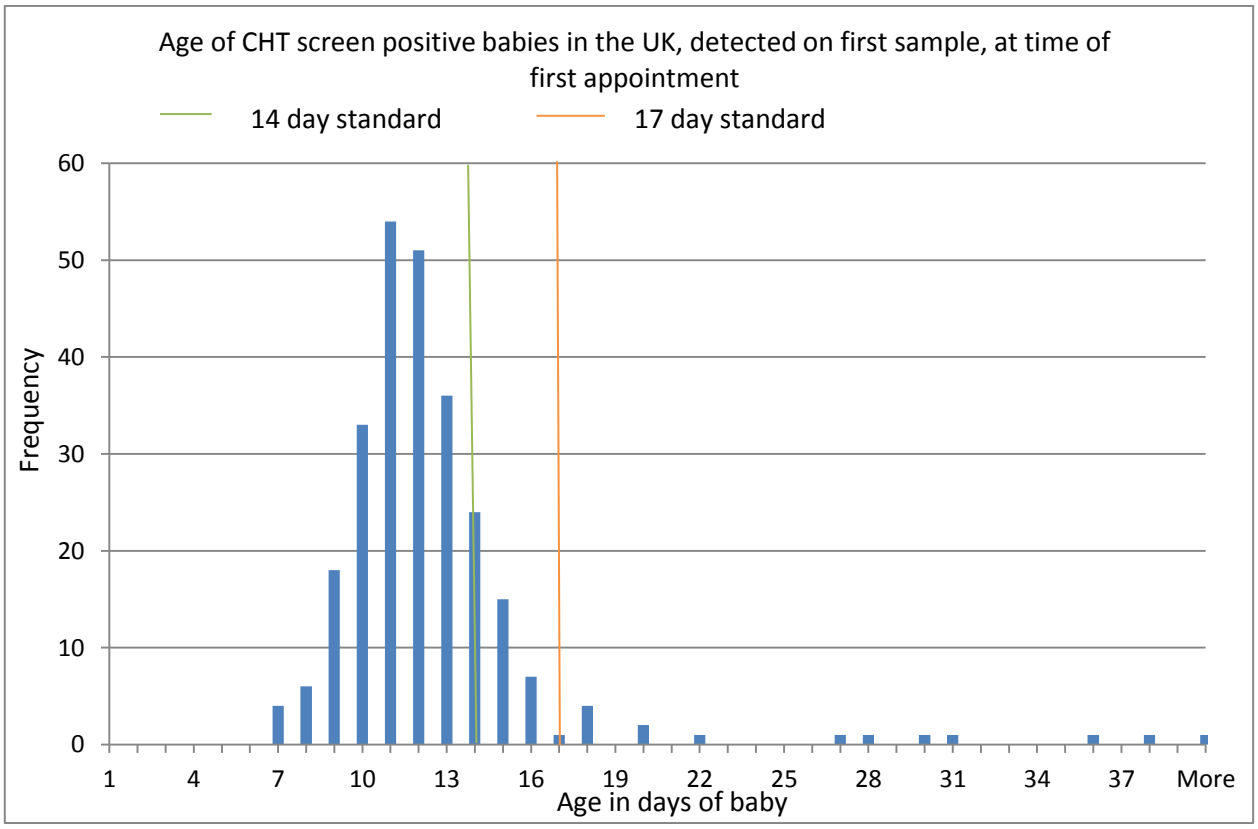
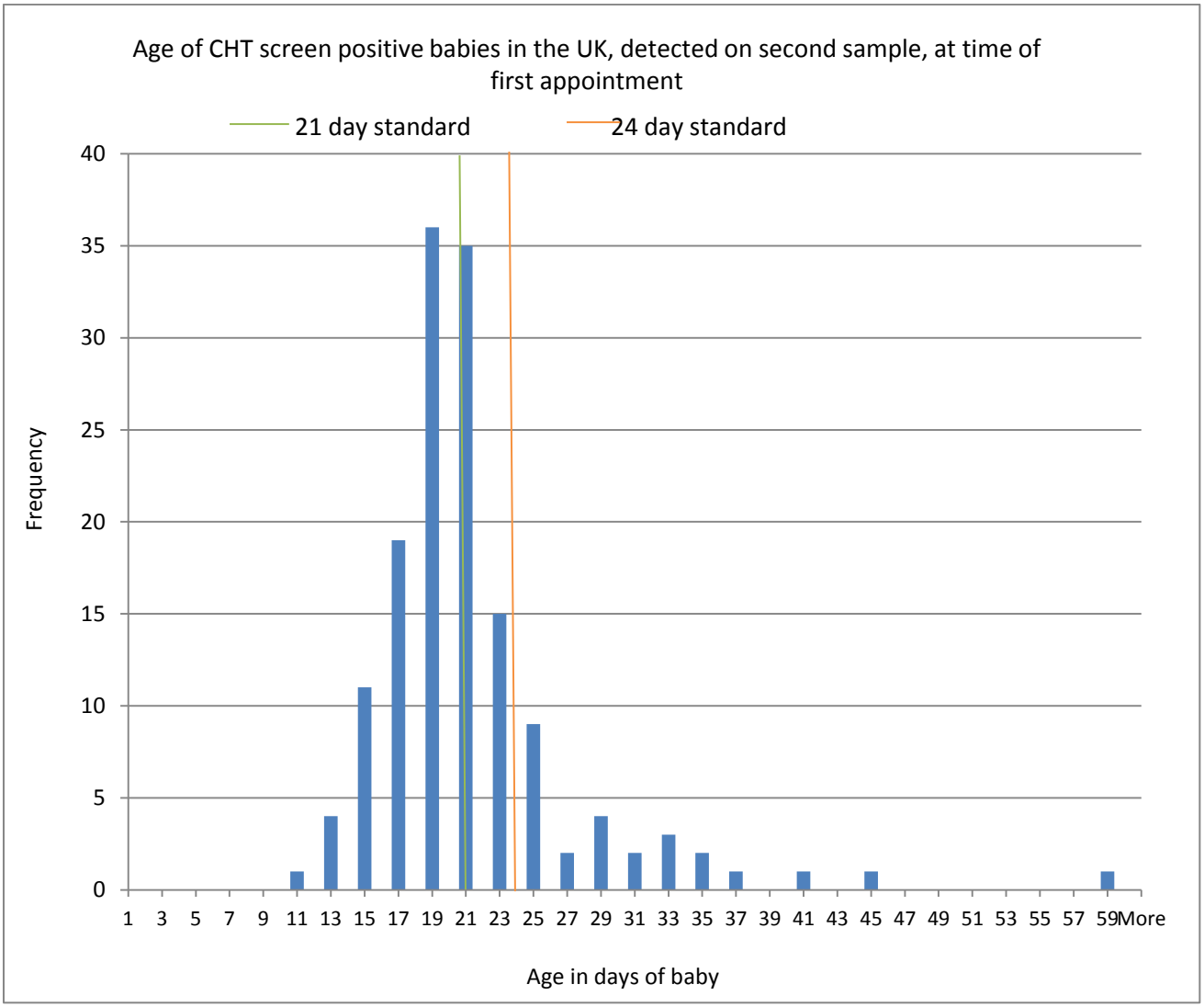


Figure 21. Age of CHT screen positive babies in the UK, detected on the second sample, at time of first appointment 2013-14



CHT results depending on use of national or local standards

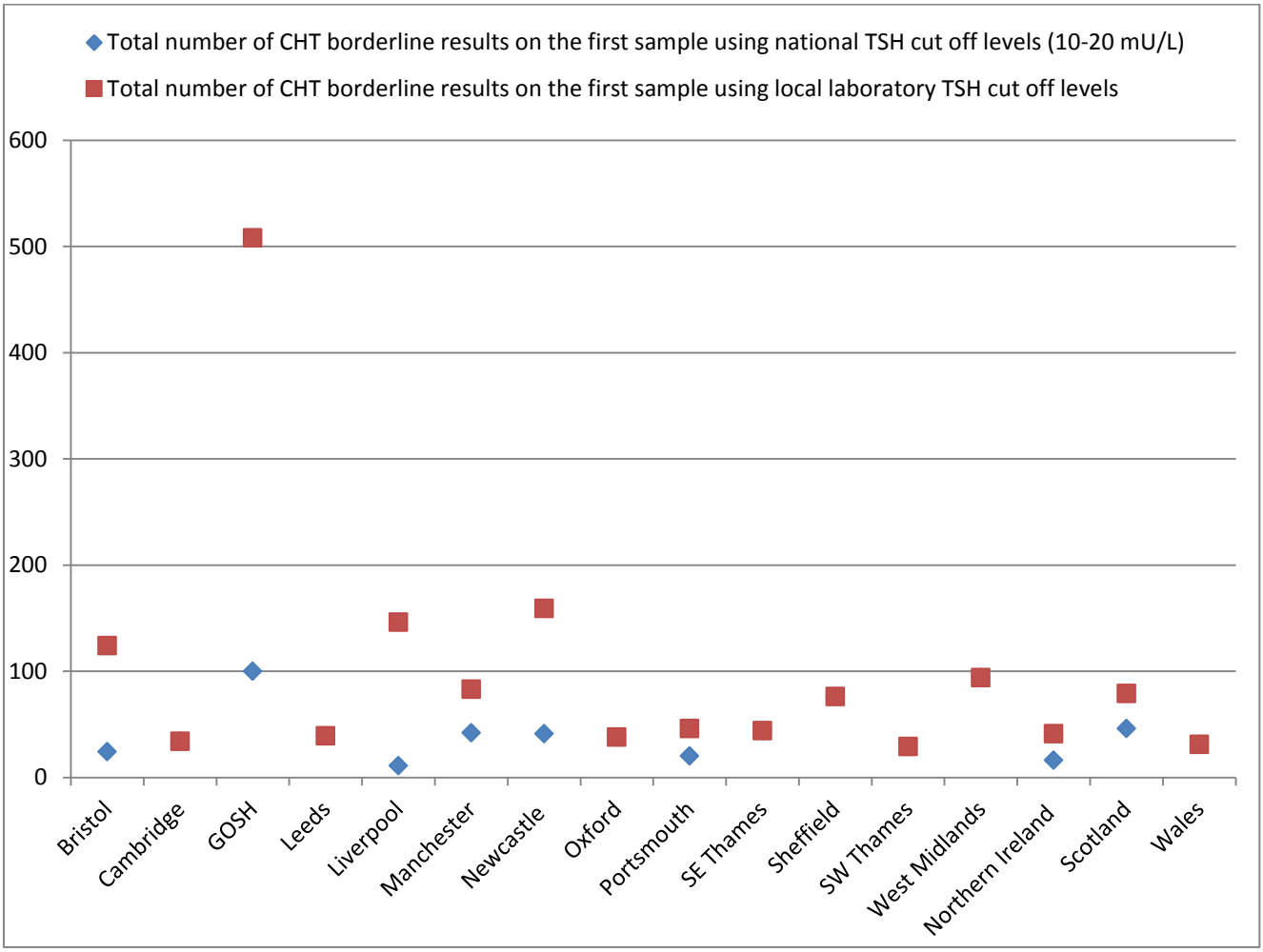
CHT is the only screening protocol in which a borderline result necessitates a second sample before a conclusive result can be achieved. Table 15 shows variation persists in compliance with the national borderline cut off level (10 mU/L). In England, an additional 828 babies had a borderline result on the first sample due to lower cut off levels in six laboratories. Figure 22 shows the increase in borderline results, comparing local laboratory borderline cut offs levels with the national levels.

Table 15. CHT results depending on use of national or local standards

Laboratory	What TSH cut off levels do you use to determine a positive screen for CHT (mU/L)	What TSH cut off levels do you use to determine a borderline screen for CHT (mU/L)	Total number of CHT borderline results on the first sample using national TSH cut off levels (10-20 mU/L)	Total number of CHT borderline results on the first sample using your laboratory TSH cut off levels	Total number of babies tested for CHT 2007-14	Total number of CHT screen positives 2007-14	Rate of CHT screen positives 2007-14 per 10,000 babies
Bristol	20	6	24	124	365,703	179	4.89
Cambridge	20	10	34	34	245,096	147	6.00
GOSH	20	6	100	508	1,099,696	1020	9.28
Leeds	>20	>10	39	39	402,183	243	6.04
Liverpool	>20	>5	11	146	261,510	228	8.72
Manchester	20	8	42	83	451,333	370	8.20
Newcastle	20	6	41	159	309,667	188	6.07
Oxford	20	10	38	38	265,840	172	6.47
Portsmouth	20	8	20	46	316,965	152	4.80
SE Thames	20	10	44	44	509,356	281	5.52
Sheffield	20	10	76	76	658,487	344	5.22
SW Thames	20	10	29	29	459,678	259	5.63
West Midlands	≥20	10	94	94	637,688	462	7.24
England			592	1420	5,983,232	4045	6.76
Northern Ireland	≥20	≥8	16	41	221,683	144	6.50
Scotland	25	8	46	79	351993	164	4.66
Wales *	20	10	31	31	311888	194	6.22
UK					6,868,796	4547	6.62

* Wales changed their cut off from 6 to 10 mU/L in October 2012 and only screen positives with a TSH of >10 mU/L have been included in the table above.

Figure 22. CHT borderline results depending on use of national or local standards 2013-14



2.11.3 Medium-chain acyl-CoA dehydrogenase deficiency (MCADD)

Table 16. Appointment timeliness and outcome for MCADD screen positive babies 2013-14

	England	Northern Ireland	Wales	Scotland
Babies screen positive for MCADD	69	5	5	2
Babies with age at appointment reported	64	5	5	2
Number seen ≤ 14 days	59	5	5	1
Number seen ≤ 17 days	62	5	5	1
All babies median age at appointment:	11	7	14	29
Range	1-23 days	4-13 days	11-14 days	10-47 days
Outcome:				
MCADD	58	5	5	1
Unaffected carrier	0			
MCADD unlikely	4			
Not MCADD	2			
Unknown: not reported	5			1

Figure 23. Age of MCADD screen positive babies in the UK at time of first appointment 2013-14 (Note that there is one outlier at 47 days)

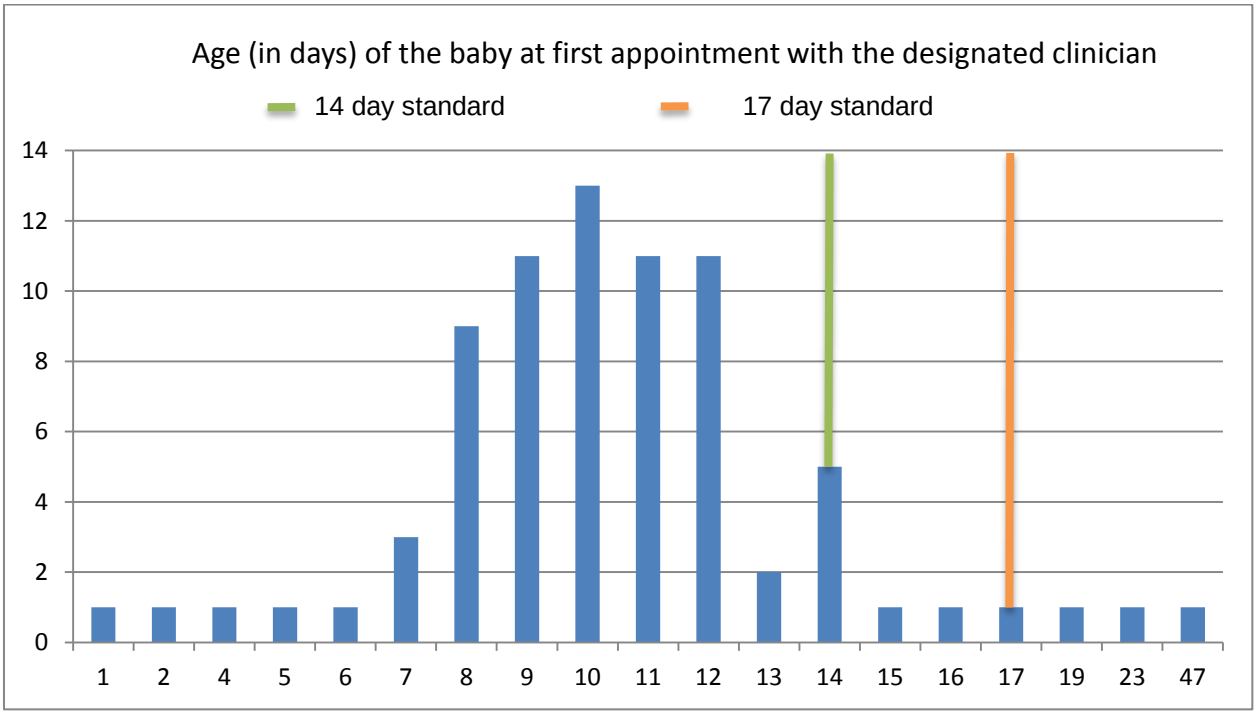
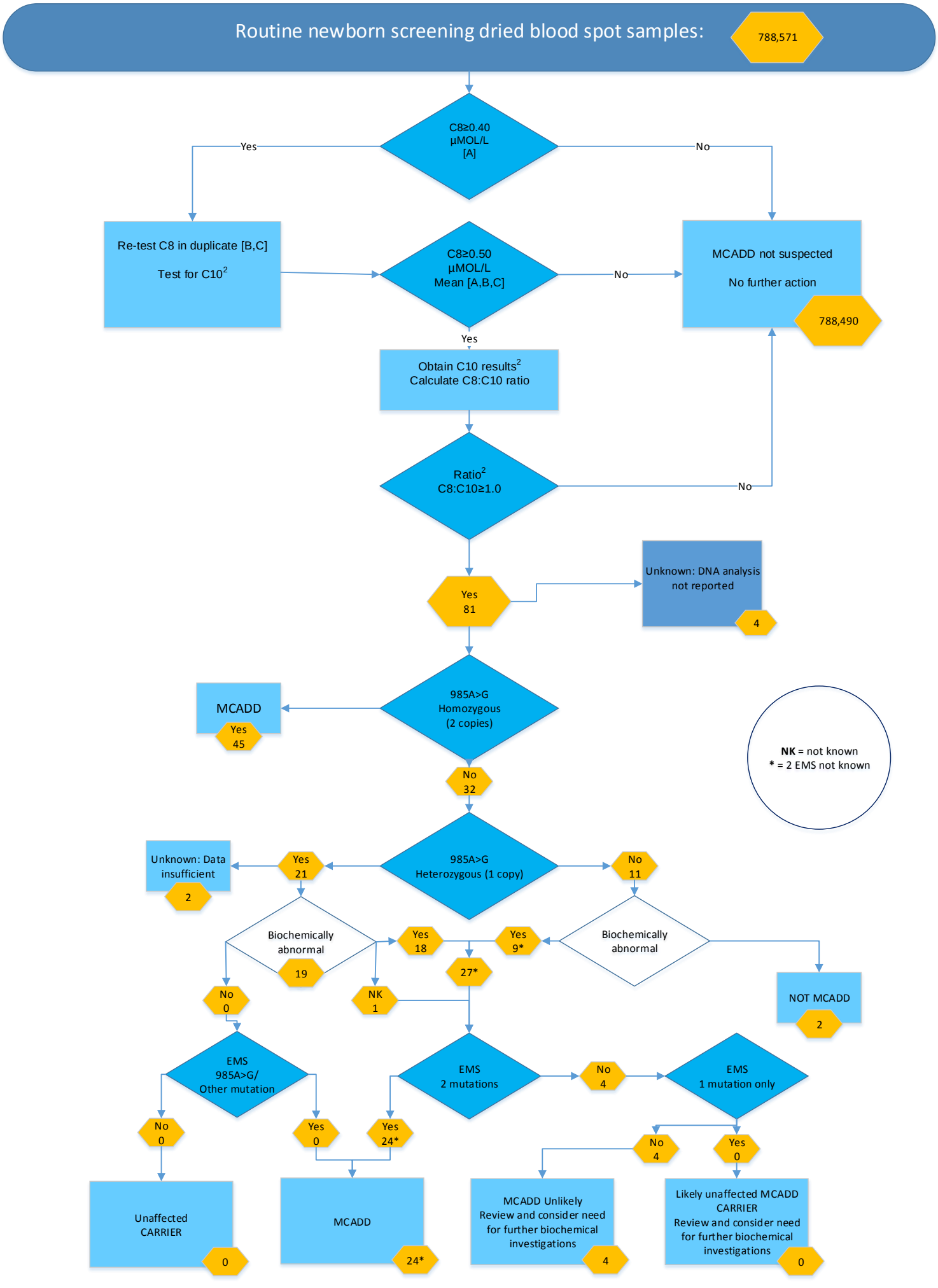


Table 17. Incidence of screen positive MCADD results 2008-14

Laboratory	Number of babies tested for MCADD	Total number of screen positives	Rate of MCADD screen positives per 10,000 babies 2007-14
Bristol	229,455	21	0.92
Cambridge	163,564	22	1.35
GOSH	741,143	56	0.76
Leeds	273,208	40	1.46
Liverpool	167,914	20	1.19
Manchester	340,906	38	1.11
Newcastle	188,494	18	0.95
Oxford	154,139	19	1.23
Portsmouth	219,038	23	1.05
SE Thames	347,948	24	0.69
Sheffield	448,056	69	1.54
SW Thames	291,236	24	0.82
West Midlands	433,180	36	0.83
England	3,998,281	410	1.03
Northern Ireland	116,946	15	1.28
Scotland	206,594	6	0.29
Wales	62,406	8	1.28
UK	4,384,227	441	1.01

Figure 24. MCADD screening and diagnostic algorithm in England, Northern Ireland, Scotland and Wales 2013-14


Routine newborn screening dried blood spot samples:
788,571
C8≥0.40 µMOL/L [A]
Yes
No
Re-test C8 in duplicate [B,C]
Test for C10[2]
C8≥0.50 µMOL/L Mean [A,B,C]
No
MCADD not suspected
No further action
788,490
Yes
Obtain C10 results[2]
Calculate C8:C10 ratio
Ratio[2] C8:C10≥1.0
No
Yes 81
Unknown: DNA analysis not reported
4
985A>G Homozygous (2 copies)
MCADD
Yes 45
No 32
NK = not known
* = 2 EMS not known
985A>G Heterozygous (1 copy)
Unknown: Data insufficient
2
Yes 21
No 11
Biochemically abnormal
19
Yes 18
Yes 9*
Biochemically abnormal
27*
NOT MCADD
2
No 0
NK 1
EMS 985A>G/ Other mutation
EMS 2 mutations
No 4
EMS 1 mutation only
No 0
Yes 0
Yes 24*
No 4
Yes 0
Unaffected CARRIER
0
MCADD
24*
MCADD Unlikely Review and consider need for further biochemical investigations
4
Likely unaffected MCADD CARRIER Review and consider need for further biochemical investigations
0

2.11.4 Cystic fibrosis (CF)

A baby in whom CF is suspected should have their first clinical appointment by:

CF suspected: two CFTR mutations detected:

Acceptable level: 95% of babies seen by 28 days of age
Achievable level: 100% of babies seen by 28 days of age

CF suspected: none or one CFTR mutation detected:

Acceptable level: 80% of babies seen by 35 days of age
Achievable level: 100% of babies seen by 35 days of age

Babies with positive screening results for CF should have their first clinical appointment where decisions on treatment are made by day 28, when two mutations have been detected, and by day 35, when a second sample is required before a presumptive positive screening result is arrived at.

Table 18. Timeliness of appointment for CF screen positive babies with two mutations 2013-14

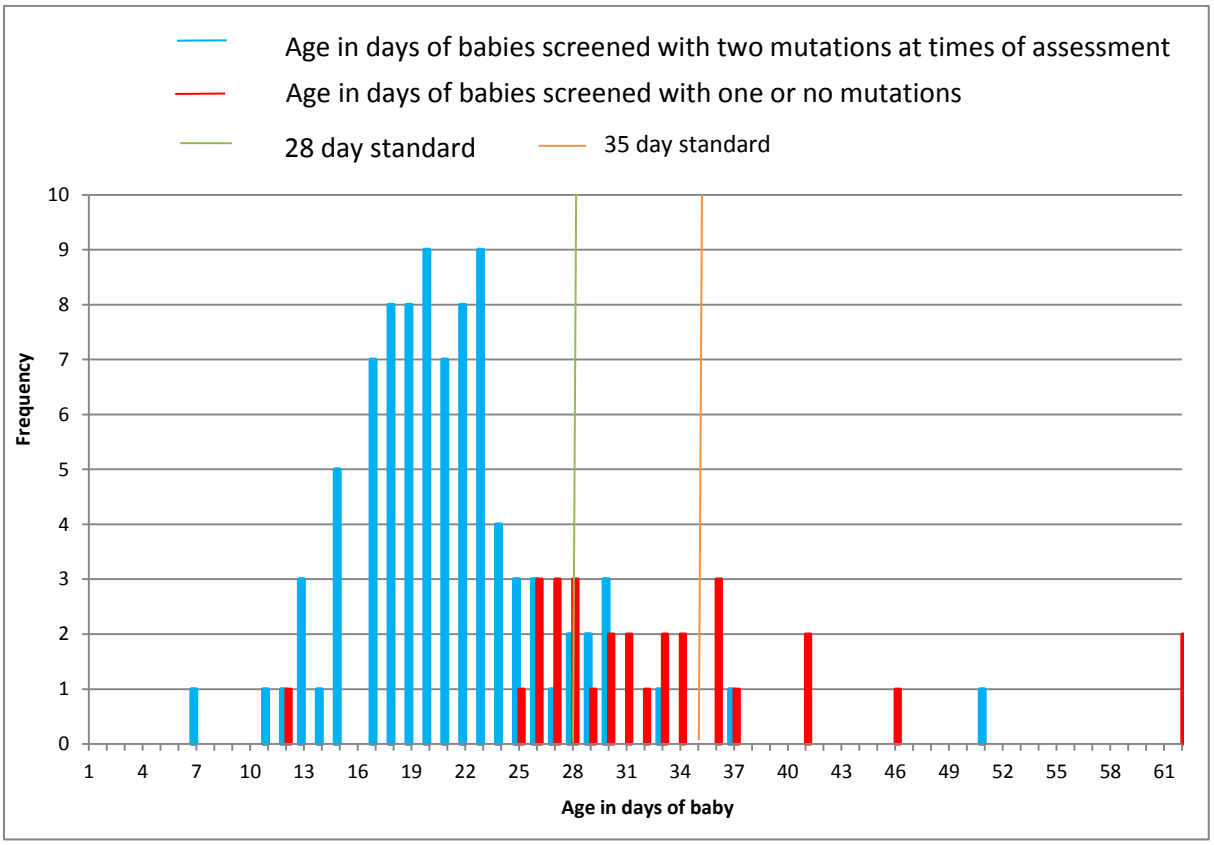
	England	Northern Ireland	Scotland	Wales
Number screened with two mutations	171	4	16	3
Number clinically diagnosed (excluded from following age data)	29	0	4	0
Number with age at appointment reported	105	4	9	0
Number seen ≤ 28 days	97	4	9	
All babies median age at appointment:	20	23	20	
Range	7-51 days	19-25 days	16-31 days	
Babies with age at appointment unknown	37	0	3	3
Outcome:				
Confirmed	115	4	9	3
CF screen positive, inconclusive diagnosis (CF SPID) (equivocal)	2			
Excluded	0			
Not reported	54		7	

Table 19. Timeliness of appointment for CF screen positive babies with one or no mutations 2013-14 (and therefore a repeat sample is required)

	England	Northern Ireland	Scotland	Wales
Number screened with one or no mutations	72	11*	8	23
Number with age at appointment reported	39	11	5	0
Number seen ≤ 35 days	27	10	4	
All babies median age at appointment:	32	27	30	
Range	12-106 days	24-36 days	26-39 days	
Babies with age at appointment unknown	33	0	3	23
Inpatient	2		2	
Baby died	2			
Not reported	29		1	
Confirmed	23		2	1
CF SPID (equivocal)	3			1
Excluded	16	11		21
Not reported	30		6	

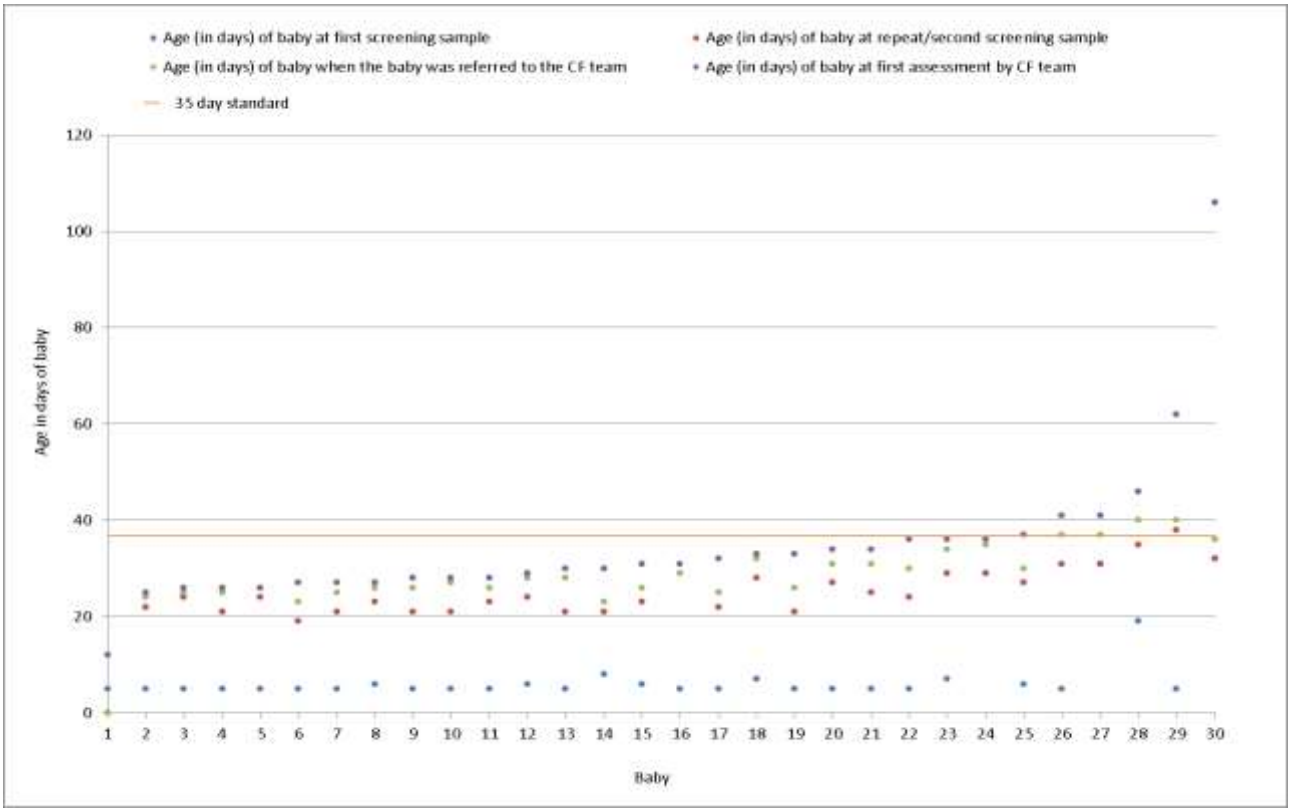
* Excludes one baby tested > 8 weeks of age but unavoidably analysed, had an IRT > CUT-OFF 2 and was referred as ‘CF suspected’.

Figure 25. Age in days of CF screen positive babies in the UK* at time of first appointment 2013-14



* Only UK countries that returned data on age at first appointment.

Figure 26. Age in days of babies in the UK* with one or no mutations at time of sampling, referral and assessment 2013-14 (where full data is provided)



* All four UK countries follow different testing protocols

The CF programme was fully implemented in England in October 2007. Results reported to the NHS Newborn Blood Spot Screening Programme suggest that the protocol is performing appropriately and numbers of babies with CF suspected and CF carrier results have been consistent over the last five years.

Table 20. Incidence of screen positive CF results 2007-14

Laboratory	Number of babies tested for CF	Total number of screen positives	Rate of CF screen positives per 10,000 babies
Bristol	290,580	164	5.64
Cambridge	194,745	87	4.47
GOSH	829,293	219	2.64
Leeds	316,850	130	4.10
Liverpool	203,995	116	5.69
Manchester	366,962	138	3.76
Newcastle	242,912	119	4.90
Oxford	208,908	51	2.44
Portsmouth	259,930	91	3.50

SE Thames	352,259	124	3.52
Sheffield	521,134	225	4.32
SW Thames	350,879	113	3.22
West Midlands	503,797	184	3.65
England	4,642,244	1761	3.79
Northern Ireland	116,529	66	5.66
Scotland	352,451	195	5.53
Wales* does not include 0 mutations	245,570	159	6.47
UK Total	5,356,794	2,181	4.07

All four UK countries follow different testing protocols; data is mapped for England in Figure 27, Northern Ireland in Figure 28 and Wales in Figure 29.

Figure 27. England CF screening and diagnostic algorithm

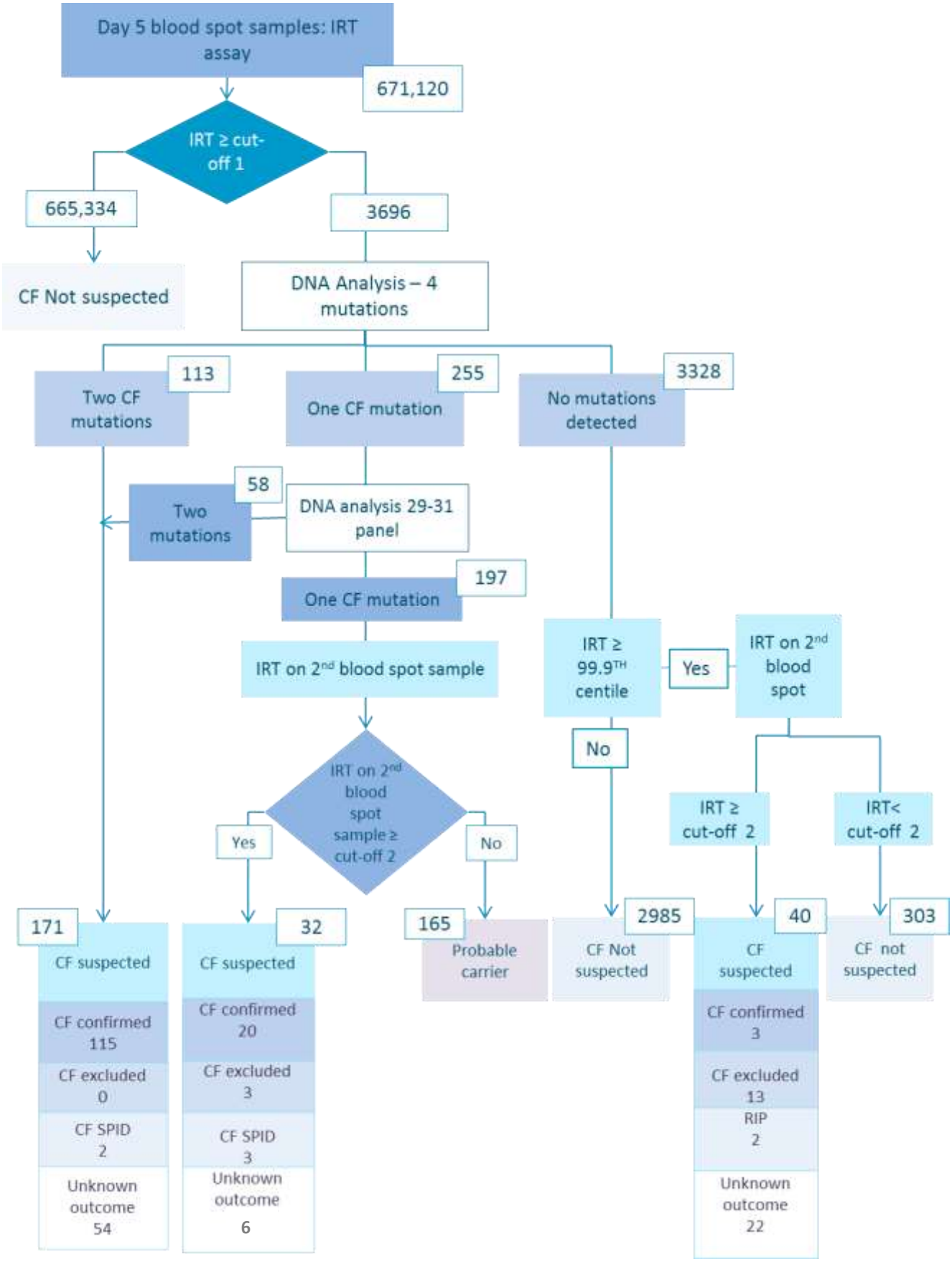


Figure 28. Northern Ireland CF screening and diagnostic algorithm

*One sample was taken after 8 weeks of age but unavoidably analysed, had an IRT > CUT-OFF 2 and was referred as' CF suspected'

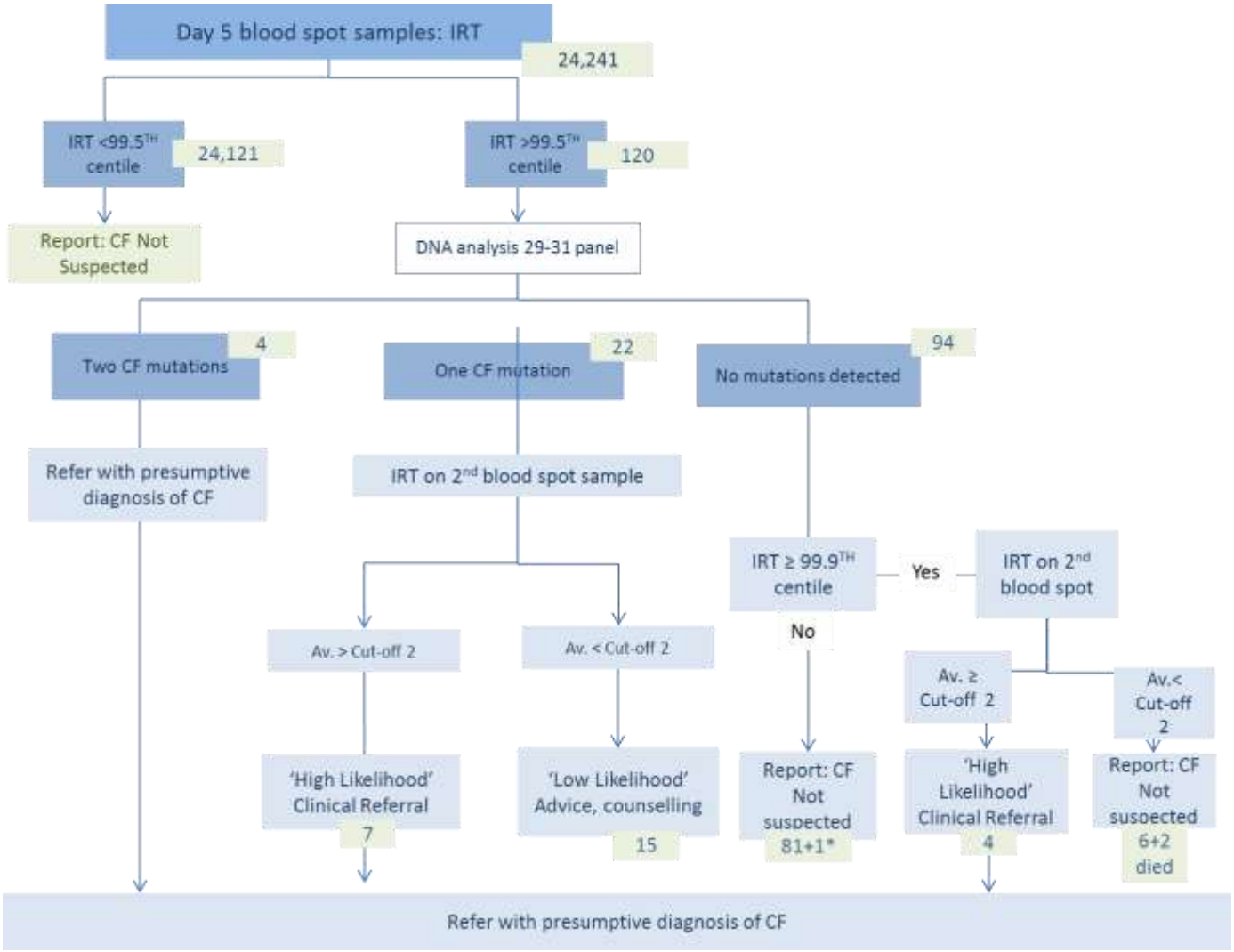
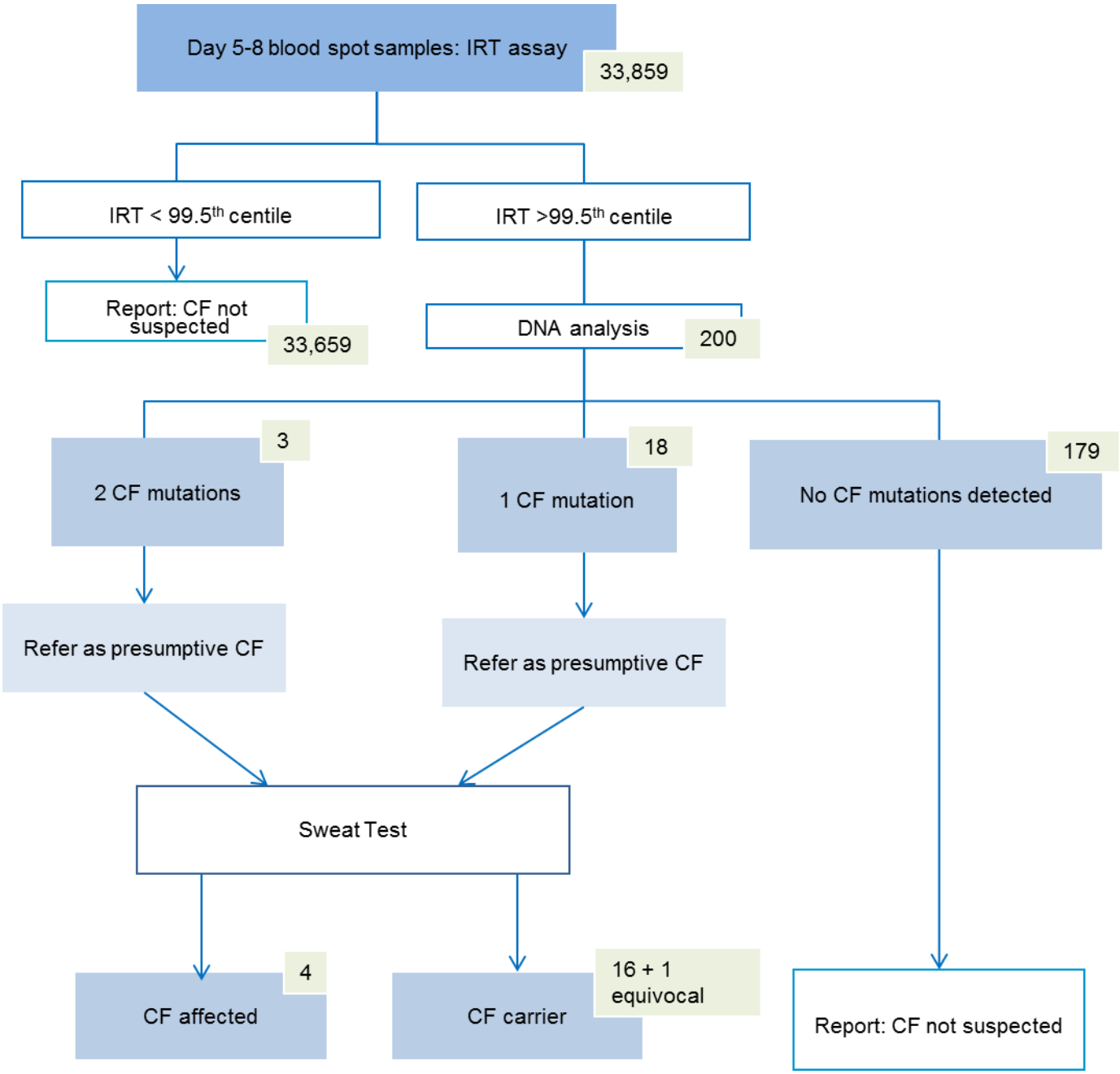
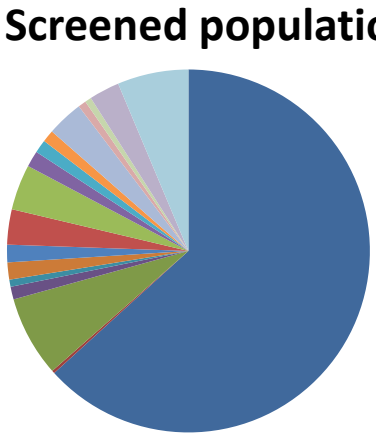
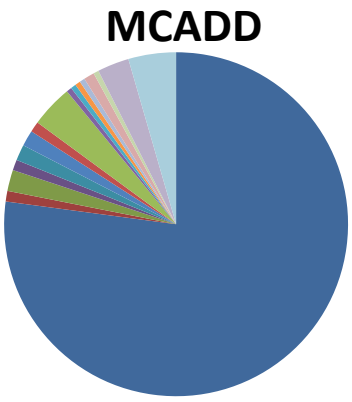


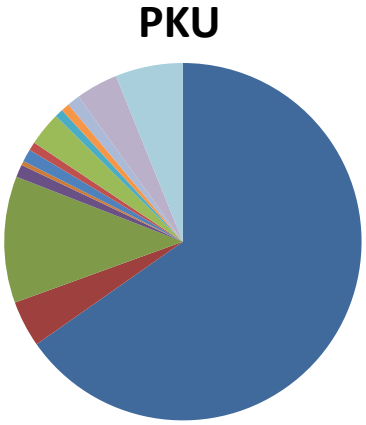
Figure 29. Wales CF screening and diagnostic algorithm

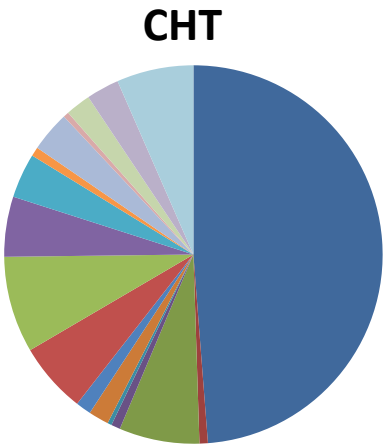


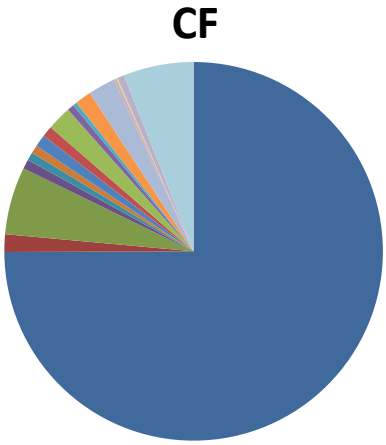
2.11.5 Ethnicity











2.11.6 Sickle cell disease (SCD)

There were approximately 668,000 babies screened through newborn blood spot screening in England. Of these, 319 were identified as affected by significant conditions (approximately 1 in 2,000 babies screened) and 8,850 were identified with carrier results (approximately 1 in 76 babies screened).

There were 668,117 babies reported as being screened by newborn screening laboratories in 2013/14. This represents a decrease in numbers screened compared to previous years, but this drop is also reflected in ONS birth figures for 2013. Significant conditions are most prevalent in black African and black Caribbean backgrounds, but these conditions are not exclusive to these ethnic categories. In 2013/14 five affected cases were identified as white British, or one in 64 cases identified with significant conditions.

Declined newborn screening tests for sickle cell disease have continued to increase and are now at approximately 1%. Nationally the rates for post-transfusion samples appear to have increased, although this appears to mainly be due to an increase in the South East Coast region.

Whilst beta thalassaemia is not currently screened for in newborn screening, F-only cases are picked up as a by-product of screening for sickle cell disease. These are probable beta thalassaemia major cases and require follow-up. In 2013/14 there were 32 F-only cases reported by the newborn laboratories.

The Sickle Cell and Thalassaemia (SCT) Screening Programme has expanded the data requested on timeliness of newborn screening to include anonymised data on screening outcomes. Data for these new fields were requested for 2013/14 so that the programme could assess whether they are appropriate, but will only be reported from 2014/15. Preliminary findings from incomplete data based on 292 babies with significant conditions of F-only results suggest that the median age for reporting a screen positive result is 15 days. This suggests that the system is capable of meeting the 28 day standard for informing parents of results.

3. Conclusion

- This is the first data report that reflects the 2013 standards for newborn blood spot screening
- This is the tenth annual data report and year-on-year data are available on some of the original standards
- Data on standard 1b (completeness of coverage, movers in) will be available in the 2014-15 data report having applied an effective timeframe of 21 calendar days of movement in being recorded on the child health information system
- Once all laboratories are providing full screening results to the NBSFS, more detailed data on standards 6 and 7 (blood spot quality and timeliness of repeat sample) will be available. This data will reflect postnatal services' responsibility for screening
- The programme will continue to seek ways of improving outcome data collection, which will enable enhanced evaluation of the screening protocols
- Data on performance of the expanded newborn screening programme will be presented in the 2014-15 report
- The work of the programme reflects improved partnership working with stakeholders, Public Health England and NHS England

4. Resources

[1] NHS England (2014) *NHS public health Functions agreement 2015-16 Service specification no.19, NHS Newborn Blood Spot Screening Programme* [Online] Available: https://www.gov.uk/government/publications/public-health-commissioning-in-the-nhs-2015-to-2016 [Accessed: July 2015]

[2] NHS Newborn Blood Spot Screening Programme (2013) *Standards for newborn blood spot screening* [Online] Available: https://www.gov.uk/government/publications/standards-for-nhs-newborn-blood-spot-screening [Accessed: July 2015]

[3] NHS Newborn Blood Spot Screening Programme (2015) *A laboratory guide to newborn blood spot screening for inherited metabolic diseases* [Online] Available: https://www.gov.uk/government/publications/newborn-blood-spot-screening-laboratory-guide-for-imds [Accessed: July 2015]

[4] NHS Newborn Blood Spot Screening Programme (2014) *A laboratory guide to newborn blood spot screening in the UK for congenital hypothyroidism* [Online] Available: https://www.gov.uk/government/publications/congenital-hypothyroidism-screening-laboratory-handbook [Accessed: July 2015]

[5] NHS Newborn Blood Spot Screening Programme (2014) *A laboratory guide to newborn blood spot screening in the UK for cystic fibrosis* [Online] Available: https://www.gov.uk/government/publications/cystic-fibrosis-screening-laboratory-handbook [Accessed: July 2015]

[6] UK Newborn Screening Programme Centre (2005) *National standard protocol for newborn screening for cystic fibrosis: Guidelines for clinical referral* [Online] Available: https://www.gov.uk/government/publications/clinical-referral-national-standard-protocol-for-cystic-fibrosis [Accessed: July 2015]

[7] Knowles, R. and Olafsdottir, F. (2012) *Initial Clinical Referral Standards after Newborn Screening for Congenital Hypothyroidism: Draft Report of the UK Newborn Screening Programme Centre (UKNSPC) Expert Working Group and Systematic Evidence Review 2010-2011* [Online] Available: http://openhealthdata.metajnl.com/articles/10.5334/jophd.ae/ [Accessed: July 2015]

[8] NHS Newborn Blood Spot Screening Programme / NHS Connecting for Health (2014) *NHS Numbers for Newborn Screening: Output Based Specification for the Blood Spot Card Label v3.4* [Online] Available: https://www.gov.uk/government/publications/nhs-

numbers-for-newborn-screening-specification-for-the-blood-spot-card-label [Accessed: July 2015]