Public Health England

NHS

Consultation on Newborn Blood Spot (NBS) Screening Standards – summary of responses

Public Health England leads the NHS Screening Programmes

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health, and are a distinct delivery organisation with operational autonomy to advise and support government, local authorities and the NHS in a professionally independent manner.
Public Health England, Wellington House, 133-155 Waterloo Road, London SE1 8UG
Tel: 020 7654 8000 www.gov.uk/phe
Twitter: @PHE_uk Facebook: www.facebook.com/PublicHealthEngland

About PHE screening

Screening identifies apparently healthy people who may be at increased risk of a disease or condition, enabling earlier treatment or better informed decisions. National population screening programmes are implemented in the NHS on the advice of the UK National Screening Committee (UK NSC), which makes independent, evidence-based recommendations to ministers in the four UK countries. The Screening Quality Assurance Service ensures programmes are safe and effective by checking that national standards are met. PHE leads the NHS Screening Programmes and hosts the UK NSC secretariat.

PHE Screening, Floor 2, Zone B, Skipton House, 80 London Road, London SE1 6LH
www.gov.uk/topic/population-screening-programmes
Twitter: @PHE_Screening Blog: phescreening.blog.gov.uk
For queries relating to this document, please contact: phe.screeninghelpdesk@nhs.net

Published January 2017
PHE publications gateway number: 2016585

Contents

Aim

This paper presents responses to the stakeholder consultation on the revised newborn blood spot (NBS) screening standards.

Background

The NBS programme aims to support health professionals and commissioners in providing high quality NBS screening services. This involves the development and regular review of quality standards against which data is collected and reported annually. The standards provide a defined set of measures that providers have to meet to ensure local programmes are safe and effective. They also help to drive improvement. The NBS standards were last revised in 2013.

Approach

We reviewed the 2013 standards and identified necessary changes (eg incorporation of expanded screening conditions) and areas to target for improvement (eg use of barcoded labels). During this process we examined performance data, lessons learnt and screening helpdesk enquiries on the standards. We drafted proposed revisions and discussed these with our clinical, laboratory and quality assurance leads, and presented them to the Screening Data Group before going out to wider consultation.

We consulted on 14 standards using SelectSurvey. The standards document and a link to the survey were published on the PHE consultations page and the PHE Screening blog. They were also cascaded to programme stakeholders by email. The consultation ran from 26 August to 26 September 2016. Participants could answer questions on all of standards or select standards of interest.

The standards

1a: Coverage (CCG responsibility at birth)
1b: Coverage (movers in)
2: Timely identification of babies with a null or incomplete result recorded on the CHIS
3: Barcoded NHS number label is included on the blood spot card
4: Timely sample collection

5: Timely receipt of a sample in the newborn screening laboratory
6: Quality of the blood spot sample
7: Timely taking of a second blood spot sample for CF and CHT screening
8: UKAS (screening)
9: Timely processing of CHT and IMD screen positive samples
10: UKAS (diagnosis)
11: Timely receipt into clinical care
12a: Timeliness of results to parents (CCG responsibility at birth)
12b: Timeliness of results to parents (movers in)

Proposed changes

- change reporting deadline for laboratory standards to 30 June
- updates to some thresholds to reflect recent performance
- report PKU coverage (standards 1a and 1b) as proxy for all 6 metabolic diseases
- focus on barcoded NHS number labels in standard 3 to drive increased use
- focus on day 5 only in standard 4 to improve timeliness of sample collection
- focus on receipt within 3 working days in standard 5 to improve timeliness
- focus on day 21 for CF repeats in standard 7 to maximise accuracy of test and timeliness of referral
- remove laboratory accreditation standards (8 and 10) as they are in the service specification (Section 7a)
- develop an audit tool to replace standard 12 (timeliness of results to parents)
- if retain standard 12, introduce standard 12b for movers in

Results: number of responses

SelectSurvey

Number of clicks on survey link = 252
Number of responders that provided details (name, organisation, role etc.) = 55
Number of responders that answered questions on the standards = 11 – 32

Email

Number of email responses = 6

(2 responses related to consent and secondary uses of blood spot samples, 1 correction to survey response, 1 response from professional body, 1 response from laboratory lead, 1 collated response from newborn screening laboratories).

Results: organisations

(exact duplications removed)
NHS England
Birmingham Women's NHS Foundation Trust
Association for Improvements in the Maternity Services
PHE – SQAS
NHS
PHE
The Pathology Partnership, Cambridge University Hospitals NHS Foundation Trust
NUH
PHE/NHSE
MedConfidential
Oxford University Hospitals NHS Foundation Trust
Solent NHS
Royal College of Midwives
Western Sussex hospitals NHS Trust
Association for Clinical Biochemistry and Laboratory Medicine
Swindon Borough Council
Lewisham and Greenwich NHS Trust
Newborn Bloodspot Screening Wales
Dorset HealthCare University Foundation Trust
Public Health Agency (N Ireland)
PHCSG
NHS Lothian
Brighton and Sussex University Hospitals NHS trust
Great Western Hospital NHS Trust
Sheffield Children's Hospital
NHS Forth Valley
Derby Teaching Hospitals NHS Foundation Trust
Sheffield Children
UKNSLN
Screening QA Service
South East Thames Newborn Screening Laboratory
NSPKU
Great Ormond Street Hospital
Wirral University Teaching Hospital
WUTH
Royal College of Pathologists

Results: roles

(exact duplications removed)

Commissioner
Matron
Inpatient Matron
President
QA Advisor
Senior QA Advisor
Screening Coordinator
Director Newborn Screening Laboratory
Screening and Immunisation Manager
ANNB Coordinator
Coordinator
CHIS manager
Professional Advisor
ANNB screening specialist Midwife
NHS SCT screening programme manager
Director of Scientific Affairs
Senior Child Health Performance Analyst
Programme Coordinator
Health Visitor and Newborn Bloodspot Screening Lead
Public Health Lead for Newborn Blood Spot Screening Programme
Committee member
Specialty Doctor (Cystic Fibrosis)
Midwife - AN screening Coordinator
Clinical midwifery manager
Consultant paediatrician
Project Lead
Neonatal screening midwife
Clinical Director
Chair
Deputy Director for Newborn Screening
Administrator & Parent Representative
CNS

Results: relationship with NBS screening programme

I work in a local screening programme	**9**
I work in the screening quality assurance service	**8**
I commission newborn blood spot screening services	**4**
I am a person with or have a family member with one of the conditions screened for	**1**
I am a member of a patient representative group	**7**
I am a healthcare professional	**15**
I am a member of a professional body associated with one of the conditions screened for	**2**
Other	**9**
Total	**55**

If you ticked 'healthcare professional', 'a member of a professional body associated with one of the conditions screened for' or 'other', please specify:

Midwife
Matron for Community and Antenatal services
Advisor in a professional organisation for midwives
Registered midwife and work in the NHS national screening programmes
The Association for Clinical Biochemistry and Laboratory Medicine
Performance analyst for the Swindon Child Health Information Service
ANNB Screening Coordinator – Midwife
Doctor
Paediatrician with an interest in paediatric endocrinology and clinical lead for the Scottish Paediatric Endocrine Group National Managed Clinical Network
Consultant paediatrician with an interest in paediatric endocrinology, local clinician managing infants with CHT and lead clinician for the Scottish Paediatric Endocrine Group national managed clinical network
NBS Programme Team – PHE
Neonatal screening midwife
Newborn Bloodspot Screening Wales Programme
Clinical Scientist
Director of Newborn Screening for Manchester Laboratories and Chair of the UK Newborn Screening Laboratory Network (UKNSLN)
ACB – professional organisation for chemical pathology and clinical scientists
Nurse
Local ANNB Coordinator
Local coordinator

Standard	Is the rationale clear?			Are the definitions clear?			Are the thresholds appropriate?			How useful do you feel this standard will be when monitoring the quality of your local NBS screening programme?					
	Yes	No	Don't know	Yes	No	Don't know	Yes	No	Don't know	Very useful	Useful	Neut.	Not very useful	Not useful at all	N/A
1a	16	1	0	13	4	0	12	5	1	5	7	1	0	0	3
1b	17	1	0	13	5	0	12	6	1	4	7	3	0	0	4
2	15	0	0	15	0	0	8	5	0	3	6	0	2	0	3
3	15	2	0	17	0	0	15	0	2	5	7	0	3	0	2
4	20	0	0	17	3	0	18	1	1	11	5	1	0	0	2
5	15	2	0	10	6	0	12	3	1	7	7	0	0	0	2
6	19	0	0	13	7	0	16	2	0	12	5	0	0	0	2
7	14	1	1	15	1	0	12	3	0	9	3	1	1	0	2
8	See comments below														
9	12	0	1	9	3	0	11	3	0	6	3	0	1	0	3
10	See comments below														
11	13	1	0	11	2	1	7	3	1	7	3	0	0	1	2
	Lower threshold for MCADD, MSUD, IVA?			**Include SCT standards?**											
	5	7	2	9	3	2									
12a	10	1	1	10	1	1	9	2	1	0	6	1	3	1	2
	Remove and develop audit tool?														
	6	7	1												
12b	8	4	1	8	3	0	7	2	2	1	3	0	5	0	2

Standard 1a – rationale

Comments:

1. Is this a rationale or an objective? The rationale is to ensure all babies etc. the objective is the second box. The verbal consent of the parent or representative not the baby.

Response/outcome/changes made:

2. The rationale has been changed to ‘This standard is to ensure that all eligible babies are offered NBS screening and, with verbal consent from a parent, tested within an effective timeframe’.

Standard 1a – definitions

Comments:

3. The definition of 'eligible babies' states that "the cohort includes only babies for whom the CCG was responsible at birth and is STILL responsible on the last day of the reporting period." The word 'still' is confusing as it excludes babies that move to a different CCG and back again within the reporting period, who are also excluded from Standard 1b, which states they must be born outside the CCG.
4. Not clear - babies registered within the CCG at birth and on last day of reporting period - is this not two different criteria? I'm confused.
5. Criteria will miss some babies who move between CHRD responsibilities during the reporting period.
6. Why 8 days? Not 5 days? This is a long explanation that could be clearer and shortened.

Response/outcome/changes made:

7. Definition of eligible babies has been changed to ‘For this standard, the cohort includes only babies for whom the CCG was responsible at birth and on the last day of the reporting period’.
8. The programme will write examples of scenarios to accompany this standard.

Standard 1a – thresholds

Comments:

9. I wanted to select yes to this question but it changes to No when I enter the message: Based on the 2014/15 data: Median age at initial clinical referral for SCT positive babies is 16 days so referral for SCT positive babies is 16 days so when messaging is in place achievable standard will be more realistic. Currently born and resident coverage by 17 days =94.4%.
10. The split achievable standard is confusing - should be simplified to ≥ 98.0% of eligible babies have a result for all conditions recorded on the CHIS at less than or equal to 17 days of age.
11. I find the differences of the different conditions slightly confusing even though I appreciate the rationale behind this.
12. Achievable target of 99.0% with results on CHIS by 17 days for IMD and SCD (this is actually relaxed slightly from the previous standard of 99.9%). It is highly unlikely that this will be achieved if SCD is kept in this section with the same target, as 0.9% of all our samples go for confirmatory testing by IEF, most will be reported as carriers, and most will not be reported to CHRD by day 17.
13. It is highly unlikely that this is achievable. With regards to sickle cell screening, Sheffield estimate that 0.9% of samples go for confirmatory testing by IEF (this is typical of most labs) , most will be reported as carriers, most will not be reported by 17 days. Second tier testing is also a feature of the protocols for CF and HCU. This testing involves external labs and tests in many cases are performed on a weekly basis. Most babies will therefore not meet the 17 day target.

Response/outcome/changes made:

14. SCD has been moved to the 98% achievable threshold.

Any other comments:

15. NBS for SCD uses a two stage process, an alternative procedure using a different principle is used for second line testing to validate the initial result - please can this be incorporated into your mitigation statement.
16. Mitigation should also include 2nd tier testing. SCD/HCU/CF screens all include a second tier test as part of the protocol. This involves an external lab and all are done on a weekly batched basis. Most babies will therefore not meet the 17 day target. Based on the Q1 data - 0.62% of all samples go for CF DNA (most will ultimately be reported not suspected), 0.9% go for IEF, 0.2% go for sickle DNA, and some go for THC.

17. Could 1a and 1b be combined? Why are they separated? Could need for exception reporting be added here? Reporting should include CHRD by individual CCG as some report by 2 or more CCGs.
18. In Wales, we would currently struggle with separating out the conditions. This may change in the future. We think that the SCD coverage should be grouped with CF and CHT rather than with the IMDs as further testing is sometimes required (sickle DNA or confirmatory testing by hematology). In these cases it would be impossible to meet the standard for these samples.

Response/outcome/changes made:

19. Comments acknowledged – thank you
20. Standard 1b allows a longer period to have results on the CHIS. Standard 1a is more timely for the born and resident population. Reporting focus is individual CCGs, recognizing some CHRD report more than one.

Standard 1b – rationale

Response/outcome/changes made:

21. The rationale has been changed to ‘This standard is to ensure that all eligible babies are offered NBS screening and, with verbal consent from a parent, tested within an effective timeframe’.

Standard 1b – definitions

Comments:

22. The definition for 'changed responsible CCG' states that the "baby was born out of the CCG but has become its responsibility because he/she moved and was notified to CHRD within the reporting period." The criterion that the baby must be born out of the CCG excludes those babies who transfer to a different CCG and back to their CCG of birth within the same reporting period, which are also excluded from Standard 1a which specifies that the CCG must still be responsible for the baby at the end of the period.
23. The standard should acknowledge that some CHRDs are responsible for more than 1 CCG eg a baby may change GP registration from CCG 1 to CCG 2 to another but the same CHRD is responsible for the CCG 1 and CCG 2. This should be changed to reflect that as otherwise there is a lot of inappropriate activity and counting.
24. The objective is not clear: To accurately identify the population to whom screening is offered [how do you know whether it has been offered or not? how do you know that verbal consent has been obtained?] and to maximise coverage in the eligible population

to whom screening if offered[how is this going to maximise coverage? how do you know who has been offered screening and who has not] who is fully informed [how do you know if they are fully informed?] and wish to participate in screening [is this really the objective?] Surely the objective is plainly: To accurately identify the eligible population and uptake of screening amongst this group.

25. In eligible babies, any less than or equal to 364 days on notification are included. The guidelines for movers in states that these are only tested if a sample can be collected before the baby reaches 1 year of age.
26. These standards will be introduced in April 2017, assuming that providers will be reporting for year April 2016 to March 2017 - means there will be no babies who fall in to the category of not eligible for expanded screening.

Response/outcome/changes made:

27. Added in brackets ‘only if the blood spot sample can be taken before they reach a year of age’.
28. The exclusion is still valid until Scotland introduces expanded screening as the numbers of movers in from Scotland would be too burdensome to be re-screened.
29. Standard 1a will capture babies who transfer to a different CCG and back to their CCG of birth within the same reporting period.
30. The newborn blood spot sampling guidelines (https://www.gov.uk/government/publications/newborn-blood-spot-screening-sampling-guidelines) provides more information about offer and consent.

Standard 1b – thresholds

Comments:

31. Not enough time to engage families from abroad to attend, and other services to appt.
32. I wanted to select yes to this question but it changes to No when I enter the message: Based on the 2014/15 data: Movers in coverage for SCT by 21 days is 75.5% but this is a new KPI so we support existing thresholds to see impact on KPI returns.
33. Due to the nature of transfers across CCG boundaries and especially babies born abroad, it is often difficult to obtain results within 21 days. Collecting the data involves a considerable amount of telephone and email communication with other Child Health Record Departments and Health Visitors and is only successful when the samples themselves have been taken and sent to the laboratory in a timely manner.
34. The split achievable standard is confusing - should be simplified to ≥ 98.0% of eligible babies have a result for all conditions recorded on the CHIS at less than or equal to 17 days of age.
35. Yes I’m more interested in the babies who did not have screening - because they have not been offered it. I think I’m finding this standard confusing. Do you record declines

under tested babies because they were offered and declined screening? This would be important to record for coverage rather than just results of tests [Sorry if I have missed something here in the documents that clarify this further - feel free to call me and discuss!

36. Some SCD, CF,HCU results will not be available by 17 days of age due to second tier testing - see comments appended for Standard 1a. Some movers in may be omitted from the data if the reporting period is based on DOB, as they may have entered the CCG responsibility within the reporting period, but not have been born within it.

Response/outcome/changes made:

37. Data supports this can be achieved but it is acknowledged that processes/pathways may need reviewing to meet this standard.
38. The achievable threshold is to drive performance improvement.
39. Declines (status code 02) should be recorded on the CHIS and included in the denominator but not the numerator – decline data is collected and reported alongside coverage data to help interpretation.
40. No baby is omitted as based on DoB

Any other comments:

41. There is a problem with reporting within the UK, as screening for all 9 conditions has been carried out but not reported on. We have been advised to rescreen these babies (who have moved within the UK) which has now proved to be unnecessary, following further research.

Response/outcome/changes made:

42. Agree there is a reporting issue that needs to be addressed by laboratories, CHRDs/CHIS.

Standard 2 – thresholds

Comments:

43. There should be an acceptable standard that CHRD complete daily checks for babies ≥ 17 days to = 8/52 as CF screening is possible and completes weekly checks for babies ≥ 8 weeks to ≤ 364 days an achievable standard that CHRD complete daily checks for babies ≥ 14 days to = 8/52 as CF screening is possible and completes weekly checks for babies ≥ 8 weeks to ≤ 364 days. At the moment the standard is not specific enough.
44. Are there levels to this or is just yes or no?
45. Suggest removing 'minimum weekly' and leave as 'ideally daily' or just 'daily'.

Response/outcome/changes made:

46. This standard is about identifying babies, not about the conditions.
47. In the current wording, it is a yes/no response, may consider a timeliness standard in the future.
48. ‘minimum weekly’ to remain

Standard 3 – rationale

Comment:

49. Is the use of barcoded labels mandated or not? Make it clear, if not mandated why are we measuring it?

Response/outcome/changes made:

50. It is not mandated as it would mean a steep rise in the avoidable repeat rate. If we can increase the use of bar coded NHS number labels, it may well be mandated in the future.

Any other comments:

51. Why is the bar code label required - what about another label which includes the baby's NHS number as I'm not sure if the labs use the bar code and providers require a specific printer for these labels and they often seem to go wrong and as this is the only use for the printer the repair of them may not be a priority.
52. Mitigations could include barcoded labels which fail to scan. These will be classed by us as not being a label, but may not be detected until the data is collected. This would not give units the opportunity to resolve issues real time. However, we would not be able to provide information on these specific ones as we cannot distinguish them from the samples without labels.
53. If the standard only measures the inclusion of a barcoded NHS number label on the card, the standard could potentially be met with up to 10% of cards not having an NHS number at all. In Wales, we will continue to have a separate standard for the number of samples received with an NHS number irrespective of whether a barcoded label is used. We do not currently use barcoded labels so we would not be able to report against the revised standard. We plan to use barcoded NHS number labels in the future.
54. The UKNSLN welcomes the move towards focusing on barcode labels. Mitigations could include barcoded labels which fail to scan. Could it be clarified if this is the 22 digit barcode or any barcode that contains a barcoded NHS number on the label?
55. Difficult for laboratories to provide data by maternity service unless NBS cards are reviewed and include the name of the maternity service taking the blood spot sample.

56. The laboratory system will only allow recording of one NHS number per patient record. If two cards are received for the same patient, one handwritten NHS number and one barcode NHS number the system will only record the way the NHS number was provided on the first sample received.
57. If the use of NHS numbers on the baby's blood spot card is mandatory then should the acceptable threshold be higher?

Response/outcome/changes made:

58. It needs to be an approved bar coded NHS number label where all the fields are in the same place (OBS compliant: https://www.gov.uk/government/publications/nhs-numbers-for-newborn-screening-specification-for-the-blood-spot-card-label) in order for the labs to enter the data quickly and accurately into their management system. All maternity units were supplied with label printers and the labs with bar code scanners.
59. If the labels do not scan, they will not be compliant with the OBS. Labs should inform the maternity units that their labels do not scan and direct them to the OBS.
60. We will still be monitoring avoidable repeats for no NHS number.
61. Yes this should be a 22 digit code that is GS1-128 compliant. More information about label content and format is in the OBS
62. Currently bar coded labels which fail to scan do not constitute an avoidable repeated provided the NHS number is valid
63. Labs should be able to report by maternity unit currently. Agree blood spot card needs to be reviewed.
64. Only one lab cannot over-write incorrect NHS number
65. The threshold is set to reflect barcoded NHS number label not just the presence of an NHS number.

Standard 4 – definitions

Comments:

66. "Exceptional circumstances" are not defined; not clear if these account for the <10% of samples not taken on day 5 (allowed under the acceptable standard) or if these are additional exceptional circumstances. We would be unlikely to be able to exclude these ones from any statistical analysis.
67. Should this have (excludes pre-transfusion samples) included in the top line of the calculation as well?

Response/outcome/changes made:

68. Agree it would be difficult to collect and therefore exclude samples that have a genuine reason not to be collected on day 5. We are aware there are circumstances where this applies hence the threshold setting.
69. Reference to '*excludes pre-transfusion samples'* has been removed from the table.
70. Added 'and numerator' to the sentence 'Pre-transfusion samples are excluded from the denominator and numerator'.

Standard 4 – thresholds

Comments:

71. Thresholds need to be higher. Acceptable - 95% and Achievable - 98%

Response/outcome/changes made:

72. There's currently only one English lab achieving the proposed acceptable threshold of 90%. Thresholds will be reviewed annually.

Any other comments:

73. We have recently seen a decrease in number of samples being collected on day 5, seemingly due to the new maternity standard of a visit being required on day 4 and a reluctance of midwives to visit on consecutive days. I don't know if there is anyway of joining up these midwifery duties.
74. RCM would consider this a new challenge in the current climate in postnatal care provision. It may result in being a positive driver to improve services or a negative one to ensure task completion. Current postnatal care is scaled down drastically at weekends and the risk maybe that visit is provided only to take the bloodspot samples. This may not be a midwife to complete a full postnatal assessment and care but in statistics recorded as postnatal visit. The worst scenario could be development of bloodspot screening clinics run by a maternity care assistant/technicians. Bank holiday weekends may also challenge the Standard 5 as for timely receiving of the bloodspot in the laboratory. On principle though RCM recognises that the standard of obtaining the sample on day 5 would be best clinical practice and on that principle support the change. If the threshold is achievable it will be interesting to see the data after change and if there is a negative impact on care outcomes, standard should be reviewed. As a stakeholder RCM would observe this.
75. Remove this statement. In exceptional circumstances the blood spot sample can be taken between day 6 and day 8 inclusive. As it sounds like sample not needed after day 8.
76. Under criteria: should read ' the proportion of FIRST blood spot samples taken on day 5'.

77. Changing this to day 5 [rather than 5-8] is long overdue! You might need to list possible mitigating reasons.
78. If day 5 is at a weekend or a Bank Holiday this puts a strain on the maternity service you only have emergency cover. The samples also do not get sent to labs who are closed so this definition should be extended to reflect this issue.
79. We also agree with changing the standard to taking the sample on day 5. This will be challenging for us in Wales as our timeliness is not currently good. In view of this we will continue to monitor samples received between day 5 and 8.
80. UKNSLN welcomes the move to focus on Day 5 for first sample collection.
81. Will this standard require continuing provision of collection dates in the quarterly stats (eg 5,6,7,8,>8)?
82. This is now the ONLY postnatal midwifery visit (and possibly there would have been none but for bloodspot sampling}. Day 5 may be best for sampling, but may not be the most appropriate for the needs of the mother. Technical procedures like this take priority, but the mother's need to talk about her birth (and possible trauma) are forgotten.

Response/outcome/changes made:

83. We are unaware of a maternity standard requiring a day 4 visit.
84. The thresholds will be reviewed using annual data collected.
85. We are aware that there are circumstances where samples cannot be taken on day 5 but a first sample should be taken by day 8.
86. Thank you for your comment. There are such a variety of mitigating reasons that it would not be possible to include all of them in the glossary.
87. The thresholds reflect the issues raised.
88. Yes this is part of the annual data collection.
89. Standard is set to detect affected babies as early as possible to prevent severe disability or even death.

Standard 5 – rationale

Comments:

90. Should include information about how long is too long for sample to be processed.

Response/outcome/changes made:

91. Added to mitigation ‘laboratories will reject samples if received more than 14 days after the sample was taken’.

Standards 5 – definitions

Comments:

92. 'Within' is unclear - I personally read it to mean 3 days or less. If that is correct would be more precise to define it as less than 4 days, or less than or equal to 3 days.
93. What are working days? The NHS is a 7 day service and babies do not cease to age on working days.
94. Difficult for maternity units who have no control over when the samples are actioned at the lab. Well the sample might arrive at the lab and sit in a bag for two days before being entered onto their system. This could influence our results for this standard.
95. Why is 3 days important? Why is sample not fit for purpose after 3 days? I think 3 days is too short, could be 5 days and still allow enough time.
96. Sample received should be defined as sample received by the lab and processed by a lab technician.

Response/outcome/changes made:

97. The word ‘within’ has been changed to ‘less than or equal to’.
98. Currently screening labs only process samples Monday to Friday.
99. Agree samples may be processed the next working day thus influencing the results for this standard. This requires local auditing.
100. The timeframe is to allow for timely access to care for screen positive babies.
101. Sample received is defined as when it is recorded on the laboratory information management system.

Standard 5 – thresholds

Comments:

102. 3 working days is appropriate if the lab guarantees to action received samples immediately. I hope it takes into account TIME as well as DATE of sample collection however.
103. If it is a long BH weekend couriers do not collect specimens and labs who process bloods are not open this needs to have a clause added to it.
104. Criteria should be within 2 days of sample collection.

Response/outcome/changes made:

105. Currently time is not a field on the blood spot card, this will be reviewed.
106. NHS England is addressing bank holiday weekend working.
107. Thresholds are based on annual data from the labs.

Any other comments:

108. Mitigations must include disruption to postal service eg weather.
109. By changing the standard from 99% within 4 working days to 95% within 3 working days, this may mean that we wouldn't capture around 4% of samples that may be quite outside the standard.

Response/outcome/changes made:

110. Disruption to postal services is not a mitigation.
111. NBSFS will help capture this data

Standard 6 – definitions

Comments:

112. Does 'less than 3 clear calendar days' of a blood transfusion mean that if the transfusion is given on Monday - tues, weds & thurs are the clear days - so the next time a sample can be taken is Friday? The removal of 72h from the standards is welcomed however as it is not possible to measure this with the information given on the screening card.
113. There should a standard 6a for babies < or='28 days and 6b for babies 29 days to 364 days as maternity units willows reflecting avoidable repeat rates for babies for which they have never had responsibility.
114. I would suggest leaving the 'too young' category out of this definition because:
    1. variation in practice by labs in relation to requesting a repeat for a day 4 sample means that we are not making fair comparisons.
    2. reporting on standard 4 could be used to report on this aspect of quality (ie % taken at less than 5 days)
    3. as historic data exists for avoidable repeat samples defined as insufficient and unsuitable, this would allow trends over time to be more easily assessed.
115. We do not exclude the <72hr post transfusion samples from our overall avoidable repeat data. We do report it as a breakdown figure so these may be excluded at a later point (ie after we have submitted the data). Clarification needed on this standard as to what is expected of the laboratory.
116. Why does this now say before 3 days rather than 4? routine sample by day 8 rather than 5? it would be better to be consistent here.
117. This will exclude any pre-transfusion cards which do not meet the currently standards for demographics/collection quality. How will poor performance for pre-transfusion cards be flagged to the relevant units/co-ordinators?

Response/outcome/changes made:

118. Please see appendix A in the blood sampling guidelines: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/511688/Guidelines_for_Newborn_Blood_Spot_Sampling_January_2016.pdf (this link will be included in the new standards when published).
119. This standard reflects first blood spot samples received by the laboratories, where babies should be less than 28 days.
120. Consensus is to retain *'too young'* category and drive consistency in practice.
121. 'Note that repeat samples requested because the previous sample was taken too soon (less than 3 clear calendar days) after transfusion are excluded from the numerator as the routine sample should be taken by day 8 at the latest' – is already included in the definitions.
122. Less than 3 calendar days is trying to be clearer than 72hrs since time of sample collection is not recorded on the card. Day 8 is the latest the routine sample should be taken.
123. Eventually this will be auditable from NBSFS data.

Standard 6 – Thresholds

Comments:

124. The acceptable threshold is not evidence based but neither is there good evidence to justify changing it. Over time fewer labs/regions have met the standard despite much effort to improve. I appreciate this is not justification for changing it. However I am concerned about the observer variability in categorising samples and that we do not have robust evidence of what works in terms of improvement (which providers need in order to develop an effective response to under performance against this standard). There is an argument for setting the standard based on centiles eg that which the majority of providers achieve, as being realistic but challenging (with the threshold rising as providers improve). The 50th centile would be around 3%, as currently defined.
125. Not sure 0.5% is realistic as so few achieve 2% now. It doesn't allow any provider to get the achievable.

Response/outcome/changes made:

126. Some maternity services meet the acceptable threshold therefore we are trying to drive improvement and reduce the number of babies needing repeat samples.
127. The achievable threshold has been changed from 0.5% to 1%

Any other comments:

128. Include within card expiry date.
129. Reporting focus should change Babies 29 to 364 days by CCG as there is inequitable data reporting across the country - some maternity units are submitting their own locally collated data informed by lab data as lab cannot report by maternity unit and some are reporting by lab data only which includes older babies as lab required to report by maternity service which is not appropriate for older babies.
130. An easy to follow pictorial guide on how to obtain a high quality sample would be useful.
131. Repeat procedures are distressing for babies - and mothers. This has been shown to possible refusal of testing for later babies.

Response/outcome/changes made:

132. Status codes with all avoidable repeat categories is referenced.
133. Agree these should be excluded from the maternity services avoidable repeat rate but this will be dependent on whether the labs can do this.
134. Please see Guidelines for Newborn Blood Spot Sampling (https://www.gov.uk/government/publications/newborn-blood-spot-screening-sampling-guidelines) referenced in definition section.

Standard 7 – rationale

Comments:

135. Should include information on taking within 3 days of repeat request clearly here.

Response/outcome/changes made:

136. Standard 7 has now been split into three standards (7a, 7b and 7c). Timeliness for a second blood spot sample for CF and CHT screening is in the definitions section of 7a, 7b and 7c.

Standard 7 – definitions

Comments:

137. What about preterm babies with borderline TSH? Do they then need a repeat 7 to 10 days after the initial borderline sample and then another one?
138. Exclusions: What is the rationale for preterm TSH repeats? Why the different threshold of 28 days or discharge home as some babies samples have been rejected by labs if they are younger than 28 days and not being discharged or card not marked for.

Discharge while another baby who is being discharged home at equivalent or younger gestational age equivalent sample is ok - very confusing. For providers and all.

Response/outcome/changes made:

139. Yes if the baby is still <32 weeks equivalent gestation.
140. This is a pragmatic decision to make sure screening is complete before being lost to follow up in the community. See section 5.9 in the Guidelines for Newborn Blood Spot Sampling (https://www.gov.uk/government/publications/newborn-blood-spot-screening-sampling-guidelines).

Standard 7 – thresholds

Comments:

141. Why day 21? In exceptional circumstances the blood spot sample for raised IRT can be taken between day 22 and day 28 inclusive - why include this?
142. Acceptable >98% and Achievable >99%
143. The standard regarding collection of IRT repeats on Day 21 is not currently achievable.

Response/outcome/changes made:

144. Standard 7 has now been split into three standards, standard 7a, 7b and 7c.
145. Standard 7a measures ‘timely taking of a second blood spot sample for CF screening’.
146. Standard 7a – added ‘to day 24’ in the definitions (‘number of second blood spot samples for raised IRT taken on day 21 to day 24 (day of birth is day 0’)
147. Standard 7a – acceptable threshold changed to ≥ 95% of second blood spot samples taken on day 21 to day 24 (this allows for day 21 to fall on a weekend when a special visit is not warranted).
148. Standard 7b – achievable threshold changed to ≥ 70% of second blood spot samples taken on day 21

Any other comments:

149. There are 2 standards here so they should be split to 7a and 7b.
150. IRT repeats are currently requested at day 24, so changing to day 21 would require a change in practice locally. It would also remove the flexibility to select sample days to minimise parental anxiety. eg nurse availability, avoiding weekends etc. Could this flexibility be included in mitigations?
151. I don’t understand why the sample can be taken when they reach day 28 or on discharge home, why the differences? This should be day 28 only.
152. In Wales, we would want to continue with the standards for timely taking of avoidable repeats and second samples for TSH (pre-term) as we are not currently meeting those

standards. The avoidable repeats timeliness is of particular concern as it affects a greater proportion of babies.

153. A number of comments received from screening lab directors regarding the proposed move to day 21 for IRT repeats. Sheffield NBSL: this will mean a change in local process. Currently we request samples to be collected on D24, as D21 does not really allow much time to return to normal in the low risk cases. D21 will likely increase the number of false positives. Also need flexibility around this date to co-ordinate with nurse availability and to avoid weekends. This does not compromise the effectiveness of the screen and is always done with the express intention of minimising parental anxiety. Birmingham NBSL: only 37% of samples for raised IRT were collected on D21 in last financial year, therefore there would need to be a change in policy/practice to move towards D21 only. Manchester NBSL: In the last financial year 57% were collected on D21. The Health Visitors would be best placed to say whether a target of 95% is achievable.
154. How will the NBSFS collect this data? Should it not be laboratory level collection? Is there an issue with this process currently?

Response/outcome/changes made:

155. The standard is there to ensure screening is complete before being lost to follow up in the community. See section 5.9 in the Guidelines for Newborn Blood Spot Sampling (https://www.gov.uk/government/publications/newborn-blood-spot-screening-sampling-guidelines).
156. Standard 7a – added ‘to day 24’ in the definitions (‘number of second blood spot samples for raised IRT taken on day 21to day 24 (day of birth is day 0’).
157. Standard 7b measures ‘timely taking of a second blood spot sample following a borderline CHT screening’
158. Standard 7c measures ‘timely taking of a second blood spot sample for CHT screening for preterm infants’.
159. Standard 7a *(timely taking of a second blood spot sample for CF screening)* thresholds have changed as agreed with the CF screening advisory board.
160. The standards will be implemented April 2017 therefore will have data collected on them 2018/19. Labs will collect this data until then and hopefully this burden removed when NBSFS is fully functional.

Standard 8 –proposal to remove standard

Response/outcome/changes made:

161. All comments on this standard have been considered. As this is a structural standard, it will now be retained in section 12 – ‘Mandatory UKAS requirements’.

Standard 9 – definitions

Comments:

162. Within 3 working days is not clear - re-define as less than 4 days.
163. Definition of a screen positive for CHT varies with equipment. GOS have changed cut-off to 18mU/L since moving to GSP.

Response/outcome/changes made:

164. Four days is not the same as three working days.
165. Reference to TSH cut-off has been removed

Standard 9 –thresholds

Comments:

166. HCU cannot be referred within 3 working days of sample receipt. 2nd tier testing has a turn-around-time of 1 week. Also mitigation must include equipment failures.
167. These thresholds are extremely tight and not achievable in the case of a run failure (a not infrequent occurrence). Mitigation must include equipment failure. HCU cannot be referred within 3 working days of sample receipt. 2nd tier testing has a turnaround time of 1 week.
168. HCU will fail this standard due to additional testing requirements in comparison to the other IMD.

Response/outcome/changes made:

169. HCU has been excluded from the definitions and threshold
170. Equipment failure is not a mitigation

Any other comments:

171. We do not look at referrals following positives results as this does not usually include maternity services, is this included when QA takes place into regional lab? Should it be included?
172. Sample receipt is when the sample is recorded as received on the laboratory information management system - some laboratories have a delay entering sample arrival in the laboratory. This could make the threshold more easily achievable.

Response/outcome/changes made:

173. The programme collected day of referral from the labs as part of annual data collection.
174. The programme is aware there are different lab processes which means receipt of sample times are not always comparable.

Standard 10 – proposal to remove standard

Response/outcome/changes made:

175. All comments on this standard have been considered. As this is a structural standard, it will now be retained in section 12 – 'Mandatory UKAS requirements'.

Standard 11 – rationale

Comments:

176. Is this part of screening? The results are reported back to the Trust and this should be part of the referral process. I would be interested to know how this data is collected.

Response/outcome/changes made:

177. Title of standard changed to '*Timely entry into clinical care'*. The word '*entry*' has replaced previous word '*receipt*'.

Standard 11 – definitions

Comments:

178. Definitions are clear but we would like to include SC standard for completeness.

Response/outcome/changes made:

179. Sickle cell disease standard included

Standard 11 – thresholds

Comments:

180. Day 14 first appointment seems late for IMDs.

181. IMDs: First clinic appointment by 14 days of age, not possible for HCU. CHT: Suspected on first sample: First clinic appointment by 14 days is extremely tight. In Manchester using last year's figures we would achieve 75%. (12/16, range 12-16 days, excluding 4 inpatients/detected prior to screening).
182. CF (1 or no CFTR mutation detected) - not clinical but not sure why this would be as low as 80% for acceptable.

Response/outcome/changes made:

183. Day 14 accounts for sample not being taken until day 5 and transportation to the lab.
184. HCU has been excluded from the IMDs to take account of second tier testing. The IMD screening advisory board agreed to include HCU in the performance threshold section. The intervention/treatment for HCU is now 'Attend first clinical appointment by 28 days of age' (thresholds: acceptable ≥ 95.0%, achievable 100%).
185. CF screening protocol requires a day 21 sample for some initial results.

Standard 11 – should MCADD, MSUD and IVA have a lower threshold?

Comments:

186. The thresholds are appropriate given the difficulties in getting samples taken on day 5 and the getting samples to the laboratory. Before changing the threshold need to focus on getting samples taken on day 5 and reducing the length of time samples are in the post.
187. Don't know - if the extra pressure on the labs is of benefit to babies.
188. I do not like to see differing levels, it confuses stakeholders.
189. It is still appropriate for these infants to be seen as soon as possible, so that treatment may be initiated.
190. Clinical referral by day 14 is challenging secondary to postal issues etc. and therefore setting earlier referral targets may not be achievable. Our recommendation would be to implement the day 14 target for all conditions and then audit the referral dates to see if it is achievable to move these thresholds to earlier clinical referral.
191. Age at referral has been made tighter in this iteration of the standards. Any move to shorten further requires consultation with screening labs.
192. Time critical conditions so should be seen asap.

Response/outcome/changes made:

193. Revised standard 4 is now requiring the blood spot sample to be taken on day 5.
194. Variation in threshold is unavoidable due to the different conditions.

195. 14 day target is not appropriate for some of the conditions due to the screening protocols.
196. The age at referral is not less than the previous achievable threshold.

Any other comments:

197. I'm not sure if this standard should be included as this is a treatment standard and the information needed is captured in standard 9.
198. We would struggle to meet the day 14 standard for IMDs and CHT due to our poor sample timeliness.
199. Need to clarify how inpatients should be counted (? exclude or use age at referral as age of appointment. Consider moving to a single set of standards which includes SCD.

Response/outcome/changes made:

200. Title of standard changed to '*Timely entry into clinical care'* which will be captured from laboratory data.
201. HCU has been excluded from the IMDs to take account of second tier testing. The IMD screening advisory board agreed to include HCU in the performance threshold section. The intervention/treatment for HCU is now *'Attend first clinical appointment by 28 days of age'* (thresholds: acceptable ≥ 95.0%, achievable 100%).
202. Timely entry into clinical care is measured by age at first clinical appointment attended. SCD now added to thresholds.

Standard 12a – remove and develop audit tool?

Response/outcome/changes made:

203. All comments on this standard have been considered and both standards 12a and 12b will be retained.

Standard 12a – definitions

Comments:

204. Needs to include status code 10

Response/outcome/changes made:

205. Status code 10 added

Standard 12a – thresholds

Comments:

206. I think 6 weeks is too long - I would opt to reduce this timeframe.
207. No standard should be set at 100%: this is never achievable.

Response/outcome/changes made:

208. This is to tie in with the 6 week newborn and infant physical examination.
209. All parents should receive their baby's results.

Any other comments:

210. The comments about CHRD not sending letters is confusing, we have no way of checking if the information has been recorded, and no reassurance that parents have received them. Also, the letters allow further information to be available such as weblinks.
211. The "normal results to parents letter" was introduced to circumvent the problem of failure to give results verbally due to lack of resources. The method of communication of normal results should be revisited - there have been a number of incidents resulting from generation of inappropriate normal results letters - often when results were pending for some conditions and the baby was subsequently found to be a carrier.
212. Where improvement needs to happen is where there is one suspected result. How are the results of the other 8 conditions given?
213. The content of letters sent to parents is officious, out-of-date, unsympathetic, and has been criticised by parents. We would like these revised.

Response/outcome/changes made:

214. Added *'to parents'* in the last paragraph of definitions.
215. Added link to template letters in definitions
216. Not all CHRDs sent letters to parents. Sometimes the results go to GP Practices.
217. Need failsafe in place prior to letter being sent. The incidents are few compared to the number of parents now receiving screening results by letter.
218. There is a template for one condition suspected result and 8 not suspected
219. Template letters will be reviewed and consulted.

Standard 12b – rationale

Comments:

220. Not all movers in will have 9 results as CF cannot be offered, also states earlier that if <1 year will not be offered extended screening therefore these cannot meet this standard. I feel there would be a disproportionate amount of work to sift these out.
221. Surely the same as 12a, why is this a separate standard when the same criteria applies?

Response/outcome/changes made:

222. Data indicates these are a vulnerable group who are not always offered screening.
223. deleted '9'
224. 12a and 12b capture a different cohort.

Standard 12b – definitions

Comments:

225. Needs to include status code 10.
226. The exclusion of babies too old for CF may mean that some will interpret this to mean any baby over 8 weeks old, this needs to be clearer.

Response/outcome/changes made:

227. Added status code 10
228. Added to mitigation/qualification: 'Babies more than 8 weeks of age are too old for CF screening but are still eligible to be screened for the other conditions'.

Standard 12b – thresholds

Comments:

229. No threshold should be set at 100% as this will never be achievable.
230. No performance threshold in standard.

Response/outcome/changes made:

231. Threshold added

Any other comments:

232. Waste of time and money. Documented verbal conversation between HCP and parent should be sufficient. Or electronic feed through red ebook be more appropriate.
233. If the process works for born and resident population then it should work for all so we suggest 12a can be proxy measure for 12b and reduce burden of data collection.
234. CHRDs do not monitor this currently they only monitor newborn results.

Response/outcome/changes made:

235. All screening programmes send result letters. Parents want written record of the results. Electronic results should also be accessible when functionality is available.
236. Data indicates these are a vulnerable group who are not always offered screening, therefore important to monitor.

Do you think all of the key points in the pathway are captured?

Yes	24
No	0
Don't know	8

If no, please explain:
Comment:

237. Results to parents and to GPs are not captured. We would like to develop and pilot a standard to drive ANNB results onto the GP medical record.

Response/outcome/changes made:

238. Agree this piece of work is needed.

Comment:

239. There has to be a cut off regarding offering the screening to movers into the UK. The standard is for the screening to be completed within 21 days, and therefore I believe the cut off should be 21 days before the first birthday. It is not as simple as the screening that the midwives carry out; these families tend to be difficult to contact and often go back to their country after registering, also it takes time to issue an NHS number. Appointments need to be made and there is always a delay. It is not ethically correct to offer something that then cannot be achieved as the screening CANNOT be done after the age of 1 year. I have just spent time apologising to a family who were offered screening but unfortunately cannot now be carried out.

Response/outcome/changes made:

240. See updated information here: https://www.gov.uk/government/publications/movers-in-screening-babies-with-no-available-records

Comment:

241. Within AN infectious disease screening there is a robust policy now for women who decline screening with face to face discussions and reoffer of screening later in the pregnancy [in view of the impact for the baby of a missed positive result in a woman]. I fail to understand why there is not the same type of follow up within the policy for parents who decline bloodspot screening given that the result of a missed diagnosis could be brain damage or death.

Response/outcome/changes made:

242. The programme is considering offering screening again during NIPE screening at 6 weeks.

Comment:

243. The standard relating to NHS numbers refers only to the use of the barcoded label. Compliance with ensuring that the NHS number is recorded on the card, irrespective of whether a barcoded label is used, is not captured.

Response/outcome/changes made:

244. The previous standard 3 was looking at two standards. The revised standard 3 aims to drives barcode label usage and reduce transcription error.

Comment:

245. The timeliness of taking avoidable repeat samples, second samples for TSH for babies born at less than 32 weeks gestation and other repeat samples previously included, are now not captured. Having separate standards for these repeats in Wales has meant that we can identify the need for improvement in these areas.

Response/outcome/changes made:

246. We have now separated standard 7 into 7a, 7b and 7c to capture timeliness of all repeats.

Comment:

247. This "consultation" was not designed with parents or their representatives in mind. It is largely technical and geared to professionals. We were not even notified of it, although we are on the consultation list of the NHS screening service.

Response/outcome/changes made:

248. The consultation was to review the standards that are written to a defined a set of measures that providers have to meet to ensure local programmes are safe and effective. The consultation was not intended to exclude parents or their representatives. There are parent representatives on our condition specific advisory boards.

Do you have any other comments?

Comment:

249. Regarding the KPIs, there needs to be exception reporting as often the time frame is breached through no fault of the service providers.

Response/outcome/changes made:

250. This is an NBS standards consultation which is separate from KPI data collection.

Comment:

251. When are you going to review the blood spot sample card? A review is long overdue. There should be boxes for in utero transfusion, known carriers in parents/ family hx [eg PKU, SCT carriers / CF etc], overall the design could be way improved.

Response/outcome/changes made:

252. The blood spot card will be reviewed.

Comment:

253. P5 - The distinction between the new conditions and previous screened conditions should be removed. It seems very odd to separate them in this way. This is also in other points in the document, eg p15, p16.

Response/outcome/changes made:

254. Reference to expanded screening on page 5 has been removed. Wording still applicable in standard 1b until Scotland screen for expanded conditions.

Comments:

255. P9 and most other places - the data reporting deadlines have all been changed to June 30th. Some (ours especially) were previously July 31st and it was difficult to meet that target.
256. The proposed deadline of 30 June for submission of data is not achievable. Most laboratories are currently struggling to meet the deadline of 31 July. If the new deadline is introduced data submitted will be incomplete - the burden on laboratories is increasing and resources diminishing. Surely it is better to keep the current deadline and obtain more complete data.

Response/outcome/changes made:

257. Laboratory data reporting deadline will be 15 July.

Comment:

258. It would be really useful for labs to report by maternity unit, as this makes monitoring quality difficult. Also, some samples are taken in other places rather than birth due to parents moving, or admission to neighbouring NICU units, the avoidable repeats should be counted by where they were taken, rather than place of birth.

Response/outcome/changes made:

259. Some labs IT systems currently cannot collect via maternity unit. NBSFS should resolve reporting by responsibility for screening.

Comment:

260. This careful and thorough review is welcomed by the ACB and its members. There are however a number of key issues for members of the ACB: 1. The suggestion to remove UKAS accreditation for screening and diagnosis. It is felt to be extremely important to have a clear and demonstrable set of quality standards against which performance of laboratories can be measured; 2. The deadlines for testing, retesting and confirmatory testing are very tight and rely on processes which are outside laboratory control. The individual or group responsibility for ensuring standards are met should be defined clearly; 3. The deadline for data collection (30/06) is felt to be unachievable by our members. The previous date of 31/07 was felt already to be an ambitious target; 4. The role of confirmatory testing is inadequately defined, and there are unrealistic / unachievable timescales for some conditions which require confirmatory testing in a 3rd

party laboratory eg HCU, SCD; 5. The move towards focusing on barcoded labels, day 5 and transport within 3 WD is welcomed by members.

Response/outcome/changes made:

261. As standards 8 and 10 are structural standards, they will now be retained in section 12 – 'Mandatory UKAS requirements'.
262. HCU has been excluded from the IMDs to take account of second tier testing. The IMD screening advisory board agreed to include HCU in the performance threshold section. The intervention/treatment for HCU is now 'Attend first clinical appointment by 28 days of age' (thresholds: acceptable ≥ 95.0%, achievable 100%).
263. An acceptable and achievable threshold for SCD has been added.
264. Laboratory data reporting deadline will be 15 July.

Comment:

265. We have many concerns about current consent procedures - which appear in official documents (though inadequately) but are not carried out in practice. In addition, consent to have a blood spot taken, apparently gives implied consent to its use for research or occasional access by the police. Consents for different issues should be separate. The only way parents can opt out of the secondary uses, is to opt out of bloodspot taking. Yet concerns about secondary uses of bloodspots often come in our client queries.

Response/outcome/changes made:

266. This consultation was for the NBS screening programme standards and consent will be addressed separately.

Comment:

267. Standard 5: calendar days & working days are different. For service providers working days captures activity better than calendar days when services are limited at the weekends. Is the avoidable repeat acceptable rate of <2 % realistic, when approx 85% of the hospitals in the last published KPI failed to achieve it. Hospitals with Level 3 NICU's do not always have their results separated out.

Response/outcome/changes made:

268. Calendar days and working days are used where appropriate.
269. Some maternity services meet the acceptable threshold therefore we are trying to drive improvement and reduce the number of babies needing repeat samples.
270. Acknowledged regarding NICU data. There are IT limitations that make this difficult.

Comment:

271. The changes in the draft for consultation were considered to essentially be driving improvements with regard to the timely collection of samples (day 5 and not anytime between day 5 and day 8), to reflect the urgency with which healthcare professionals need to act, particularly with the introduction of the expanded screening. Early diagnosis of these conditions is even more necessary because of the speed with which children can decompensate and decline rapidly. There is also a focus in the draft document on data integrity with the use of barcodes. This has been ongoing for some time however not all centres use barcodes currently and so there is a risk of misidentification. The comments was made that the rationale for the exclusion of pre-transfusion samples from the numerators and denominators was not clear. It was considered that a baby should be tested pre-transfusion. In the draft document Page 29 states that the standard of reporting does not apply to carriers of a condition. However College respondents could not find in the draft document anywhere a statement on the sharing of information with carriers. Is it proposed that carriers are all routinely informed, or not? The comment was made that it is also not clear in the draft document when and whether cascade screening is then offered?

Response/outcome/changes made:

272. Regarding carriers - there are different models for giving these results, therefore excluded in standard 12a and 12b. All results must be given to parents. Cascade screening is discussed when parents receive results.