NHS

Screening Programmes

Newborn Blood Spot

Consultation on Guidelines for Newborn Blood Spot Sampling – summary of responses

December 2015

Overview

The NHS Newborn Blood Spot Screening Programme invited comments on a revised version of the Guidelines for Newborn Blood Spot Sampling. The consultation ran for four weeks (1 September – 29 September 2015). This document is a report based an anonymised summary of the responses received and any subsequent changes to the guidelines.

Thank you to everyone that responded to the consultation.

Background
The Guidelines for Newborn Blood Spot Sampling are intended to provide a consistent and clear approach to newborn blood spot sampling. They aim to support recommendation of newborn blood spot screening to parents, informed choice and collection of good quality blood spot samples. They are written for the screening programme in England.

The guidelines were last revised in 2012. A small project group (with representatives from laboratory, quality assurance, commissioning, midwifery, neonatal and health visiting services) was established in June 2015 to review evidence, discuss issues and produce an updated version of the guidelines for consultation.

Revisions to the guidelines made prior to consultation

- information added on what might happen if a baby with a condition is not detected and treated early
- new section added on why blood spot sample quality is important
- updates to section on 'if parents decline screening' (including proposal to give a letter to parents who choose not to have their baby screened)
- updates to diagram C (correct and incorrect blood application)
- updates to section on blood transfusions including new flowchart
- scenarios added on CHT preterm policy

No changes were made to the section on storage and further use of blood spot cards prior to the consultation. However, this section is subject to change following a public consultation (planned for early 2016) on whether residual samples from newborn blood spot screening should be kept, stored and used for health monitoring and research.

Responses received

- 1 completed response received by email prior to consultation
- 32 completed survey responses (completed one or more questions and submitted survey)
- 162 uncompleted survey responses (clicked on survey link but did not submit – either completely blank or only completed name etc.)

Responses submitted from

- East Lancashire Hospitals NHS Trust
- Gloucestershire Care Services NHS Trust
- PHE
- PHE / Screening and Immunisation team Manchester
- University Hospital Coventry & Warwickshire NHS Trust
- Epsom and St Helier NHS university Trust
- Luton & Dunstable Hospital
- Leicestershire Partnership NHS Trust
- Medway NHS Foundation Trust
- PHE/SIT
- North Bristol NHS Trust
- SET
- Evelina London Children's Hospital
- NHS
- NHSCT
- Mids and East Screening QA
- Oxford University Hospitals
- Guy's & Thomas' NHS Foundation Trust
- Newborn bloodspot Screening Wales
- Newborn Blood Spot Programme
- Royal College of Midwives
- King's College London
- Regional newborn blood spot quality improvement group (N Ireland)
- QA ANNB Screening PHE

Role/background

Parent	1	3%
Parent representative	0	0%
Healthcare professional	23	70%
Healthcare professional / other	4	12%
Other	2	6%
Did not state	3	9%
Total	33	

- Antenatal & Newborn Screening Midwife
- Health visitor/newborn screening lead
- Screening coordinator
- Senior QA Advisor
- Midwife
- Head of QA development
- Screening Coordinator
- IT Manager
- Child Health Records Manager
- Midwife Professional Advisor
- Children's Nurse and Researcher
- Public health consultant
- Community Midwife
- Health Visitor
- Acting Antenatal and Newborn Screening Coordinator
- Clinical Nurse Specialist
- SQAA
- Programme Coordinator (Midwifery and nursing background)
- Newborn Bloodspot Screening Wales Programme
- NBSFS

Country in which you live / work

England	25	76%
Wales	1	3%
Northern Ireland*	4	12%
Scotland	0	0%
England / other	1	3%
Did not state	2	6%
Total	33	

* Work in England but organisation covers UK

Introduction

Should specific reference be made to screening being recommended by a healthcare professional?

Yes	25	76%
No	3	9%
Not sure	4	12%
Did not answer	1	3%
Total	33	

Comments

- Should be recommended by PHE
- It is an important part of the pathway
- More general terms ought to be used - ' Public Health England / National Screening programme recommends‘
- I would combined bullet point 2 and 3 though as they are related
- This provides a sound basis to parents on the process
- While screening is optional and no coercion should be applied, there is a strong evidence based argument that the advantages of NBS screening outweigh the risks
- RCM thinks as the aim of the guidelines support recommendation of newborn bloodspot screening to parents is sufficient

Outcome/changes made:

- Updated section 1.4 to state that a healthcare *professional* should *offer* screening and *record* the parents’ decision
- The introduction states that the guidelines support healthcare *workers* in *promoting* newborn blood spot screening

Introduction

The previous guidelines stated ‘(or UK country equivalent)’ – is this still relevant given that they are English guidelines?

Yes	9	27%
No	17	52%
Not sure	5	15%
Did not answer	2	6%
Total	33	

Comments

- Should be recommended by PHE
- Not necessary now and could lead to confusion
- Should the question read paragraph 1 as bullet points 1 and 2 do not relate to English guidelines
- England only
- Yes, as the guidance is used for other Home nations
- What difference will this make?
- Other countries may use these guidelines
- Not relevant to state this
- It clearly states that the guidelines are written for the screening programme in England
- I don't understand the question
- I think it would be important to explore what parents understood by this

Outcome/changes made:

- Removed reference to ‘UK country equivalent’ in the revised guidelines as it is clearly stated that the guidelines are for use in England and that healthcare workers in the other UK countries must be aware of variation in practice

Introduction – any other comments?

- Page 6 Bullet point 7 should say 'gestational' age and not age appropriate
- Why blood spot quality matters - Need to strengthen the bit re; avoidable repeats that it may cause a delay in identifying a baby with the condition and therefore delay treatment. In order to take the newborn blood spot sample you will need Baby's NHS number (use of a bar-coded label is recommended) - wonder if it is better to say (use of an accurate bar-coded label is recommended)
- p.4 in the box (giving the problems arising in untreated infants) why does MSUD and IVA have death 'in some cases'?
- Water for cleansing: does this need clarification re use of sterile water for babies in augmented care? https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/140105/Health_Technical_Memorandum_04-01_Addendum.pdf

Outcome/changes made:

- Added reference to potential delays in identifying a baby with a condition
- Emphasised the need for accurate and complete bar-coded labels in section 2

- Amended box on page four to read ‘and possible death’

1.5: If the parents consent to screening

Should the guidelines state that support staff should check that consent has been gained before taking the sample?

Yes	29	88%
No	0	0%
Not sure	2	6%
Did not answer	2	6%
Total	33	

Comments

- Definitely. It is a blood screening test checking for abnormalities so all support staff should check that consent has been gained
- the screener needs to be sure informed consent was taken and who gave it to ensure it was someone with PR not all dads have PR at day5
- This is a good failsafe mechanism
- Consent should always be checked
- Anyone taking a sample should check that informed consent has been obtained
- Consent should be taken and an explanation of what happens to the data, who it is shared with. This makes the whole data sharing process easier. Parents assume that the NHS is a single organisation. Why do we have to consent to every organisation on the pathway
- There needs to a record on the card that this has been done
- As long as the maternity support workers or healthcare assistants have been given appropriate training, I don't think there is any reason why they cannot obtain consent
- obtaining consent and checking is essential
- I think this should be explicit to avoid samples being taken without consent being obtained by a professional

- RCM believes as stated in 1.3 (p.7) the information and discussions recorded require a health professional with competence above the level of MCA for consent to be valid
- Evidence suggests that parents can see the taking of the blood spot sample as a 'fait accompli' and as such arrangements such as those suggested to ensure consent has been obtained would seem important
- Ideally, consent should be sought at point of service delivery by test-taker. Parent may have changed their minds and decided that they no longer want their baby screened. The sequencing of process activity is a bit confusing , e.g. family history needs to be taken at antenatal booking and consent activity should be closer to sampling

Outcome/changes made:

- The guidelines now state that a healthcare professional should offer screening and record the parents' decision (section 1.4). The healthcare professional responsible for offering screening should also complete any actions related to a declined screen (sections 1.9 and 1.10)
- The guidelines also state that sample takers should check that consent has been obtained before taking the sample (section 3.1) – we are not highlighting support workers as it may apply to other non-registered staff, e.g. phlebotomists

1.8 (and 6.1): If the parents decline screening

Do you think that the guidelines should state that above a certain age the CHRD should be informed directly (using the template letter provided rather than sending the card to the laboratory)?

Yes	9	27%
No, this should be determined by local policy	15	46%
Not sure	4	12%
Did not answer	5	15%

Total	33	

If yes, what age would be appropriate?

- After 6-8 weeks age
- over 28 days
- One year
- No limit to age, as child could have moved into area at any age
- this could be a local policy 6.1 states up to 12 months as a provider threshold

Comments

- the lab we send to like the decline card to audit movers in screening
- This would make the process more simpler for the HV service
- As screening is offered up until one year of age, so too should a decision to decline be evidenced up until that time
- there should be one system for dealing with declines. Either all declines are sent direct to CHRD or sent to the laboratory irrespective of age
- We should have one process in place - this may be information we want nationally at some stage and would need to go to one source. An alternative would be ensure all the letters are copied to CHRDs
- This will prevent follow up asking for bloods etc
- There needs to be national consensus as staff more trust to trust
- The screening is offered to all children up to the age of 1. The bloodspot card seems only relevant to community midwifery and initial sample collection and repeats. Local policy for children moving into the area should dictate the system for discussing the screening test; gaining consent and recording a decline
- NBSFS should be accessible by all parties and should inform of the decline
- Declined cards should be sent to the lab which is logged and CHRD informed at the same time rather than having to send a separate letter
- How would it be ensured that the failsafe is in place up to one year of age if the cards are not sent to the laboratory? In Wales the laboratory must receive a card for all declines up to the age of one year. If not, the baby would be identified by the NBSWS failsafe and would be followed up
- Generally, uniform practice throughout the country is to be promoted but this may not be a priority at this time
- The last point regarding best practice to inform NBS lead; could you clarify the reasoning behind this. Is it for auditing/quality control/failsafe etc.?
- Preferred answer is 'No‘ without the reference to local policy. Decline should be the same process across all laboratories for all eligible babies ie up to 1 year, with blood spot card completed and submitted to laboratory and results

issued to CHRDs for recording on CHS and forwarding to HV. Staff will otherwise become confused, creating opportunity for notification failure, with babies followed up unnecessarily for screening which parents have already have declined
- I think this is giving mixed messages – I thought the card must ALWAYS be sent to the laboratory, so that a outcome can be recorded by CHRD

Outcome/changes made:

- The guidelines recommend that for every declined screen, the blood spot card marked decline is sent to the screening laboratory and that letters are sent to the child health records department, GP and health visitor – a template letter to adapt for local use will be available to download from GOV.UK
- The guidelines state that the healthcare professional responsible for offering screening should complete actions related to a declined screen

1.9 (and 6.1): Decline letter for parents

Do you think that the national programme should provide an optional template letter to use when parents decline screening?

Yes	27	82%
No	2	6%
Not sure	3	9%
Did not answer	1	3%
Total	33	

Comments

- Absolutely and a copy be kept in the baby's 'Red' book
- as long as it is optional it gives clear guidance for a local one to be adapted if felt necessary. we do have to be mindful though that a number of parents are either not literate or English is not their first language so a clear explanation at

the time is essential. letters generally just incur a cost but are not a effective as direct communication
- This would enable a better understanding for the family
- This will give consistent guide for all areas
- This is a useful template and thus ought to be made available
- Optional but with a request that if possible all providers use this letter- would help to standardised especially if we ask for the letters to be copied to CHRDs
- To enable the presentation of consistent, and high quality information
- Letter should be mandatory in variety of languages
- If parent have made an informed decision to decline screening what is the purpose of the letter?
- Unnecessary complexity. Parents already have a written record of the decline in the PCHR and a copy of the pre-screening leaflet describing benefits of screening. It would be better to add information on declines into the pre-screening leaflet than to introduce this letter/another information flow for practitioners to manage. In addition or alternatively practitioners could advise parents who to contact if they change their mind and record this in the PCHR and maternity/professional record, at time of decline to screening offer
- I think one needs to ask what the benefit and purpose of the letter is? How will it be audited? The pre-test info resources are very clear and informed consent is gained and documented. What's the benefit and purpose? Also, if you're producing letters for this screening programme you should have it for all. I don't understand the benefit as it's based on informed consent with documented trails

Outcome/changes made:

- The revised guidelines now state that a template letter is also available to complete and give to parents that decline screening. A separate version is available for movers in. The healthcare professional responsible for ensuring that screening has been offered should ensure that the parents receive the letter

Section 1 – any other comments?

- Page 8, Paragraph 2 should be an opt in rather than an opt out for Research
- Section 1 is focussed on newborn period. Suggested the following amendments1.1 Ensure parents have access to the Screening tests for you and your baby booklet at least 24 hours before the sample is taken: newborn babies - women are given a copy at or prior to the antenatal booking appointment older babies - parents should receive the booklet at least 24 hours before the appointment 1.3.record in the health care record ie

maternity, health visiting, other and the PHCR1.6 ...for newborn babies the blood spot screening sample should be taken on Day 5....For older babies., the blood spot screening sample should be taken as soon as possible and within 21 days of the child health records department receiving notification that the baby has transferred into the area

- Parents should be asked if they have a family1.2 history of any of the inherited metabolic diseases. I realise this relates to the NPSA report but what about parents who might know they are both sickle carriers but declined PND-asking limited to inherited metabolic diseases does not include these1.8 If parents decline screening the sample taker is to inform the GP and health visitor can't be called the sample taker as no samples are being taken or this term needs to be defined
- 1.8:It would be useful to have the rationale for 'It is best practice to also inform the NBS lead midwife/manager'
- page 7; 1.2 suggest add something re timing of these questions as not clear. I presume this is expected to be done in the antenatal period as the action to be taken is to plan and act earlier
- 1.3 I wonder about the wording of this. My understanding is that in reality, parents are given the opportunity to decline storage of their cards for research purposes rather than being asked if they wish to be contacted about research
- The wording 'parents should be asked if they wish to be contacted about….' Suggests that they will be asked if they consent
- It may be wiser to explain that the cards are kept for research purposes and that if the card is used they will be contacted. Are they happy for their card to be kept for research
- 1.4 If the parents consent for screening
- Perhaps better wording would be 'When parents consent for screening'
- Women should be asked if they have a family history of any of the inherited metabolic diseases.
- 'Women' – should this not read, 'Establish from mother/family/guardian if there is a known history of any metabolic diseases'

Outcome/changes made:

- No changes have been made to the section on residual blood spots and research as we are awaiting publication of a public consultation – currently parents do not have the opportunity to decline storage of their baby's card for research purposes
- Added rationale for informing NBS lead midwife/manager
- Changed 'sample taker' to 'healthcare professional responsible for ensuring that screening has been offered'
- Added 'antenatal period' and 'postnatal period' headings to improve clarity

- Moved reminder about provision of pre-screening booklet 24 hours before taking the sample to postnatal period section and added a reference to information provision in the older babies section

2.2 and 2.5 (and 4.1): Checking details with parents

To support a 'fresh eyes' approach, it is proposed that the sample taker should ask parents to check that the details on the bar-coded label and card are correct. Is this appropriate?

Yes	27*	82%
No	2	6%
Not sure	2	6%
Did not answer	2	6%
Total	33	

* answered yes and not sure

Comments

- Definitely. These should always be checked with the parents prior to the procedure
- There is a lot of evidence to support that more mistakes are made with a double checking model
- I agree with extra set of eyes. We see human error frequently, this will also help if no bar code label is used
- Anyone taking a sample needs to verify the accuracy of labelling
- it is not only appropriate but essential
- They may pick up wrong spellings and other errors
- Yes, but be cognisant of literacy and those for whom English is not their first language
- Parents should be asked to state name address baby's date of birth, which the staff confirm on the bar code label

- Where this is appropriate I think it is an approach. Families that cannot read or cannot read the language may find this difficult. Is there a need to be prescriptive?
- Although this should not be relied upon
- I generally spell out the details in front of them
- yes this is local policy at this trust and it has identified issues that could have led to errors
- It is essential as demographics often change following birth and maternity records are not always updated accurately. Parents can confirm the demographics (eg parent telephone number)and other details are correct which will help prevent delays in screening and referral of screen positive babies
- It is consistent with the participatory and interactive model of health care which will be familiar to many parents
- I'm not sure about this and feel it's problematic. Correct and accurate form filling is a health professional responsibility not parental. Double checking by a second party has proven to cause more errors in blood transfusion so why is it acceptable here? Also, often the parents will just agree and aren't aware of the context of the details, dates etc and it gets complicated when English is not first language or there are multiple births. I feel asking the parents to check the details go against health professional's responsibility and obligations.

Outcome/changes made:

- The revised guidelines state that the completed label and blood spot card should be checked with the parents and any necessary changes made

Section 2 – any other comments?

- Page 10, section 2.2, bullet point 3 should be written in block capitals. Too many mistakes are made from 'legible' handwriting. People may think their own writing is legible when in fact it is not
- It is unlikely that older babies will have a bar coded label - need a newborn section and older babies section Also, an older bay from overseas may be awaiting the issue of a NHs number so include If a baby does not have a NHS number eg moved in from overseas, do not delay taking the blood spot screening sample, alert the laboratory by recording NHS number not yet available as baby moved in from overseas in the comments box
- Chapter 2- Use of the correct barcoded label is recommended. There are so many errors with using the wrong bar code labels I don't think it is sufficient to simply say bar code label- it is for the baby and all the details need to be accurate- this needs to be defined somewhere at the beginning. This saves

health professionals' time in data entry and minimises transcription errors- I personally don't feel the saving time is an issue here and dilutes the message re: minimising errors and the need for repeat tests etc.

- yes can you please include details on how essential it is to include a contact number for the mother. We have had 2 cards now where no number or the incorrect number has been given. This made tracking the family for a positive diagnosis very difficult.
- 2.2 Is there any scope for emphasizing the importance of accurate data and possible the most common errors (eg Mothers NHS number on card, DOB instead of date of sample)?
- Reason for sample if not taken on day 5-8 - add e.g. repeat and reason for repeat

Outcome/changes made:

- Emphasised need for accurate and complete bar-coded label at beginning
- Changed ‘legible handwriting’ to ‘block capital letters’
- Added a comment about not delaying screening for movers in that do not have an NHS number

3.5: Diagram A (puncture sites)

Should Diagram A be updated to include a reference to older babies as well as full-term and preterm babies? Note that supporting evidence in the literature is not available

Yes	13	40%
No	9	27%
Not sure	8	24%
Did not answer	3	9%
Total	33	

Comments

- there should be some sort of guidance for practioners taking movers in bloodspots , these are invariably older children and possibly performed by HV's who don't screen on a regular basis therefore any evidence based guidance is helpful
- This would be welcome by HV's as there are increasing numbers of movement in older babies
- The reference doesn't add any value to the guide in my opinion
- Any other preferred sites for sample taking for older babies? Label diagrams in 3.5 as to which is A and which is B
- would be helpful
- To enable clarity in the process for parents
- This document is for newborn screening not for monitoring of Hep B vaccination programme
- This would be useful information for safety

Outcome/changes made:

- Corrected layout of labels and added ‘These sites are also suitable for infants up to a year of age’ to diagram A (now Figure 1)

Section 3 – any other comments?

- It is perhaps best practice in the winter months for the Practitioner taking the sample to have warm hands. We have noticed in this trust that there was an increase in the repeat samples requested over the winter months
- Like the diagrams in 3.7
- 3.1 Ensure the baby is cuddled- this is not always possible3.7 this prevents babies with a condition being missed or babies without a condition being referred for further tests unnecessarily
- Over prescriptive; Section is too wordy and elements are patronising ie: ideas on how to comfort baby; putting on gloves etc.
- More clear labelling of diagrams A & B in section 3.5
- What scientific evidence is there apart from marking on the inside of the envelope that a sample has been compressed. We have found that taking better samples leads to a longer drying time which is not always possible to leave out to air dry especially in the home. Samples are classified as compressed but haven't really been. Given the science that backs up most of the other standards this is not very robust
- Advising parents of the need to remove plaster must be emphasized and documented. A small minority of babies may adversely react to even

hypoallergenic plaster if left on too long and it can cause a great deal of distress.

- Useful additions to the guidelines noted: 'The first drop of blood should be used'. It is thought that sample takers may read this as use only first drop of blood. An alternative may be 'You do not need to discard the first drop of blood' or the rationale could be added to explain that the first drop no longer needs to be discarded (some sample takers ask about this).Also good to see 'Spots that exceed the dotted lines on the filter paper are acceptable.....' as sample takers do enquire about this. Diagram C:It may add emphasis for the 'incorrect' samples if 'babies with a condition may be missed' (in bold) is added in the reasoning section to those sample giving risk of false-negative result, and by adding 'babies may be referred for further tests unnecessarily' (in bold) for the risk of false-positive samples. Some sample takers may need reminding of the impact of false-negative and false- positive samples.
- 3.5 The labels for diagram A and B are not adjacent to the diagrams3.6 Is the comment on expanded screening (no need for extra spots) now superfluous?3.7 The front and back of the cards are not clearly labelled as such
- page 14; 3.5 suggest label the images A and B
- 3.2 Clean the heel by washing thoroughly with plain water using cotton wool/gauze. The water should not be heated and the baby's foot should not be immersed. Does this need clarification re use of sterile water for babies in augmented care? https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/140105/Health_Technical_Memorandum_04-01_Addendum.pdf 3.4 calcaneal osteomyelitis (inflammation or infection of the heel bone).3.6 Fill each of the four circles completely. Always ensure that the sample is dropped on to the front of the card and not the back. 3.6 No extra punches are needed to perform testing for the new conditions.

Outcome/changes made:

- Updated section 3.7 to read ‘Evidence shows that poor quality samples could lead to a baby with a condition being missed (false-negative result) or a baby without a condition being referred for further tests unnecessarily (false-positive result)’
- Updated labelling in diagrams A and B (now Figures 1 and 2)
- The reference to support the blood spot quality sections has been published and added to the guidelines – compressed samples can be difficult to detect but can also appear lighter in colour with a pale area in the centre of the spot
- Added rationale for not discarding the first drop of blood
- Removed reference to expanded screening
- Updated sentences on calcaneal osteomyelitis and dropping the sample onto the front of card

Section 4 – any comments?

- Interesting that central validation of samples is 'not recommended'... for the use of courier services, central validation seems to be an appropriate response
- 4.3Inform parents that they will receive the results newborn babies- process as described older babies - timeframe for results should be included and who will give them the results
- Incorrect spelling of DISPATCH (despatch in document)
- 4.1 Is there any guidance on how long cards should be left to dry?4.1 Avoid placing envelopes in internal mailing systems. (rationale : this may cause delay in despatch) 4.3 Note that the programme does not have access to screening results. This is a bit confusing - could this be reworded?
- 4.1 – as above for 2.2 & 2.5. Why ask the parents to check. It's the responsibility of the person taking the sample. This is not practiced anywhere in blood transfusion of other sample taking
- Bottom of 4.1 Record date, method, blood spot card serial number and location of sample despatch, as per local protocol. If a post box is used, record its post code (visible on each box) - Should this be recorded 'centrally'. i.e the unit needs central audit of blood spots taken and sent. Recording in individual diaries does not help with audit and tracking as a whole

Outcome/changes made:

- Added a sentence about drying time
- Clarified reference to the programme not having access to results
- Added reference to older babies receiving results in section 6

5.3: Pre-transfusion sample

It is proposed that the guidelines state that sample takers should follow local guidance/policy on whether to discard the pre-transfusion sample or send it to the laboratory if the baby has not had a transfusion.

Do you agree with this proposal?

Yes	20	61%
No	7	21%

Not sure	4	12%
Did not answer	2	6%
Total	33	

Comments

- It would seem appropriate to forward all samples to the laboratory if they have been obtained. This might be useful in the case of incorrect data re transfusion and /or blood is being used for research
- There is a risk of the pre-transfusion sample getting lost could the pre-transfusion sample be sent to the lab directly?
- I would prefer that as discarding blood sends the wrong message out i feel- as it is so precious
- Gold standard screening can be achieved when national standards are applied rigorously. Define national practice and get everyone to deliver the same high quality care to the same standards
- Consensus will avoid errors
- This is a very detailed document and could be adopted in its entirety and should be a national decision; given that there are so few NBBS labs
- It should be standard practice for all pre transfusion samples to be attached and sent to the lab with the day 5. Too many babies move around between different services and it causes great confusion. One standard practice please!
- We send to the lab when taken as we believe it can be lost or damage/contaminated if left in records for 5 days
- However, it would be preferred to state that pre-transfusion sample be discarded if baby do not have a transfusion to avoid confusion
- If there are local policies/guidance in place there will not be consistency in this which could be problematic when babies move between different neonatal units. There would need to be a robust process to manage the pre-transfusion samples and the destruction of pre-transfusion sample cards
- In general I think a national guideline is to be preferred (rather than local policy) but I think this is probably not a priority at this time if change would cause problems for some
- This would help to avoid confusion and may also prompt a discussion around this locally to raise awareness

- but need to highlight trust will need to follow body fluids disposal policy and not just place in shredder etc.

Outcome/changes made:

- Followed overall consensus and made no further changes to section

5.5: Recording time of transfusion and routine sample

It is proposed that sample takers record the date and time of the last blood transfusion and the date and time of the routine sample on the blood spot card so that the laboratory can calculate 72 hours accurately.

Do you agree with this proposal?

Yes	22	67%
No	1	3%
Not sure	7	21%
Did not answer	3	9%
Total	33	

Comments

- Needs a date/time area on the Blood Spot card to complete this
- time is very important to include
- It is much easier to apply a three full clear days policy (we did this in London and you can have scenarios/ examples)- date and time will be difficult in practice and I anticipate this will cause more problems
- Accurate data capture supports better clinical outcomes
- For Babies born in another trust staff may not have data
- In all cases will this information about the transfusions be available to reference by staff?

- We are repeatedly having to ask staff to leave 4 days clear despite the guideline saying 3 days (72 hours). Most of the software currently cannot accommodate a time for transfusion or sample so either the form and software needs changing or the wording- which would be quicker, cheaper and simpler, be changed to 4 days ie transfused 10/09 sample due 14/09
- This will allow the routine sample to be taken as soon as 72 hours has passed after the transfusion rather than waiting for the next calendar day, and therefore would avoid further delays in screening
- I think it all hinges on how important it is that a full 72 hours has passed. I heard an interesting discussion with users about this and they felt that the person taking the blood spot may not know the time of the last blood transfusion and this may cause delays in taking the test. Also, they raised the question: is it the start or finish of the transfusion (which could run over several hours). However, if the time of transfusion is not given on the card, it is possible that an infant completed a transfusion in the evening and the sample is taken in the morning 3 days later, which is less than 72 hours.

Outcome/changes made:

- After careful consideration of the responses, changed wording to 'three **clear** days' (without reference to the 72 hours). In practice it is difficult to capture the times correctly in order to calculate 72 hours. Additional guidance on how to interpret 'three clear days' has been added to the guidelines

5.9: CHT preterm repeat

When a baby has a CHT preterm repeat taken on the day of discharge home, it is proposed that the sample taker writes 'discharged home' on blood spot card as well as recording 'CHT preterm'. This will ensure that the laboratory knows why the repeat was taken before day 28 and does not ask for a further sample.

Do you agree with this proposal?

Yes	23	70%
No	0	0%
Not sure	6	18%

Did not answer	4	12%
Total	33	

Comments

- There can be confusion here so this would give better clarity
- will help labs who have great difficulty with this and have to guess currently
- It is very important to include this information as currently lab ask for a repeat if taken before day 28 and baby discharged home say day 27
- Not sure of the pros and cons

Outcome/changes made:

- The guidelines now state that if the CHT preterm repeat is taken on the day of discharge home, the sample taker should write ‘discharged home’ on the blood spot card as well as recording ‘CHT preterm’

Section 5 – any other comments?

- Special circumstances - admission blood spot sample to be taken on admission to level 2 and 3 NICUs as blood transfusion unlikely for babies on level 1 NICUs Amendments 5.6 Additional costs will be incurred by the Trust 5.8 Inform parents of any outstanding screening tests, and record this in the PCHR and health care record
- I am concerned that if day 0 samples are kept with the notes until the 5 day sample is taken, it may be mislaid. Should the recommendation be to send day 0 sample directly to the laboratory and process if transfused / as per local policy?
- 5.5 when receiving multiple transfusions recommendation to take day 8 irrespective of last transfusion. Understand rationale but this has a negative effect on avoidable repeat rates calculated by the labs for KPI. Can labs be instructed to discount these from their stats.
- 5.1 The third sentence lacks the elegant clarity of the rest of the document 5.6 Clarify that this is referring to a transfused baby
- 5.1 Venepuncture or venous / arterial sampling from an existing line is an alternative method to collect the sample and place it on to the blood spot card. comment : so there no confusion that a venous sample in a bottle should not

be used for newborn blood spot screening sample. 5.2 The routine screening test for SCD cannot be performed on the day 5 sample if the baby has received a blood transfusion before the day 5 sample has been taken. 5.5 There is very good information regarding definition of blood transfusion/transfusion of blood products in the glossary which should be incorporated into section 5. It is important that guidance is clear re. 72 hours from COMPLETION of blood transfusion. 5.6 If a transfused baby has not had a pre-transfusion sample taken, the laboratory WILL forward the routine day 5 sample to the SCD DNA laboratory for analysis as a failsafe.

Outcome/changes made:

- Repeats due to samples being taken on day 8 irrespective of the last transfusion (i.e. 'too soon after transfusion') should not be recorded as an *avoidable* repeat by the laboratory
- Reworded the last sentence in 5.1 for clarity
- Reworded 5.6 to read 'If a baby who has been transfused has not had a pre-transfusion sample taken'
- Reworded 5.1 to say 'Venepuncture or venous / arterial sampling from an existing line can be used to collect the blood spot sample onto the card'
- Added reference to definition of blood transfusion in glossary
- Changed 'may' to 'will' re DNA costs

Section 6 – any comments?

- There is no mention of KPI's or timeframe for movers in bloodspot screening which is 21days. This is a very tight timeframe and possibly unrealistic but does exist so should be in the guidance.in my experience the lab sends a letter to Gp's informing them if CF was not tested is this not national protocol in which case it is duplication if the screener does as well.
- Useful for Health visiting services.
- not quite sure if this chapter is the right title? Seems to have all sorts of things in there muddled up together Suggest additional Chapters Older babies Repeat samples Failsafe the guidelines are aimed at health care professionals mainly, coverage is a public health term and may be misleading to themAmendments6.1 If the conclusive results cannot be found, blood spot screening should be offered Local policy is to stipulate how many attempts to contact the family ....could include a minimum of three attempts 6.3 failsafe arrangements are they in addition to NBFS?
- Clarity around babies who have been screened in other UK countries, i.e. Scotland, should be offered as movers in under 1 year. This is confused

between documents. As a precaution most HVs offer re-screening to ensure coverage. If there is documented evidence of the full screen in that country, should this be a re-offer?

- 6.1'Only written confirmation of conclusive results.....' Suggest adding 'UK NBS' before 'results' so that staff don't accept screening results from outside UK.‘ Record clearly on the blood spot card the method of sample taking'. What is the rationale for this and what samples/which babies does this apply to?
- 6.1 Sentence: If the conclusive results cannot be found, a sample should be taken, using .....Should this read If the conclusive results cannot be found, screening should be offered .....6.2 Suggest replacing the the symbol > with text (more than) for consistency
- 6.1 Para 1. Should new conditions be mentioned for babies born January 2015 onwards?6.1 Tests carried out in non UK laboratories may not be consistent with programme standards eg Republic of Ireland carries out blood spot sampling at 3-5 days of age. Only written confirmation of conclusive results (that you can interpret), from a UK laboratory should be accepted. 6.1 All reasonable attempts should be made to find the results; however, this should not unduly delay screening. This is a mixed message and it is not clear what 'All reasonable attempts' and 'unduly delay' mean? Experience in N Ireland -where the 'failsafe' identifies movement in babies without conclusive screening results- is that practitioners searching /waiting for results significantly delays screening. N Ireland failsafe guidance states: 'Where there is no documented evidence of conclusive screening test results, which are consistent with the UK programme, available to the practitioner at time of contact with an infant moved in from outside N. Ireland, i.e. where PCHR/professional records are not available; where results are not recorded within available records; or, where screening test results available relate to a screening programme which is not consistent with the UKNSPC screening programme, i.e. the results relate to tests carried out in a non-UK lab (including RoI), the practitioner must go IMMEDIATELY to offer.‘
- I think this is giving mixed messages – I thought the card must ALWAYS be sent to the laboratory, so that a outcome can be recorded by CHRD.

Outcome/changes made:

- Added reference to screening being offered by a healthcare professional in line with section 1
- Added rationale for not offering screening for the expanded conditions if a baby has been screened for the five conditions offered prior to the expansion of the programme
- Changed wording to ‘If the conclusive results cannot be found, parents should be given information and screening offered (see section 1)…. If the parents

consent to screening, take a sample using the blood spot card (completed as described in section 2) and sent to the screening laboratory'
- Changed < to 'less than'

Appendices

Is Appendix 2 (blood transfusion flowchart and scenarios) useful?

Yes	25	76%
No	3	9%
Not sure	1	3%
Did not answer	4	12%
Total	33	

Comments

- Excellent
- Confusing and cannot be interpreted without reference to the guideline; so therefore limited use
- Flowchart SCD pre transfusion sample should be before routine day 5 boxes
- Scenarios are useful
- Very useful scenarios
- Small point - the key explaining the green symbol might be better without the numbers in it (5.5) - it took me a moment to realise that it was a key, and not a symbol that had become detached from the flowchart
- See reference to completion of transfusion

Outcome/changes made:
- Amended key for clarity
- Changed '3 days (72 hours)' to '3 clear days' in chart and scenarios
- Added calendar to help illustrate 3 clear days

Appendices

Is Appendix 3 (CHT preterm policy scenarios) useful?

Yes	26	79%
No	0	0%
Not sure	3	9%
Did not answer	4	12%
Total	33	

Comments

- Do not see how these will be used. All detail in policy document
- Very useful scenarios - addressing many of the queries from neonatal unit staff. Scenario 6: There have been some queries from staff about what is meant by the 'last' transfusion. In view of this we reworded our guidance to '.....once 72 hours have passed without a blood transfusion‘
- The headings read ‘Scenario’s’ & ‘Answers’. Perhaps the word ‘solution’ or ‘resolution’ would be better as the scenario is not a question.
- For the baby that was being discharged at day 27 but stayed in an extra night, would the lab have accepted the sample had they documented ‘discharged home’. This has happened in our region a few times, yet a repeat has always been requested even with phone calls to the laboratory.

Scenarios to add

- an IUT scenario
- I would suggest that the learning from failsafe reports could inform of any other scenarios required
- Additional scenario : Baby born <32 weeks who, for whatever reason, does not have a viable (day 5) sample taken for CHT until they are 28 days old - is a follow-up Preterm CHT sample required?

Outcome/changes made:

- Changed ‘3 days (72 hours)’ to ‘3 clear days’

Comments on layout

- Good
- Easy to read and navigate around
- Easy to follow
- Chapter 6 not quite sure if this chapter is the right title? Seems to have all sorts of things in there muddled up together Suggest additional Chapters Older babies Repeat samples Failsafe
- Good
- Too long and too prescriptive; especially compared to the other screening documents. Limited use in day to day practice.
- Like layout overall clear
- Very good.
- Very clear. Very reader friendly.
- Clear
- They are clear and logical

Outcome/changes made:

- Comments acknowledged

Would you like to see the 'quick reference guide' reproduced?

Yes	29	88%
No	1	3%
Not sure	0	0%
Did not answer	3	9%
Total	33	

Comments

- Useful for clinical staff
- Essential

Outcome/changes made:

- Quick reference guide to be reproduced

Preferred format

	Printed	Online (PDF – full colour)	Online (PDF – easy print)	Online (HTML format)
Full guidelines	2 (4.76%)	21 (50%)	12 (28.57%)	7 (16.67%)
Quick reference guide	12 (27.27%)	14 (31.82%)	13 (29.55%)	5 (11.36%)

Note: four didn't respond to question

Outcome/changes made:

- Full guidelines to be published online in full colour
- Quick reference guide to be printed and published online in full colour

Do you support the revised guidelines?

Yes	29	88%
No	1	3%
Not sure	0	0%
Did not answer	3	9%

Total	33	

Comments

- Excellent, clear and very useful
- They are clearly written with an excellent balance between detail and clarity with an impressive rationale and evidence base
- RCM believes they are comprehensive and clear to support best practice around blood spot screening and will be recommended as a professional CPD resource for screening programmes

Outcome/changes made:

- Comments acknowledged – thank you

Any other comments?

- Avery good piece of work so far, thank you
- I will send some additional suggestions directly to Lucy and Christine sample takers calendar and results letters for parents where baby is screen positive for one of the conditions Can you also include your results letter to parents template in the guidelines please?
- There is a section that recommend giving baby sucrose or glucose if available, this should be removed as not recommended, breast feeding giving formula milk as analgesia is adequate.
- Glossary:P43 - glutaric aciduria type 1 - words 'of the' missing from 1st line before 'the amino acids lysine and tryptophan'.
- I thought the glossary was a strange hybrid - some of the explanations look like they belong in an easy read version while other explanations happily include technical terms (mitochondrial enzyme). My personal view is that it is a document intended for professionals (and throughout refers to things such as professional guidelines without apology) and it would be better to maintain that style. SEE WORD DOCUMENT SUBMITTED FOR COMMENTS ON GLOSSARY
- Appendix 1: Template letter for parents that decline newborn blood spot screening. If this template is included in the guidance it should include reference to reduced accuracy of tests for older babies.
- Well done and thanks!

Outcome/changes made:

- GA1 glossary entry amended
- Results letter to parents updated – versions added where baby has screened positive for one condition or is too old for CF screening
- Added calendar to blood transfusions scenario
- Comments acknowledged