

Task brief: Safe continuance or restoration of NHS Newborn Blood Spot Screening Programme

Newborn Blood Spot Screening Programme context

Safe continuance or restoration of newborn screening for newborn blood spot (NBS) will follow a hierarchical approach targeting babies requiring rapid intervention first. Even though there has been little disruption to the programme restore needs to be considered whilst recognising that usual screening of newborns is ongoing during the recovery period.

Programme activity has varied since the COVID-19 pandemic has become more widespread that are affecting local services ability to screen all babies. With regard to NBS screening the data from the Newborn Blood Spot Failsafe Solution (NBSFS) and feedback from the screening laboratories it has been shown that there were minimal delays in samples being received by the screening laboratories, and these are now resolving.

Restoration approach

PHE screening have developed a hierarchy pyramid to demonstrate an approach to restore of programmes. The pyramid demonstrates a top down approach to enable targeting of those babies requiring rapid intervention first, leading to the maintenance of usual screening.

The pyramid has been further edited for this plan to be programme specific in order that the approach demonstrates the specific risks, issues and mitigations required by the NBS screening programme.

Technical guidance to support the newborn blood spot screening programme was issued through NHSEI to Heads of Public Health Commissioning (HoPHC) initially on 30 March 2020, with a revised version sent out on 22 April 2020. This provided guidance on maintaining screening services. Further guidance has now been produced to support restore please see Appendices for restore guidance.

Figure 1: Hierarchy pyramid for Newborn Blood Spot Screening Programme

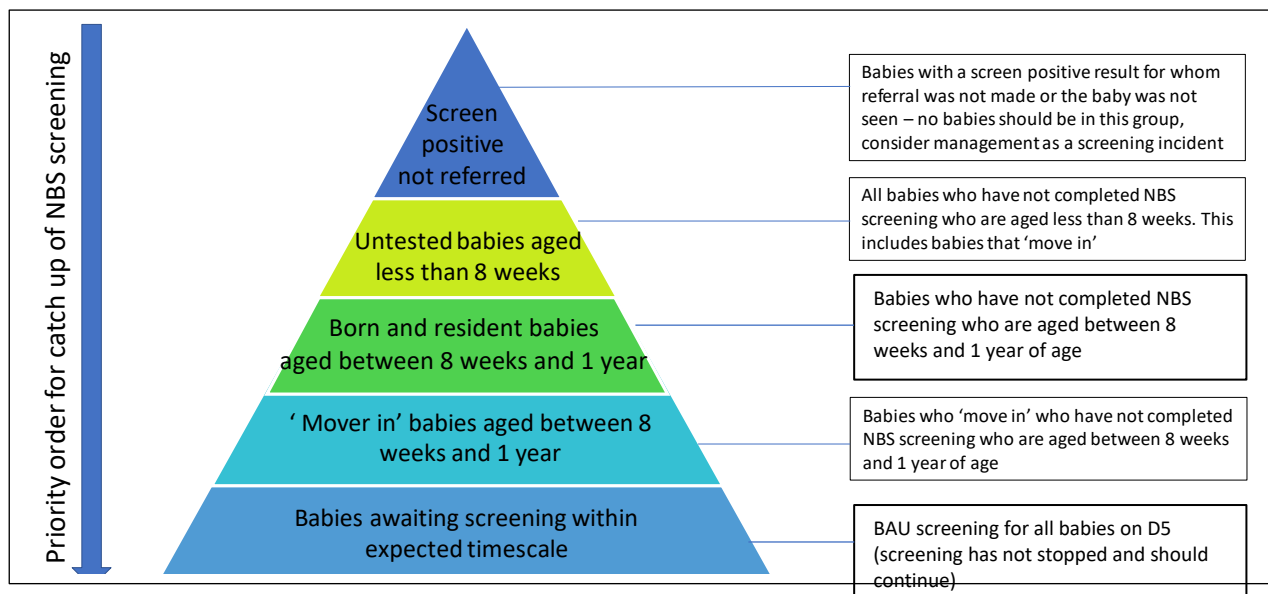


Table 1: Newborn Blood Spot Screening Programme risk stratification

Risk stratification	Characteristics of this sub-cohort
Babies requiring rapid intervention	<p>Babies aged less than 8 weeks of age that have not been screened need to be prioritised to enable screening for CF as well as the other 8 conditions.</p> <p>Newborn Blood Spot Failsafe Solution (NBSFS) can identify these babies with information added to the individual baby's notes section as well as documented in the mother and baby records.</p>
Born and Resident babies over 8 weeks and under a year	<p>Newborn Blood Spot Failsafe Solution (NBSFS) can identify these babies with information added to the individual baby's notes section as well as documented in the mother and baby records.</p>
'Mover in' babies over 8 weeks and under a year	<p>CHIS are responsible for identifying these babies, they will not be on NBSFS. CHIS will need to liaise with CCG to offer screening.</p>

Appendix 1:

COVID-19 newborn blood spot screening programmes restore guidance

20 May 2020 (expires 19 June 2020, see re-issue 20 June 2020 for update)

1. Background

Antenatal and newborn screening must continue as specified in the NHS England Service Specification for each programme.

The Newborn screening programme is time critical and early detection and intervention for some of the conditions screened for is essential. Delay can result in significant mortality and morbidity.

2. Purpose

This document provides guidance on how best to restore NBS screening programme as the COVID-19 pandemic evolves and services return to business as usual.

3. Scope

This restore guidance is specific to the **Newborn Blood Spot screening programme** and is targeted towards newborn screening laboratories, midwives, sample takers and health visitors engaged in testing and the Child Health Information Systems (CHIS) who record the results. It will be valuable for Screening Co-ordinators charged with briefing midwives, for Laboratory Directors responsible for testing and for managers of CHIS.

1. It is believed that it is safe to take samples from a baby in a family in isolation provided that protective clothing and good practice are used. If a mother is affected, then it may be sensible for someone else to hold the baby during bleeding.
2. Once a sample is obtained and dried it is believed that it is safe to post or transport by courier, in the usual manner.
3. Careful scrutiny of the data from the Failsafe system together with the weekly reports from the Regional Newborn Screening Laboratories suggests that:
 - Services have been well maintained since the beginning of the current restrictions on social distancing implemented on 23 March.
 - Sample collection has been performed on time.
 - Transport of samples, while sometimes subject to slight delay, has generally continued to deliver samples within the key performance indicator set for delivery.
 - Laboratories have maintained services including the usual turnaround time.
 - Clinical referral for screen positive cases and reporting to Child Health Information Systems has been maintained.
 - Parents wishing to decline testing has increased modestly in some areas and a small number of parents have asked to re-schedule testing.

4. Taken together these findings indicate that parents, maternity and laboratory services have adapted well during the current period and early fears about service disruption have not been realised – all are to be congratulated on this achievement. On that basis as we restore services it seems reasonable to revert, **with effect from 20th May** to the testing requirements and operational practice prior to 23 March. In particular:

- Unsuitable/insufficient samples, or samples collected on expired cards can no longer be accepted and a repeat sample will be requested.
- The requirements to provide demographic information including date of sample collection and of course the NHS number will be reinstated.
- Samples received later than 14 days after they were taken will not be reported and a repeat will be requested.
- ‘Mover in’ babies should be screened up to one year of age

It is recognised that visits may already be arranged and to accommodate this, **with effect from 3rd June:**

- Day 4 samples will no longer be accepted and a repeat sample will be requested.
5. Labs should continue to monitor the number of samples arriving daily and continue to provide the current weekly status report to the Programme.
6. If midwifery visits need to be delayed this should be recorded (see bullet point 12. below) and a visit re-scheduled. As children with some of these conditions can become acutely ill during the first few weeks of life, testing should be performed as soon as reasonably possible after day 5 and every effort should be made to obtain a sample before one month of age.
7. The previous technical guidance, issued on 21st April 2020, allowed laboratories, if resources were limited, to consider prioritising testing for conditions (IMDs and CHT) in which a delay may result in immediate harm to the baby and to prioritise reporting screen positive results over daily reporting of normal results to CHIS (Child Health Information Services). As services now appear to be able to operate normally these provisions are no longer needed but can be discussed with the Blood Spot Programme and QA teams if local circumstances prevent a complete return to normal.
8. Referral of positive cases should be made in line with agreed practice and confirmatory testing should be conducted in the usual way.
9. The requirement to check and report IVA, MCADD and MSUD results on Saturday mornings will be re-instated.
10. It remains important that midwifery teams track all delays and declines using the Failsafe tracking system (NBSFS) and NHS Digital have produced new status codes to allow this to be recorded for NBS screening in light of COVID-19. Failsafe is under development to hold the declines/delays due to COVID-19. It will have a field on the tracking page so that delays can be filtered to find those babies. Labs will apply the codes, there is no need to record them on the card. We are asking maternity to record declines and delays in the individual baby's notes section in their record on failsafe as well as documented in the mother and baby records. If it is a decline usual practice applies, midwife completes a card, sends it to the lab and

informs CHIS and GP/HV. If it is a delay it is preferable but not mandatory to send a card to the lab.

The codes are:

- Code 0208: NBS declined due to epidemic
- Code 11: NBS delayed due to epidemic (delays requested by the parents or/and the sample taker)

If screening is not completed for a range of reasons including an inability to get the family to respond or a breakdown in midwifery care this would need to be reported as an incident to SQAS rather than via a status code.

11. All NBS Labs have business continuity arrangements in place in the event they are unable to maintain the service. In this event the Blood Spot Screening Programme and SQAS should be informed immediately. If laboratory services cannot be maintained a backup laboratory would be contacted. Initially the back-up laboratory as defined in the lab's own business continuity plan should be approached and if they are unable to provide support, the Blood Spot Programme should be notified and other laboratories may be approached via UK Newborn Screening Laboratory Network (UKNSLN).
12. During the period of social distancing a small number of families have been reluctant to undertake newborn blood spot screening for their baby. This has resulted in delays for some and midwifery services have been asked to record this (see 12. above) and re-schedule collection as soon as practicable (see 6. above).
13. The current period has caused some parents to decline testing for their baby, some specifying the current situation directly caused by COVID-19 as cause and others simply expressing a more general wish to decline testing. Uncertainty and anxiety may understandably have contributed to these responses. It has been agreed that, as part of our recovery plans, families should be offered the opportunity to reconsider that decision. **It is important that families have the “right to choose” so this should be a re-offer of testing without any pressure to accept and it should be documented.** The timing and organisation of this re-offer will be determined by local maternity services who can choose both an appropriate time for their community and the means which best meets the needs of the families involved and the service. It should be remembered that if testing following a re-offer is delayed beyond 8 weeks of age for the baby then it will no longer be possible to screen for cystic fibrosis, screening for the other conditions will remain valid. On that basis, if there are a number of babies affected when families are re-offered testing, those who are oldest but still under 8 weeks should be re-offered testing as a priority.
14. It is recognised that declines are more common among “movers in” for a variety of reasons. It may not be appropriate to re-offer screening to all “movers-in” who declined screening during this period and these should be assessed on a case by case basis.
15. Looking to the future, while the understandable anxiety associated with the pandemic may have prompted an acute and modest increase in declines associated with the advice on social distancing which has been mentioned (see – 15 above), it is likely that this uncertainty associated with COVID-19 may continue to impact on parents' views of screening and other health contacts for some time to come. On

that basis midwives should, if possible, delay an initial decision by parents to decline screening during any extended COVID-19 period suggesting that the family use a longer time (perhaps two weeks during which time testing should be recorded as delayed) to make their choice. This will provide an opportunity for the parents to carefully consider the possible implications for their baby. The family should then be approached again to make a final decision, at that time testing can be performed or a decline recorded.

4. For further queries

PHE.screeninghelpdesk@nhs.net

Contributors

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Liz Robinson	Project Lead, NBS

Appendix 2:

Newborn blood spot screening programmes technical guidance during the coronavirus (Covid-19) pandemic

1. Background

Antenatal and newborn screening must continue as specified in the NHS England Service Specification for each programme.

Antenatal and newborn screening programmes are time critical and early detection and intervention for some of these medical conditions screened for is important and can have significant mortality and morbidity.

It is important the women and babies with screen positive/higher chance results are given the information they need to make the right choices for them and are safely referred onto the correct care pathway. This can be a highly anxious time for women/parents and they must be adequately supported by health professional advice and information.

2. Purpose

This document provides additional technical guidance on how best to deliver these screening programmes as the Covid-19 pandemic evolves and staff and capacity become more challenging.

This guidance provides recommendations on screening continuity in response to Covid-19. It is acknowledged that maintaining the current service during these unprecedented times will be challenging.

3. Scope

This technical guidance is specific to **Newborn Blood Spot screening programme**

1. It is believed that it is safe to take samples from a baby in a family in isolation provided that protective clothing and good practice are used but maternity units would make that determination based on staffing levels, availability of protective clothing and risk. If a mum is affected then it may be sensible for someone else to hold the baby during bleeding.
2. Once a sample is obtained and dried it is believed that it is safe to post or transport by courier.
3. If the post or courier services are disrupted the samples/babies will be tracked via the Newborn Blood Spot Failsafe Solution (NBSFS). Royal Mail have been contacted to check if contingency plans are in place to safeguard these samples. Labs monitor the number of samples arriving daily and in addition, during this period, have been asked to provide a weekly status report to the Programme.
4. Day 4 samples will be accepted.
5. If midwifery visits need to be re-scheduled samples should be taken as soon as possible after day 5. As children with some of these conditions can become acutely ill during the first few weeks of life, testing should be performed as soon as reasonably possible and every effort should be made to obtain a sample before one month of age.

6. 'Mover in' babies should still be screened up to one year of age. It is accepted that there may be difficulty in tracking, locating and testing an individual child. This should be assessed against other health care priorities by the health care worker involved and their manager. It may not be possible in all cases and, if reasonable efforts have failed, this should be documented.
7. Any unsuitable/insufficient samples, or samples collected on to expired cards that are no more than 5 years old, can be accepted – although labs are expected to exercise reasonable judgement and, if it would be clearly unreliable to analyse and report the sample, then a repeat will be requested.
8. Labs should still **ensure that the NHS number is present on the card.**
9. Permitted transit time for samples will be extended from 14 days to one month
10. In the event that Lab staffing is very limited, testing may need to be prioritised. IMDs and CHT should be tested and reported within the current turnaround times. Testing and reporting for CF and Sickle may be delayed, but samples should be tested and reported as soon as it is practical.
11. Reporting screen positive results can be prioritised over labs daily reporting of "normals" to CHIS, but upload to NBSFS is **imperative** and should be maintained so that babies can be tracked. If labs are forced to delay or suspend sending results to CHIS, labs will notify CHIS.
12. Referral of positive cases should be attempted by the current routes and, if these are modified, new guidance from the providers should be followed. Confirmatory testing may be delayed, but clinicians may elect to begin to treat the child based upon the information that they have and this will remain their responsibility.
13. The requirement to check and report IVA, MCADD and MSUD results on Saturday mornings will be operated at the discretion of the Laboratory, dependent on staffing.
14. Two new subcodes are to be used when reporting and recording screening results affected by COVID-19.
Code 09 - not screened/ screening incomplete:

Subcode 0911 – affected by COVID-19 - not screened

Subcode 0912 – affected by COVID-19 - screening delayed
15. If a laboratory's services cannot be maintained, if possible, a backup laboratory would be used. Initially the back-up laboratory as defined in the lab's own contingency plan should be approached and if they are unable to provide support, the Blood Spot Programme should be notified and other laboratories may be approached via UKNSLN. The QA team will be alerted.

3. Additional things to consider

3.1 Information for parents

It is important that parents understand which appointments they should attend and especially in situations where appointments need to be rescheduled.

3.2 Screening safety incidents

As far as possible, the principles in the [national guidance](#) should be followed. Incidents or potential incidents should be reported to the screening quality assurance service (SQAS) and commissioners so that they know about problems occurring. SQAS will continue to give advice whilst recognising the intense pressure that many providers staff will be under.

3.3 QA visits and network meetings

All screening QA visits and network meetings are postponed from 23 March until further notice.

This will support our NHS colleagues who are focusing their efforts on frontline activity. We will regularly review this situation and keep staff and stakeholders informed.

Communication to both providers due a QA visit and network meeting attendees will be via regional quality assurance teams.

4 Data requests/submissions for key performance indicators and standards

Our aim is not to put any additional pressure on screening providers or the wider NHS.

Performance against thresholds – we appreciate meeting some thresholds is challenging and will caveat any reporting of data during this time.

5 PHE Screening publishing and social media activity

We have stopped all social media activity, including blogging and tweeting, and will not be publishing any new guidance on GOV.UK at present; including quality assurance executive summary reports.

6 Documenting changes as they happen

We anticipate that there will be a need to evaluate the impact of the pandemic had sometime in the future, so we advise providers document dates and changes made to the delivery of screening for audit purposes.

7 For further queries

PHE.screeninghelpdesk@nhs.net

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Appendix 3

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20 April 2020 (expires 19 May 2020, see re-issue 20 May 2020 for update)

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The Newborn screening programme is time critical and early detection and intervention for some of the conditions screened for is essential. Delay can result in significant mortality and morbidity.

It is important the women and babies with screen positive/higher chance results are given the information they need to make the right choices and have timely referral onto the correct care pathway. This can be a highly anxious time for women/parents and they must be adequately supported by health professional advice and information.

2. Purpose

This document provides additional technical guidance on how best to deliver these screening programmes as the Covid-19 pandemic evolves and staff capacity becomes more challenging.

This guidance provides recommendations on screening continuity in response to Covid-19. It is acknowledged that maintaining the current service during these unprecedented times will be challenging.

3. Scope

This technical guidance is specific to the **Newborn Blood Spot screening programme**

1. It is believed that it is safe to take samples from a baby in a family in isolation provided that protective clothing and good practice are used. If a mother is affected, then it may be sensible for someone else to hold the baby during bleeding.
2. Once a sample is obtained and dried it is believed that it is safe to post or transport by courier, in the usual manner.
3. The samples/babies will be tracked via the Newborn Blood Spot Failsafe Solution (NBSFS) and if there is disruption to the post or courier service, this will be picked up. Royal Mail have been contacted to check if contingency plans are in place to safeguard these samples. Currently they believe that services, both collections and deliveries are being maintained. Any interruption to local services should be investigated. Labs monitor the number of samples arriving daily and in addition, during this period, have been asked to provide a weekly status report to the Programme.

4. Day 4 samples will be accepted.
5. If midwifery visits need to be delayed this should be recorded (see bullet point 15. below) and a visit re-scheduled. As children with some of these conditions can become acutely ill during the first few weeks of life, testing should be performed as soon as reasonably possible after day 5 and every effort should be made to obtain a sample before one month of age.
6. 'Mover in' babies should still be screened up to one year of age. It is accepted that there may be difficulty in tracking, locating and testing an individual child. This should be assessed against other health care priorities by the health care professional involved and their manager. It may not be possible in all cases and, if reasonable efforts have failed, this should be documented.
7. Any unsuitable/insufficient samples, or samples collected on expired cards that are no more than 5 years old can be accepted. Labs are expected to exercise reasonable judgement, if it would be clearly unreliable to analyse and report the sample, then a repeat will be requested.
8. It is mandatory for sample takers to include **the NHS number on the blood spot request card. This enables all babies born in the UK to be tracked via the NBSFS.**
9. If an initial sample does not arrive in the lab within 7 days of collection, a repeat sample should be taken. If a repeat sample arrives in the laboratory after a delayed initial sample, if possible, the repeat sample should not be analysed and the results given for the initial (delayed) sample.
10. In the past it has been recommended that samples received later than 14 days after they were taken should not be reported and a repeat requested. This interval is now extended to 28 days.
11. If Lab staffing is very limited, testing may need to be prioritised. IMDs (Inherited Metabolic Disorders) and CHT (Congenital Hypothyroidism) should be tested and reported within the current turnaround times. Testing and reporting for CF (Cystic Fibrosis) and SCD (Sickle Cell Disease) may be delayed, but samples should be tested and reported as soon as it is practical.
12. Reporting screen positive results can be prioritised over labs daily reporting of normal results to CHIS (Child Health Information Services), but upload to NBSFS is **imperative** and should be maintained so that babies can be tracked. If labs are forced to delay or suspend sending results to CHIS labs are asked to notify CHIS, maternity services and SQAS (Screening Quality Assurance Service).
13. Referral of positive cases should be attempted by the current routes. If these are modified new guidance from the providers should be followed. Confirmatory testing may be delayed, but clinicians may elect to begin to treat the child based upon the information that they have and this will remain their responsibility.
14. The requirement to check and report IVA, MCADD and MSUD results on Saturday mornings will be operated at the discretion of the Laboratory, dependent on staffing.
15. It is important that midwifery teams track all delays and declines using the Failsafe tracking system (NBSFS) and NHS Digital are updating the status codes to allow this to be recorded for NBS screening in light of COVID-19.

The codes are:

- Code 0208: NBS declined due to epidemic
- Code 11: NBS delayed due to epidemic (delays requested by the parents or/and the sample taker)

Previously proposed subcodes for code 09 (not screened/ screening incomplete) have been disregarded for COVID-19 related reasons as a 09 code denotes the end of the NBS screening pathway for a baby. The baby would no longer be tracked on the NBSFS.

If screening is not completed for a range of reasons including an inability to get the family to respond or a breakdown in midwifery care this would need to be reported as an incident to SQAS rather than via a status code.

16. All NBS Labs have business continuity arrangements in place in the event they are unable to maintain the service. In this event the Blood Spot Screening Programme and SQAS should be informed immediately. If laboratory services cannot be maintained a backup laboratory would be contacted. Initially the back-up laboratory as defined in the lab's own business continuity plan should be approached and if they are unable to provide support, the Blood Spot Programme should be notified and other laboratories may be approached via UK Newborn Screening Laboratory Network (UKNSLN).

4. Additional things to consider

4.1 Information for parents

It is important that all parents receive PHE's Screening Tests For You and Your Baby information about antenatal and newborn screening and should be signposted to the [online version of this leaflet](#) if required. PHE has more guidance on how to do this effectively, including a range of resources to support health professionals which can be requested from the [screening helpdesk](#).

As leaflet usage changes, services should review any screening leaflet standing orders with the [national print provider \(APS\)](#) to manage local stock levels appropriately.

4.2 Screening safety incidents

As far as possible, the principles in the [national guidance](#) should be followed. Incidents or potential incidents should be reported to SQAS and commissioning teams SQAS will continue to give advice whilst recognising the intense pressure that many providers will be under.

4.3 Screening Quality assurance visits and network meetings

All screening QA visits and network meetings are postponed from 23 March until further notice.

This will support our NHS colleagues who are focusing their efforts on frontline activity. We will regularly review this situation and keep staff and stakeholders informed.

Communication to both providers who are due a Quality Assurance visit and network meeting attendees will be via SQAS.

4.4 Data requests/submissions for key performance indicators and standards

Our aim is not to put any additional pressure on screening providers or the wider NHS.

Q3 KPI data – request for data with a deadline of 31 March was made some time ago. Thank you to those services who have already submitted data. If services still want to submit data, please do so. If you need an extension please contact us via phe.screeningdata@nhs.net

Q4 KPI data – we are not formally requesting data as we usually do but at the request of a few providers will make the maternity service submission and CHIS/CHRD templates available at <https://www.gov.uk/government/collections/nhs-population-screening-data-guidance-and-templates>.

The usual deadline for returns is 30 June, if your service can return data please do so. We will accept returns until the end of September 2020. If you can prioritise submitting the coverage KPIs we would encourage you to do so. This will provide assurance that eligible women and babies are completing screening where the offer is accepted and will also help us to understand the impact of the pandemic.

The coverage KPIs are NB1 and NB4 for newborn blood spot.

Performance against thresholds – we appreciate meeting some thresholds is challenging and will caveat any reporting of data during this time.

2019 to 2020 annual data returns – For the Newborn blood spot screening laboratory and CHIS returns we will distribute the annual templates and guidance and extend the deadline for returns to December 2020.

4.5 UKAS visits to screening laboratories

From 16 March 2020 United Kingdom Accreditation Service (UKAS) ceased performing on site assessments and started implementing remote assessments due to COVID-19.

Whilst many UKAS customers can accommodate remote assessments, it became apparent that this is not possible for the healthcare services that are impacted by this crisis.

Following discussions with NHSE/I and PHE, UKAS will postpone assessments of affected services by up to six months. Assessment profile dates will be rescheduled to take this into account and the timeframe will be kept under review.

UKAS has been provided with a list of directly affected services in England (approximately 60% of accredited laboratories) but is aware that many healthcare scientific and diagnostic services will be indirectly affected and we are expecting that the entire schedule of assessments due between April and September may now all be moved back six months. This would include approximately 80 ANNB laboratory assessments.

4.6 PHE Screening publishing and social media activity

We have stopped all social media activity, including blogging and tweeting, and will not be publishing any new guidance on GOV.UK at present; including quality assurance executive summary reports.

4.7 Documenting changes as they happen

We anticipate that there will be a need to evaluate the impact of the pandemic at some time in the future, so we advise providers to document dates and changes made to the delivery of screening for audit purposes.

5. For further queries

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Tessa Morgan	Screening data and information manager

Summary of Document Changes

Final Draft V1.0	11.05.20	CC programme draft
Final Draft V2.0	11.05.20	Formatted with embedded documentation
Final Draft V2.2	11.05.20	Documentation added as appendices
Final Draft V2.3	17.05.20	CC; RS & SC amendments and comments
Final Draft V2.4	19.05.20	Collated track changes and comments
Final Draft V3	24.05.20	Edited, removing generic text to focus on changes required
Final Draft V4	26.05.20	Collated track changes