Bradford Teaching Hospitals
NHS Foundation Trust

Annual Report 2017-2018

Antenatal and Newborn Screening Programmes

Fiscal Year	**2017-18**
Provider	**Bradford Teaching Hospital Foundation Trust**
Author(s)	**Victoria Jones**
Job Title	**Specialist midwife – screening**
Email	**Vicky.jones@bthft.nhs.uk**
	Contributions from: **Heidi McCarthy (Down's, Edwards and Pataus' screening / Fetal anomaly screening)** **Pushpa Mistry (Hearing screening)** **Sobia Khan / Pauline Garnett (Sickle cell and Thalassaemia screening)**
Date of Report	
Report signed off by:	
Name	**Sara Keogh**
Job Title	**Head of Midwifery**

CONTENTS

FOREWORD

Aim of Report

This report is produced to contribute to ongoing assessment of the quality of the delivery of the six NHS antenatal and newborn screening programmes (ANNB) against NHS Screening Programme requirements. This will provide a benchmark for future service planning and quality improvement initiatives.
The NHS screening agenda is driven by a range of NHS and Department of Health policies and standards. For a contemporaneous list of relevant documents please see www.screening.nhs.uk

The UK National Screening Committee (UK NSC) currently recommends the offer of:

Antenatal screening:

- Infectious diseases screening (HIV, Hepatitis B and Syphilis)
- Sickle cell and thalassaemia screening
- Screening for fetal anomalies
  Down's, Edward's and Pataus' syndrome screening
  Fetal anomaly ultrasound

Newborn screening:

- Bloodspot Screening (Phenylketonuria, Medium Chain Acyl CoA Dehydrogenase Deficiency (MCADD), Cystic Fibrosis, Congenital Hypothyroidism, Sickle Cell) including extended screening
- Newborn Hearing Screening
- Newborn Physical Examination

EXECUTIVE SUMMARY

AREAS OF ACHIEVEMENT

- Reporting of ID3 (hepatitis B coverage) and ID4 (syphilis coverage) key performance indicator (KPI) data to Public Health England commenced. This data has consistently met the achievable threshold.
- Improvement in the Fetal Anomaly Screening Programme (FASP) Standard 8a data (suspected/confirmed fetal anomalies seen locally within 3 working days).
- Reporting of FA2 KPI data commenced (ultrasound coverage). This data has consistently met the achievable threshold.
- Steady improvement in ST2 data (sickle cell and thalassaemia screening by 10 weeks gestation) which now exceeds the acceptable threshold.
- Increase in ANNB screening deputy hours from 7.5 hours a week to 15 hours a week.
- Bradford Newborn Hearing Screening Programme has been recognised nationally for the high standard of care it delivers to babies with suspected hearing loss and their parents. Consistently meeting the achievable threshold for NH1 and NH2 KPI data (coverage and time from screening outcome to attendance at an audiological assessment appointment).
- Improvement in women's experiences regarding the offer of ANNB screening compared with the previous year, highlighted in a locally conducted audit.
- The Midwifery led Newborn and Physical Examination (NIPE) clinics, continues to evaluate well.
- Majority of reports/results are now received electronically via NHS mail for Bradford women who are referred to Leeds. This has greatly improved timeliness of communication and information governance safety.
- Palliative care clinics run by one of our Consultant Neonatologists, with strong links from the Forget Me Not team, has improved links between antenatal and postnatal care.

AREAS FOR DEVELOPMENT / GOING FORWARD

- Recruitment for an ANNB screening failsafe officer has been approved to ensure the screening pathway is complete from offer of test to receipt of result. A consistent failsafe will ensure missed screening is identified and escalated in a timely manner whereby reducing the risk of incident recurrence and harm.
- To develop an effective process which facilitates the management of women, following failed venepuncture.
- To continue driving locally developed strategies for repeat offenders until the <2% acceptable NB2 (avoidable bloodspot) KPI data performance has been achieved.
- To produce a detailed action plan as KPI FA1 data did not reach the acceptable threshold during 17-18 (completion of trisomy laboratory request forms).
- To cascade staff training in preparation for the introduction of Non Invasive Prenatal Testing (NIPT) as an additional option into the NHS Fetal Anomaly Screening pathway by the 30th July 18.
- Explore ways to report Trisomy screening coverage data (FA3) due to be reported September 2018. This will be problematic as these results are not recorded on Maternity IT system at present.

AREAS OF CONCERN

- KPI FA1 has not met the acceptable threshold during 17-18 (completion of trisomy laboratory request form).
- KPI NB2 data has not met the acceptable threshold during 17-18, however a local strategy commenced in October has made some improvement (avoidable bloodspot).
- Trisomy screening results are not documented in the women's maternity IT records, therefore unable to provide future KPI (FA3).
- Due to the lack of an electronic interface between the maternity and the pathology IT system the validity and quality of data, such as KPI data and annual report data is reliant on manual systems to identify and escalate missed screening whereby reducing the risk of recurrance and harm. The 'test tracking' of all screening blood results onto the maternity IT system is therefore required which is a continuing challenge and has been highlighted as an issue/risk.
- Due to insufficient screening hours and no administration support we have been unable to facilitate a screening midwife during the consultant fetal medicine scanning sessions. Additionally all planned screening audits, devised on the annual essential and desirable screening audit schedule were not completed.
- No formal arrangement in place to input outcome data into NIPE smart for screen positive referrals.
- Not meeting the 8 day turnaround time from receipt of sample in the laboratory to confirmation of a positive result (in line with Infectious Diseases Screening Programme Standard 4)
- Unable to confirm if all women are notified of their screening blood results at their next antenatal appointment.

ANTENATAL & NEWBORN SCREENING – Service Overview

LOCAL POPULATION STRUCTURE

The total population of Bradford district is 534,300, an increase of 3,100 (0.6%) since the previous year (ONS 2017). The increase in the District's population is largely due to "natural change" with around 3,600 more births than deaths, although this has been balanced by a larger number of people leaving Bradford to live in other parts of the UK.

More than one quarter of people living in Bradford are younger than 20 years of age. Bradford has the third highest percentage of the under 16 population in England after the London Borough of Barking and Dagenham and Slough Borough Council.

The population of Bradford is ethnically diverse, 63.9% of the population describe themselves as British White and 20.3% as Pakistani, which is the largest proportion in England.

Information from the Annual Population Survey in 2016 found that 65.1% of Bradford population aged 16-64 is in employment which is significantly lower than the national rate of 74.0%.

Table 1 –Maternity Activity

2017-18 Activity	Number
Women booked for maternity care	6152
Total deliveries recorded by Trust/unit (including live births / stillbirths)	5912
Bradford Teaching Hospitals NHS Foundation Trust	

STRUCTURE AND ACCOUNTABILITY

In line with the NHS England NHS Screening Programmes' service specifications each Provider should ensure that there is appropriate clinical oversight, management and governance of the screening programmes with the designation of a clinical lead, screening programme coordinator and establishment of a multi-disciplinary steering group / programme board including NHS England representation. The provider will ensure that responsibility for the screening programmes lies at director level

Bradford has two separate groups, antenatal screening and newborn screening.
The meetings are held quarterly for antenatal screening and bi- annually for newborn screening (more often if needed)

The remit of both groups is to assess and review current antenatal and newborn screening programmes, plan for future developments and work towards provision of evidence based services that are both equitable and acceptable for pregnant women and their families and in line with National recommendations. The groups also oversee audit, management, training and screening incidents in order to improve the overall quality of the service provided. Multi-disciplinary membership allows systematic communication and dissemination of information to all stakeholders. Minutes of the meetings are widely circulated and issues fed into Maternity core group meetings.

Antenatal Steering Group Membership

Member	Title / Role
Dr Janet Wright	Consultant Obstetrician/ Gynaecologist- Clinical Director **– Chair**
Dr Padma Munjuluri – Deputy Chair	Consultant Obstetrician/ Gynaecologist- **Deputy Chair**
Sara Keogh	Head of Midwifery
Vicky Jones Alex Fozard	Specialist Midwife – Screening Screening deputy
Karen Lomas Heidi McCarthy / Penny Fleming	Superintendent Ultrasound Screening support sonographers
Kate Horsfall Samantha Taylor	Screening and Immunisation Manager Screening co-ordinator West Yorkshire area team Public health England
Jo Mallinson Helen Avdiyovski	Community Team Leader Community Team Leader (Secondment)

Associate members participate as and when their specialist knowledge is required. This list is not Exhaustive and from time to time other associate members are invited.

Associate Member	Member
Daniel Herrera	Principal Clinical Scientist,
Gill Shaw	Manager Antenatal Services
Sulleman Moreea	Consultant Hepatologist
Paul McWhinney	Consultant Infectious Diseases
Adrian Williams	Consultant Haematologist
Pauline Garnett /Sobia Khan	Genetic Counsellors (HBO)
Alison Powell	Matron
Representatives from each Midwifery community	Screening champions

team	

Newborn Screening Group Membership

Member	Title/role
Dr Chris Day	Consultant Neonatologist- **Chair**
Dr Sunita Seal	Consultant Neonatologist- **Deputy Chair**
Sara Keogh	Head of Midwifery
Vicky Jones Alex Fozard	Specialist Midwife- Screening Screening deputy
Pushpa Mistry	Newborn Screening Co-ordinator / Audiologist
Kate Horsfall Samantha Taylor	Screening and Immunisation Manager Screening co-ordinator West Yorkshire Area team Public Health (England)
Joanne Mallinson Helen Avdiyovski	Community Team Leaders / Lead - Newborn Screening
Rebecca McMichael	Child Health Systems Specialist
Liz Robinson	Regional Quality assurance Manager

Rebecca McMichael (Child Health System Specialist) commenced maternity leave in October 2017. Essential reporting requirements have been covered by Emma Whiteley and June Greenwood (Child Health Information Systems Co-ordinators) in Rebecca's absence.

There is no current representation from health visiting team.

Associate members participate as and when their specialist knowledge is required. This list is not exhaustive and from time to time other associate members are invited.

Associate Members

Member	Title / role
Caroline Griffith	Laboratory Lead – Newborn bloodspot screening

Clinical oversight

Victoria Jones (1 WTE) is the designated clinical lead for antenatal and newborn screening.

SCREENING CO-ORDINATION

The NHS England NHS Screening Programmes' service specifications detail that the screening programme provider should ensure that there are one or more named individuals responsible for the coordination of the delivery and planning of the programmes with appropriate administrative support to ensure timely reporting and responses for information requests. If there is only one named coordinator, the Provider should ensure that the cover arrangements are adequate to ensure the sustainability and consistency of the screening programmes. The Provider will ensure that they have a screening midwife /coordinator and deputies in post to oversee the screening programmes

Jo Taylor – Seconded to screening 1 day a week (7.5 hours). Commenced maternity leave in October 17
Alex Fozard - Seconded to screening 2 day per week (15 hours). Commenced post in January 18

Pushpa Mistry- Newborn Hearing screening Local Manager (1 WTE)
Karen Lomas- Superintendent Ultrasound
Heidi McCarthy – Screening support sonographer
Penny Fleming – Deputy screening support sonographer
(2-3 half day sessions per month depending on staffing)
No clerical support has been available for this financial year

All members are based at Bradford Royal Infirmary. There were no formal arrangements to cover annual leave / absence for the screening co-ordinator during 2017-2018.

The responsibilities of the screening co-ordinator include:

- Oversee and co-ordination of all antenatal and newborn screening programmes.
- Monitor local delivery of programmes to ensure that they are equitable, evidence based and consistent with local and national recommendations.
- Co-ordinate local screening governance groups. Including chairing these meetings in the absence of the clinical leads and taking minutes.
- Co-ordinate audit of service provision and quality standards in-line with the audit schedule.
- Available as a resource and specialist in the field of antenatal and newborn screening, assisting and advising colleagues in the care of women and babies undergoing screening.
- A large part of the role is to be available to support pregnant women in the decision making process, provision of additional information, and signposting to outside agencies and appropriate referrals to other services.
- Maintain and support a programme of education and training of health care professionals in all aspects of antenatal and newborn screening.
- Liaise with multi-disciplinary team in order to provide holistic care
- Represent the trust at relevant local, regional forums and national events in order to keep abreast of changes in screening.
- Investigate all screening incidents and implement and communicate any lessons learnt.
- Respond to screening complaints in a timely manner.
- Maintain records (databases) of high risk, positive, avoidable repeats and declines.
- Locate and provide outcome data to external bodies and internal purposes.
- Collating and submitting the increase of National data requirements over the last year, i.e. KPI and annual data.
- Involvement in failsafe systems to provide assurance screening blood samples are reported and managed appropriately.
- Maintain a small caseload of women who are HIV positive, maintaining clinical skills, credibility and ease of communication / continuity of care / provision of additional support for this vulnerable group of women.
- Fulfil the Trusts requirements for a Band 7 post- this includes participation in recruitment, hot desk rota (day to day running of the Maternity unit e.g. resolving staffing issues, support staff when unit busy).
- Administration and clerical work (compiling packs for AN and PN hepatitis B, raised NT packs and un-booked women in labour, and scanning reports/letters to Medway IT system).

SUMMARY OF ORGNAISATION'S ANTENATAL AND NEWBORN SCREENING GUIDLEINES

Screening Programme Detail all relevant guidelines for each screening programme	Guideline or pathway in place Yes/No	Last review date	Next review due
Sickle Cell & Thalassaemia	Yes	July 16	July 19
Infectious Diseases in Pregnancy	Yes	March 18 (minor changes)	November 18
Fetal Anomaly (Trisomies 21, 18, 13)	Yes	May 18	June 20
Fetal Anomaly (Ultrasound)	Yes	June 18	July 18
Newborn Blood Spot	Yes	May 16	August 18
Newborn and Infant Physical Examination	Yes	February 18	February 20
Newborn Hearing	Yes	October 17	October 19
Pre-Conceptual and Pregnancy Care of the woman with pre-existing Diabetes and Management of the woman with Gestational Diabetes	Yes	June 16	November 18

PARENT INFORMATION

The NHS Screening Programmes produce a standardised parent information booklet for antenatal and newborn screening 'Screening tests for you and your baby' and it is recommended that all women receive a copy in early pregnancy

In this Trust:
'Screening tests for you and your baby' booklet is sent out as soon possible but ideally 1-2 weeks prior to the booking appointment. Women are advised to read the booklet prior to the booking appointment and directed back to it towards the end of the pregnancy in order to read the newborn screening section. Midwives are aware that this booklet is available to download in different languages and in audio version. Unfortunately we do find that a significant proportion of Bradford women do not read this booklet prior to the booking appointment. Any language barriers are identified at referral and documented onto the maternity IT system so interpreters can be organised if required.

Supplementary national leaflets are used in relation to screening and include the Chorionic Villus Sampling (CVS) and Amniocentesis Information for Parents Leaflet. For women receiving high risk results, leaflets about diagnostic tests are e-mailed by the screening co-ordinator. This allows woman instant access to good quality national information.

The Hepatitis B, HIV and Syphilis national leaflets are used for women positively identified through the infectious diseases screening programme. These are available in different languages and used if appropriate.

Women who are found to have a multiple pregnancy are directly referred to the multiple pregnancy clinics and recounselled regarding Trisomy screening by the screening co-ordinator. Contact details for the screening co-ordinator are given.

Parent information leaflets from support agencies are also used if appropriate, both locally and nationally for example ARC HIV i- base etc.

Screen negative results for Down's syndrome screening and newborn blood spot are sent by letter. All other screen negative results are given by the community midwife at the next antenatal clinic appointment or at the time of the test i.e. Fetal anomaly scan and newborn hearing screen.

DATA COLLECTION

In this organisation data collection is by Medway (System C) maternity system.
The most appropriate denominator for antenatal screening recommended by the UK NSC is the number of women **booking** for delivery. The Trust is now confident about the denominator as all bookings are recorded on the maternity system; this data is also used to validate data used for payment by results.

The offer and consent for screening tests (HIV, syphilis, hepatitis B, and sickle cell and thalassaemia) are inputted onto the Maternity IT system at the booking appointment. When the results are received they are uploaded to the Maternity IT system. This provides us with our KPI ID1, ID3, ID4 and ST2 data. For women with no results on the Medway maternity system a manual trawl using the ICE pathology system is required to ensure all women who have consented to screening have a conclusive result and so accurate data can be submitted.

A local database is kept by the screening co-ordinator for screen positive results for all antenatal screening programmes.

The main challenges with collecting and analysing data are:

- Accounting for women who have booked but then go on to miscarry- these are not always recorded and it is unclear at what gestation
- Un-booked women who present in labour
- Women who transfer their care during pregnancy
- Cross border issues. Some Airedale catchment areas have Bradford postcodes therefore the lab is unable to separate the data for bloodspot screening
- Information is now stored contemporaneously on the maternity IT system Medway, however results have to be inputted manually by the community midwives , therefore data for KPI ID1, ID3, ID4 and ST1 has been problematic.
- There is no interface between Medway IT system, IT pathology system (ICE) or CRIS system therefore screening results have to be inputted manually.
- Poor linkage of pregnancy and newborn outcomes.

The information presented in this report relates to the cohort of women who booked for maternity care or babies born between **1 April 2017 and 31 March 2018**

KEY PERFORMANCE INDICATORS

The NHS Screening Programmes require Key Performance Indicator data to be collated and submitted on a quarterly basis. Further information is available at:
https://www.gov.uk/government/collections/nhs-screening-programmes-national-data-reporting

A summary of 2017-2018 KPIs for this Trust can be found in the table below.
(Please refer to appendix 1 for definition of KPI'S)

Antenatal	ID1	ID2	ID3	ID4	FA1	FA2	ST1	ST2	ST3
KPI Standard	≥95.0%	≥70.0%	≥95.0%	≥95.0%	≥97.0%	≥90%	≥95.0%	≥50.0%	≥95.0%
Q1	99.7%	100%	99.6%	99.7%	96.3%	99.4%	99.6%	53.1%	99.0%
Q2	99.3%	50.0%	99.2%	99.0%	96.0%	97.7%	99.1%	56.5%	97.2%
Q3	99.6%	00.0%	99.6%	99.6%	96.8%	96.1%	99.2%	58.0%	97.5%
Q4	99.5%	100%	99.4%	99.5%	94.9%	reported Sept 18	99.4%	52.3%	92.1%

Newborn	NB1	NB2	NH1	NH2	NP1	NP2
KPI Standard	≥95%	≤2.0%	≥97%	≥90%	≥95.0%	≥95.0%
Q1	92.7 %	5.1%	99.9%	98.0%	98.1%	no cases
Q2	93.2 %	5.0%	99.5%	98.7%	97.9%	no cases
Q3	91.4 %	3.3%	99.8%	97.3%	96.1%	no cases
Q4	91.2%	3.0%	99.8%	100%	97.5%	33.3%

In this Trust

ID3 (hepatitis B coverage) and ID4 (syphilis coverage) were new KPI's introduced in April 17.

Completion of 'test tracking' screening results is variable therefore a manual trawl is always required for approximately 10% of the screening cohort for ID1, ID3, ID4 and ST1. This is very time consuming but required to achieve complete assurance that all women consenting to screening have a conclusive result.

The data for Newborn bloodspot (NB2) is difficult to collate as the screening laboratory separate data based on postcode. They are at present unable to separate Bradford and Airedale data therefore the raw data is unreliable. This was identified as an action following the QA visit in September 2015. KPI data is collated locally by extracting information from CHRD requests for avoidable repeats. This data is then added to a local spreadsheet providing us with a continuous record of our avoidable repeat rate. Data from samples 'taken on day 4' and 'in transit 15-28d' which is provided from the laboratory is included in our NB2 data.

The laboratory manager provides details of the sample taker for avoidable repeats, allowing action and training to be given to staff who consistently have avoidable repeat samples.

Bradford midwives have commenced clearly marking samples as 'RAE' in preparation for the lab to allocate repeats correctly.

KPI data for completion of trisomy request forms (FA1) has not met the acceptable threshold this year. At present the individual responsible for omitting information (midwife, sonographer and/or midwifery support worker) is informed by email. Plan is to produce/implement a detailed action plan in 2018.

NB1 and NB3 data has been extracted from the Child health information system and provided by Emma Whiteley and June Greenwood (Child Health Information Systems Co-ordinators). NB1 (conclusive PKU result by 17 days) remains a challenge and to some extent is reliant on NB2.

ID2 data is reliant on a woman attending her appointment with the Hepatology specialist, this is always a very small cohort, therefore if a women DNA the data is misleading.

SCREENING INCIDENTS

In order to assure governance and safety of screening programmes it is important to report and share learning from screening incidents. This should assist in the prevention of recurrence and support service improvement and failsafe processes.

During this financial year there were 5 screening incidents reported through the internal incident reporting system, 2 were declared as serious incidents. 3 were initially reported by St James's hospital.

Incident date	Ref	Serious incident /Patient Safety Incident /	Description / investigation findings/ action

		Near Miss	
12/4/17		Serious Incident	A Level 2 comprehensive investigation was commissioned on the 12th April 17 following raised concerns regarding the Infectious Diseases Screening Programme. 153 women who had infectious diseases screening bloods taken during their booking appointment in March 17 were identified as not having results and not processed correctly. **Investigation findings** The investigation team conducted a physical walk through both laboratories which enabled the identification of specific problems and interventions required. The different systems in place for the handling and management of the antenatal screening samples between the two sites created a situation whereby samples were not assessed and tested correctly. With the transfer to the JV there appears to have been no clear process in place for the handover and the roles and responsibilities of the various personnel involved. The root cause was poor communication and preparation prior to the transfer to identify the key differences in the provision of the screening service before the go-live of the Joint Venture. **Action** Serious incident investigation report produced  Final report V5.docx
10/11/2017		St James's hospital incident	Over 50 bloodspots obtained and posted around the region on the 01/11/17 did not reach the St James Leeds laboratory. **Investigation findings** Escalated to Quality Assurance. The whole region was affected; the most likely cause was that the samples were all together in some unknown location/lost. **Action** All Bradford samples repeated in timely manner. Other means of transport are being explored by Leeds laboratory, eg. courier service, change of envelope to be more identifiable
17/1/18	St James's hospital	St James's hospital incident	The EQA results for AFP (used as part of the quadruple test for T21) were far from the consensus values. On reviewing the batch for AFP performed on 23/11/2017, the 3 internal QCs at the beginning of the batch were within limits, however the last 2 QCs were out. All together it makes very likely that the results reported for AFP were incorrect and the risks for Downs syndrome reported for 20 patients are also incorrect. (7 were from Bradford) **Investigation findings** Preliminary analysis of the data indicates that all women reported as low risk are very likely to stay as low risk even if the "correct" AFP MoM was 0.6. Root causes included poor documentation of actions, no second checks of data, routine violations of procedure, no external backup of system data, poor attitude to quality principles and staffing - limited support. Recommendations were made. **Action** All 7 women booked in Bradford affected by the incident were contacted and offered private non-invasive testing. Letters were sent confirming

			their decision made.
09/03/18		Serious Incident	On the 9th March 2018 the Trust declared a serious incident in relation to the Sickle Cell and Thalassaemia Programme. A cohort of 22 women, were identified as having missed screening for sickle cell and thalassaemia when collating data for the quarterly KPI data submission. The women were of advanced gestation or postnatal when identified. A Trust investigation was commenced. **Investigation findings** The main concerns were around the availability of the local FOQ form, non-compliance of the test tracking process and dual reporting of systems. Additionally a major concern is the lack of a consistent failsafe process to identify and escalate missed screening whereby reducing the risk of recurrence and harm. This incident is still in progress. **Action** Awaiting serious investigation report.
15/3/18	St James's laboratory	St James's hospital incident	Approximately 90 newborn bloodspots posted from around the region did not reach St James's hospital laboratory. (Approximately 31 were obtained and sent from Bradford) **Investigation findings** It was noted in the screening laboratory in the preceding weeks that royal mail deliveries were erratic rather than following the usual pattern of samples received. The most likely cause was that the samples were all together in some unknown location/lost. Reported through Quality Assurance **Action** 31 affected Bradford samples repeated in timely manner. Other means of transport are being explored by Leeds laboratory, eg. courier service /change of envelope to be more identifiable

Section 1: Sickle Cell & Thalassaemia Screening Programme

	Comments
Laboratory used for antenatal screening	Leeds
Does this laboratory perform second line / confirmatory testing? If no, which laboratory is used?	Yes
Is SCT screening requested: Electronically Paper Both	Paper request forms are used.
Is the FOQ integrated into the request form?	The FOQ is integrated into the request form

Clinical Arrangements, Management of Results and Failsafe Processes

Negative results are reported to women by their midwife including those whose pregnancy has ended early.

All women that have been identified with screen positive results are referred directly to the Haemoglobinopathy Genetic Counsellors by Leeds Teaching Hospital Laboratory and the results are reported electronically via the NHS net email account. This information is recorded in the maternity IT system by the HBO counsellors allowing other health professionals access to this information.

All newborn screen positive results are sent directly to the HBO Counsellors by the Leeds Teaching Hospital Lab via a paper report. The Counsellors make arrangement to see the parents at their clinic within 6 weeks of receiving the result. The results are attached to a full paper report copy of the Newborn bloodspot results as a failsafe that is also fed back to the parents.

Arrangements have been made with Leeds lab to send a copy of the screen positive results to Haemoglobinopathy assistant at BTHFT simultaneously via the nhs.net as well as for the Counsellors. In order to have Failsafe arrangements the Haemoglobinopathy assistant sends out an additional electronic copy to the Counsellors from Bradford Teaching Hospital email account. This copy will include NHS number, home address, contact numbers and where possible partner details with previous test results if tested.

Haemoglobinopathy Genetic Counsellors are responsible for making arrangements to offer and test the father of the baby of all screen positive women. An initial telephone contact is established to confirm partner details. Those fathers that have agreed to be tested are offered a blood test by either inviting them to the clinic or to attend hospital for a blood test. All screen positive results for fathers are followed up by the counsellors to make appropriate arrangements for further counselling and referrals and maternity IT system updated accordingly.

Screen negative results are monitored by the screening co-ordinators quarterly when reporting National KPI data.

Regular joint meetings with the laboratory are held in order to identify good practices, highlight concerns and resolve problems.

Audits completed

Sickle Cell and Thalassaemia Satisfaction survey report

Haemoglobinopathy Genetic Counsellors conduct audits for all screen positive this includes antenatal women and newborn seen at the clinic.

Conclusion and recommendations

In conclusion the service showed an overall positive approach by the service and counsellors. To date all standards have been met and adhered to and therefore there are no additional recommendations. From the current audit no specific recommendations have been made however in the future specific antenatal related questions could be incorporated in order for the service to identify the needs of the antenatal women.

Reporting of ST4 KPI data is to commence from April 18 (antenatal sickle cell and thalassaemia screening – timely offer of prenatal diagnosis (PND) to women at risk of having an affected infant).

Section 2: Infectious Diseases in Pregnancy Screening Programme

	Comments
Laboratory used for antenatal screening	Airedale Laboratory
Does this laboratory perform confirmatory testing for all conditions? If no, which laboratory is used?	Confirmatory testing is performed at Leeds General Infirmary
Is IDPS screening requested: Electronically Paper Both	Paper requests

Clinical Arrangements, Management of Results and Failsafe Processes

In this Trust, screening is routinely offered to all women regardless of gestation for Hepatitis B, HIV and Syphilis.

'Screening tests for you and your baby' National leaflet is sent to women prior to their booking appointment. Consent is obtained and tests are taken at the booking appointment or at the earliest opportunity if the woman presents late or in labour un-booked. Packs are available on Labour ward and the Birth Centre with patient information booklet, booking blood forms and blood collection bottles. These are well received by labour ward and birth centre staff.

As per national guidelines the above tests are recommended and normalised as part of antenatal care. An opt out policy is adopted for the purposes of these tests. Local policy was developed in line with NICE and the National Screening Committee guidelines. From April 2017, reporting of KPI ID3 and ID4 data commenced. The 95% HIV, hepatitis B and syphilis uptake rate target set by the department of health is exceeded and Bradford has a consistently high uptake rate for all the infectious diseases screening of over 99%.

All serology samples are manually booked in by Bradford laboratory and then sent to Airedale laboratory for testing. 'Possible positive' samples are sent from Airedale to Leeds laboratory for confirmatory testing. 'Possible positive' results are routinely reported to the screening co-ordinator by Airedale laboratory by telephone or using the generic NHS.net email account. A number of meetings with the Joint Venture Pathology staff have taken place to refine this reporting process which has greatly improved throughout the year.

Negative results should be discussed with the woman at her next routine antenatal appointment. Trust guidance is to ensure that all women screened receive a conclusive screening result. At present there is no documented evidence of this process however we are exploring the feasibility of mandatory fields to record this information in the Maternity IT records. For women who decline the screening co-ordinator is informed and the test is reoffered ideally at the 20 week scan appointment. In Bradford the routine practice is to obtain booking bloods at the booking appointment therefore all results are acted upon as per guidelines including women who have failed pregnancies.

Following failed venepuncture women in the community are given request forms and asked to attend the phlebotomy services at SLH or BRI. If the booking takes place at a GP surgery and a phlebotomist is

available their assistance is requested. Some women do not attend these services in a timely manner delaying results/entry into treatment. We do not have a formal process for failed venepunctures.

When informed of a confirmed positive result, the woman is contacted to attend for further information and a confirmation sample. All women with positive results for HIV have multidisciplinary team (MDT) management with obstetrician, infectious disease consultant, pharmacist and paediatrician. Women with a positive syphilis result are managed by the obstetrician, GUM consultant and paediatrician. All women with positive syphilis serology results are referred to the sexual health consultants at the sexual health clinic for treatment, contact tracing and follow up. There are monthly MDT meetings held at the Sexual health clinic where discussions regarding the management for all pregnant women who are HIV and/or syphilis positive are discussed.

All Hepatitis B positive pregnant women are seen and counselled by the screening co-ordinator, within 7 days of receiving the result for a new diagnosis. A comprehensive antenatal checklist is used to ensure all appropriate steps are followed:-

- Timely electronic referral to Hepatology nurse specialists
- Notification to the woman's GP
- Discussion with neonatologist, baby notes are pre- prepared with the vaccination and immunoglobulin if indicated prescribed and stored into the mother's maternity folder ready for delivery.
- A notification is sent to CHRD and PHE via NHS.net with the woman's details, blood markers and an EDD

At the counselling appointment the woman is also informed about the importance of the vaccination programme for the baby, testing of contacts and general infection risk measures. This information is reinforced by a patient information leaflet and contact number of the screening co-ordinator for subsequent questions and safety net if appointments for subsequent vaccinations for the baby have not been received.

A comprehensive postnatal pack is used when the first vaccination is administered. This works as a form of communication between the disciplines and acts as a failsafe for coverage of the vaccination programme. A further failsafe was introduced as a result of a historical incident where a baby's second hepatitis B vaccine was delayed due to the relevant documentation not being sent to CHRD in a timely manner. The screening co-ordinator does a regular check to identify deliveries to hepatitis B positive women and informs the CHRD department. If the notification has not been received the screening co-ordinator is informed.

All HIV positive women are case-loaded by the screening co-ordinator. The screening coordinator will complete the booking, and provide all the antenatal care. This has been invaluable in providing continuity of care and support to this vulnerable group of women, clear communication pathways with the infectious diseases consultants, obstetrician that the woman is booked under, HIV specialist nurses and other support agencies. This model of care has reduced anxiety for the community midwives who may only see one HIV positive woman once every 1-2 years, allowed the screening co-ordinator to remain clinically credible and retain her midwifery skills.

Positive results are inputted onto the Medway maternity system by the screening co-ordinators with an alert for staff on the labour ward and postnatal wards e.g. - High risk Hep B positive- baby needs vaccine and immunoglobulin.

Bradford and Airedale Joint Venture

The provision of antenatal screening for BTHFT was transferred from Leeds to the Joint Venture between Airedale NHS Foundation Trust (ANHSFT) and Bradford Teaching Hospitals in March 17. Major concerns were escalated regarding the risks to the antenatal serology screening service from March/April 17 onwards. A serious incident was declared in April 17 (see appendix 3). Concerns were also escalated in relation to:

- Lack of a monthly failsafe of all positive screening results.
- Positive results/insufficient/unsuitable samples not consistently reported using the generic antenatal screening NHS.net email account for timely action.
- The reporting of 'possible positive' antenatal screening results prior to sending for confirmation. The PHE service specification no 15 (17-18) Infectious disease in pregnancy states results should not be communicated, either written or electronically until confirmatory tests are completed.
- Failure to meet the 8 day turnaround time from receipt of sample in the laboratory to confirmation of a positive result (Infectious Diseases In Pregnancy Screening Programme Standard 4).

A number of actions were implemented following the infectious diseases serious incident investigation which resulted in immediate improvements.

We now have a process that identifies any woman that has consented to screening however the sample has not been processed / received, as from May 17 a weekly spread sheet of all antenatal bookings is sent to the Airedale laboratory by the screening co-ordinator. The spread sheet is returned to the screening co-ordinator with the test results included. We also use this as a failsafe to ensure positive results have been acted upon and as an alert about insufficient, indeterminate, unsuitable and missing samples, to monitor and action. Unfortunately this information is not always available on ICE. Reports of samples which require a repeat are sent to the requestor by the laboratory to arrange a repeat. This failsafe provides confidence but has generated a huge increase in administrative work for the screening co-ordinator.

BTHFT and ANHST are working collaboratively with Leeds to address the concern of not meeting the 8 day turnaround time for confirmed positive results. The requesting process at Leeds has been adapted to ensure that results are returned to ANHSFT using a generic IPS chemistry nhs.net account, reducing delays with paper copies of results being returned using the second class postal service. ANHSFT have also altered practices to ensure that these results are inputted within 24 hours (excluding weekends) to verification the same day by the Consultant Microbiologist. This has improved the turnaround time however results are still routinely taking much longer than 8 days to be returned by Leeds for confirmatory testing, streamlining conversations continue.

The PHE Service Specification no 15 (2017-2018) Infectious Diseases in Pregnancy Screening Programme states results should not be communicated, either written or electronically to the maternity service until confirmatory samples are completed on the screening sample. In 17-18 we did not meet this standard as 'possible positive' antenatal screening results were communicated to Antenatal Screening and a paper result is sent to the requesting clinician prior to sending the sample to Leeds for confirmatory testing. This increased the risk of false positive results being communicated to the patient or uploaded to their maternity records prior to the confirmation of sample.

Additionally the Airedale Operational Manager is working towards providing the screening co-ordinator with a monthly list of all positive results so complete reassurance can be achieved.

Audits completed

KPI ID1, ID2, ID3 and ID4 data is collected and sent quarterly

Conclusions and Recommendations

Significant improvements have been made throughout the year in relation to the infectious diseases screening pathway and the Joint Venture. We now have reassurance that women who enter the screening pathway but no sample is process/received are identified. Going forward an effective formal process which facilitates the management of women in who venepuncture has not been effective needs to be implemented. Work is in progress so only results from confirmatory positive samples are communicated to maternity services and providing a monthly failsafe of all confirmed positive results.

Data collection continues to be an on-going issue due to the absence of linkage between laboratory and maternity systems, lack of data entry clerk, incomplete documentation, and out of area bookings whose samples are analysed within other trusts. The issue is beginning to resolve with women who book with the Trust as community midwives recording of results improves. However, some incomplete/inaccurate data issues persist for women who book outside the Trust and this is unlikely to resolve in the near future.

The data entry of results into the maternity IT system continues to improve but a manual trawl is required for approximately 10% of the screening cohort. The challenge of getting midwives to record screening results continues and has been highlighted as an issue.

Retaining the HIV caseload, although small is becoming a challenge for the screening co-ordinator. This is due to the role expanding over the years with increasing national data requirements and neonatal screening developments. This model of care is unique and not many screening co-ordinators provide this service, the service. As this service evaluates really well with a high patient satisfaction rate, it is therefore recommended this service continues.

Excellent communication links exist with other specialities involved in the pathways for care for women identified with a positive serology result and these need to be maintained.

Section 3: Fetal Anomaly Screening Programme (Down's, Edwards' and Patau's syndromes)

	Comments
Laboratory used for combined screening	Leeds
Laboratory used for quadruple screening	Leeds
Fetal medicine service	Internal / Leeds Fetal medicine Unit

Clinical Arrangements, Management of Results and Failsafe Processes

The Trust has a Screening Support Sonographer (SSS), who has protected administration time incorporated within the normal working day to perform/complete audits. The screening co-ordinators are responsible for management of screen positive results and the SSS and deputy are responsible for the management of the ultrasound aspects of the programme.

Trisomy screening is offered to all pregnant women booking within the recommended timeframe i.e. up to 20 weeks gestation (eligible population).

First trimester screening (combined test) is offered to women who book by 14 weeks gestation. This is performed during the early pregnancy scan and involves the nuchal translucency being measured, followed by a maternal serum sample being obtained. Detection rate 85%, screen positive rate of < 2% with a risk cut-off of 1:150.

The Midwife Support Workers (MSW's), rotate in obtaining the blood tests in the routine NT scan clinics. They are given a list of names attending and are aware to document if they have declined screening or a failed pregnancy, so this can be followed up.

Midwives are informed automatically from the CRIS system if a woman does not attend her NT appointment

If the nuchal translucency cannot be measured at the first attempt, a further attempt is made that same day which is in line with FASP recommendations. Should this be unsuccessful then the woman is offered a second trimester (quadruple) screening test appointment which is given before she leaves the department. Second trimester screening is also available for those women who book too late for the combined test i.e. 14+2-20+0 weeks gestation. Detection rate approx. 80%, false positive rate 4% with a risk cut-off of 1:150. Quadruple tests are performed on around 25% of women accepting screening.

There are 9 sonographers who undertake the nuchal translucency scan. All ultrasound practitioners contributing to a NHS first trimester combined screening programme for Down's syndrome are required by the UK National Screening Committee and the NHS Fetal Anomaly Screening Programme (FASP) to provide screening data via the laboratory twice each year. This is externally evaluated by a quality assurance system known as DQASS (Down's syndrome screening Quality Assurance Support Service).
DQASS reports for 2017-18 - well evaluated service, with all sonographers' green/upper amber rated.

All screening test samples taken are logged and the list is sent to the Bradford laboratory following each session. These are then checked against the samples actually received in the laboratory to ensure all samples are accounted for. All samples are centrifuged in the Bradford Laboratory prior to

transportation to the Leeds Biochemical genetics laboratory; again the list of samples taken is sent to Leeds and checked against the actual samples received. If any samples are identified as missing either in Bradford or Leeds then the screening co-ordinator/ antenatal clinic staff are alerted in order for a repeat to be arranged in a timely manner.

A list of all samples received in the Leeds lab is sent weekly to the screening co-ordinator, this is used to ensure a result has been received for all samples sent. In addition a tracking book is used to record all samples taken, these are then cross checked with results received and any outstanding samples are identified and acted upon.

Low risk results are sent by letter to the woman within the recommended timeframe usually by the staff in the antenatal clinic. The screening support midwife and screening Co-ordinator oversees this and do a weekly check to ensure results have been received for all tests taken

High risk results are actioned by the screening co-ordinator/deputy and an appointment made with either one of them, or a consultant if requested by the woman, for further information, counselling and the offer of prenatal diagnosis within NSC specified time frames. Women wishing to have a CVS are referred to the Fetal Medicine Unit in Leeds and amniocentesis is offered in house. Private non-invasive testing (NIPT) is discussed as an option but is sourced independently. The number accessing NIPT has increased due to the accuracy of the test and lack of risk involved. During 17-18, 16% of all our high risk women sought this private test at a cost of approximately £300.

Low PAPP-A (low pregnancy associated plasma protein A)

As per RCOG guidelines and local agreement women with PAPP-A levels <0.415 MOMs are offered growth scans at 28, 32 and 36 weeks. Since the introduction of this the workload for the screening co-ordinators has increased as this involves co-ordinating a scan and clinic appointment, informing the women and updating the Maternity IT system. We have noted an increase in the number of phone calls from women who are anxious on receipt of this information. An updated patient information letter is in progress.

FA3 (coverage for Down's Edwards' and Patau's syndrome screening) is a new KPI commencing April 18. At present we will be unable to provide this data as low risk combined screening test results are not uploaded routinely onto the maternity IT system. Ways of providing this data need to be explored.

Audits completed

Failed NT audit ongoing and reported biannually as part of the essential audit schedule
CRL/NT image review
Dating scan audit
Quadruple test audit

The SSS or deputy SSS reviews 1 set of CRL & NT images per sonographer per month, using the FASP image review template. If any sonographer scores poorly, another image is reviewed.

Sonographers are given feedback on a 3 monthly basis unless issues are highlighted, in which case feedback is immediate.

Conclusions and Recommendations

- Audit information is readily available due to all samples being analysed at Leeds biochemical genetics Laboratory.

- To explore ways of providing future KPI (FA3) data

National Developments

Non-invasive prenatal testing (implementation 2018/19)

Section 4: Fetal Anomaly Screening Programme (Ultrasound)

	Comments
Fetal medicine service	Internal / Leeds Fetal Echocardiography / Leeds Fetal Medicine Unit

Clinical Arrangements, Management of Results and Failsafe Processes

Fetal anomaly scan appointments are given to women immediately after NT scan/dating scan appointments.

Scans are completed following the FASP guidelines. The patient is informed of the results by the sonographer performing the examination. A printed report is given to the woman for her information and the results are available to staff on the pathology IT system.

If the scan is incomplete a second scan is arranged up to 2 weeks later, whilst the patient is in the scan department. Unless the appointment is in an evening, when the re-scan appointment will be arranged by the clerical staff the next morning and the appointment posted to the patient.

If a woman is found to have a suspected abnormality an appointment is arranged for them to see a consultant obstericians/Radiologist with a specialist interest in fetal medicine. At this appointment the woman is counselled and follow up arranged, however there is no capacity for midwife support for women.

If there is a suspected fetal heart abnormality, an electronic referral is sent to Leeds fetal echocardiography unit by the sonographer performing the first scan. An appointment is given to the woman to see one of the Bradford consultants to discuss the results of the fetal echo.

If a woman fails to attend for their anomaly scan, a copy of the request card is sent back to the midwife the following day, this is an automated service.

NT /dating and 20 week scans are requested by midwives on the same request card, these are vetted by a sonographer prior to appointments being arranged. A 30 minute scan is arranged at approximately 20 weeks.

Scan lists have a mixture of dating, 20 week scans and growth scan. Sonographers will scan whoever is next in line rather than have separate lists on most occasions.

Following a diagnosis of a lethal fetal abnormality, some women in Bradford choose to continue with their pregnancy. To provide these women and their families with support Bradford provides a well-established palliative care clinic, managed by one of our Neonatal Consultant, Dr Vasudevan The aim is to offer support and help in preparing for the potentially short time they will have with their baby. Forget Me Not Trust are part of this team. Referrals are received from fetal medicine or the woman's named consultant. This service provides parents and their families with a better quality of care and outcomes for families with potentially life limiting fetal diagnoses. This team also has links with Leeds genetic team for future referrals, testing as appropriate. A nurse from Forget Me Not attends the weekly fetal medicine/fetal anomaly MDT meetings which provides a holistic model of care.

Audits completed

- 20 week scan image review – monthly.
- Audit referral time rates between sonographer suspecting an abnormality and referral to a specialist (FASP standard 8a & b) – recommendations currently in discussion to look at workflow to improve this rate.
- KPI FA2 data is currently being collected manually by the SSS

Conclusions and Recommendations

- Continue to utilise available national and regional patient information resources.
- Continue to improve mechanisms for feedback from postnatal findings to sonographers to enhance learning.
- Continue with the weekly MDT meetings where all identified fetal anomalies are discussed and images viewed. A list of cases to be discussed is circulated prior to the meeting. Lessons learned are feedback through antenatal screening meetings / clinical governance meetings.
- KPI FA2 data requires a manual trawl therefore exploring alternative ways of collating this information.
- Improvement in FASP standards 8a and b – (3 working days between suspected anomaly and specialist local scan) but still not achieving acceptable standard.
- Discussions in place between Bradford fetal medicine and Leeds fetal medicine to commence MDT meeting.

Section 5: Prenatal Diagnosis

	Comments
Laboratory used for genetic testing	Leeds
Laboratory provides QF PCR FISH Full karyotype	High risk trisomy, raised NT, ultrasound anomaly, previous baby with trisomy and CF

Clinical Arrangements, Management of Results and Failsafe Processes

A weekly ultrasound/fetal anomaly MDT meeting is held where the previous weeks confirmed fetal abnormalities are discussed including their follow up plans. This meeting is attended by ultrasonographers, neonatologists, midwives, obstetricians and a nurse from Forget Me Not Trust. All cardiology and fetal medicine referral are all sent electronically using NHS.net accounts. All cardiology reports and most fetal medicine reports are now received by the same method. The receipt of electronic reports improves timeliness of communication and information governance safety. The screening co-ordinator uploads these reports to the woman's IT maternity system and also sends a copy to her named consultant, for any action required.

All woman having CVS, requesting invasive tests in multiple pregnancies and failed amniocentesis in Bradford are referred to the Fetal Medicine unit in Leeds. Amniocentesis is performed in house by two of the obstetricians with a special interest in fetal medicine- Dr Janet Wright and Dr Padma Munjuluri. There are 2 consultant scanning days. Monday afternoon- Dr Munjuluri and Thursday morning- Dr Wright, Dr Munjuluri and Dr Wason (Consultant Radiologist)

All amniocentesis samples are sent by taxi to the cytogenetic lab at St James Hospital in Leeds. A rapid analysis result QFPCR is available within 2 working days (usually the next day if the sample is received before 3pm) and a full karyotype only for samples where there is an abnormal QFPCR , the result is available 2-3 weeks thereafter. Array CGH (microarray comparative genomic hybridisation) is available for all samples sent with a positive QFPCR, abnormal scan or nuchal thickening of 3.5mm or more. The advantage of array CGH is that it can detect an increased proportion of genetic imbalances in patients with abnormal scan findings. Unusual results are interpreted and discussed at MDT meetings in Leeds and support given by the Consultant Geneticists to Local referral units.

As a failsafe the screening co-ordinator records the details of all women undergoing prenatal diagnosis and records outcomes on the local database. The taxi driver is asked to sign a transport form when collecting a sample, in order to have an audit trail in the event of a missing sample. Fortunately this has not occurred.

Woman are given the option of how they wish to be informed of the result at the time of the test, most opt for telephone contact. In the event of abnormal results provision is always made for the woman and her partner to be seen the same day by an appropriate consultant (wherever possible by the consultant who performed the invasive test) for further discussion/ counselling/ follow up arrangements.

QFPCR results are telephoned to the screening co-ordinator or antenatal day unit staff if the screening co-ordinator is not available. Results are sent electronically through the NHS email.

A pregnancy outcome form is sent from the cytogenetic laboratory to the BTH for all women who have had an invasive test – these are filed in monthly order of EDD and completed by the screening coordinator- outcome is recorded on the screening database and forms sent back to the cytogenetic laboratory.

Audits completed

Plan to audit aspect of FASP programme in the next financial year

Conclusions and Recommendations

- Bradford women welcome and value the opportunity to have invasive tests in the form of amniocentesis locally. Often waiting to get to the eligible gestation to have an amniocentesis locally rather than access the earlier invasive test CVS in Leeds.

- The majority of reports from fetal cardiology and fetal medicine are now received electronically which has greatly improved the quality and timeliness of communication and service provision.

- Data for annual reporting purposes was problematic due to lack of integration of IT systems therefore the data submitted was accurate as possible.

- Midwifery support during Thursday morning fetal medicine clinic would assist the consultants/sonographers with referrals/admin/counselling.

- Lack of midwife support for consultant scanning sessions. The availability of a midwife support would provide an invaluable support for the women and more efficient pathway of care.

Section 6: Newborn Blood Spot Screening Programme

	Comments
Laboratory used	Leeds

Link to bloodspot screening pathway

Newborn Blood Spot Screening.docx

Bradford used the Tenderfoot heel incision devise, in January this was changed to Neoheel heel incision devise for all newborn bloodspots, this has been well received.

Clinical Arrangements and Failsafe Processes

The named person responsible for co-ordination of the Blood Spot screening programme is Vicky Jones (clinical responsibility for the missing/repeat samples are Jo Mallinson and Helen Avdiyovski community midwifery team leaders).

The main objective of the screening programme is to ensure the early detection and referral of those babies, found to be high risk, to improve their health and prevent severe disability or even death. It is also essential to minimise the adverse effects of screening, including anxiety, inaccurate information and unnecessary investigation and to provide reassurance to the majority of parents whose babies are thought not to be affected.

In order that treatment and clinical referral targets are met the timely receipt of the initial and any repeat/second blood spot samples by the screening laboratory (tertiary site) is imperative. Eliminating delays in despatching the blood spot screening cards is vital to allow the laboratory to analyse samples at the earliest opportunity and reduce the risk of sample deterioration.

- The NSC 'Screening tests for you and Your Baby' parent information, in an appropriate format, is provided antenatally and screening is discussed with the woman/couple by the midwife, at least 24 hours before taking the blood spot sample.
- NHS number bar-coded labels for babies are produced at the time of birth notification, to be applied to the blood spot card.
- The labels are kept with the baby's postnatal records so that they are available for blood spot screening.
- Consent for screening and the decision is recorded in the maternity records.
- The blood spot card is completed contemporaneously and staffs are advised not to pre-label.
- The sample is taken in accordance with the NSC blood sampling guidelines.
- Samples are usually taken on Day 5 irrespective of current medical condition, prematurity or feeding status.
- Newborn Blood Spot samples are despatched to the screening laboratory within 24 hours (ideally the same day) using designated pre-labelled, postage paid envelopes.

For babies admitted to Neonatal Unit (NICU):

- Admission day blood spot samples are saved on an individual health need basis.

- In premature infants (less than the equivalent of 32 weeks gestation at the time the sample is taken) an initial blood spot sample is taken between 5-8 days and a repeat blood spot sample taken for CHT at 28 days of age or the day of discharge, whichever is earlier.

If the parent(s) decline screening for their baby, either for specific conditions or the full programme, the blood spot screening card is completed and clearly marked 'DECLINE' (specifying test or all tests) and sent to the laboratory. This enables the decline to be noted in the laboratory and passed on to the child health records department for recording. A letter is sent to the child's GP by CHRD on behalf of the screening co-ordinator, informing him that the child has not been screened.

Requests for repeat sampling are communicated via Child Health Records departments. Avoidable repeat samples, and second samples requested for clinical need for babies less than 28 days old, are obtained via maternity services. Repeat/second samples are obtained and sent to the laboratory within 72 hours of request. Other repeat/second samples are obtained via primary care services.
The results are sent via the usual pathways to the Child Health Records Department from the New-born Screening Laboratory; using the national status codes.

The Leeds Screening laboratory audits avoidable repeat / inadequate samples.

The trust has not achieved the 2% avoidable repeat standard and this has been an on-going challenge. A number of actions have been instigated in order to improve the standard including staff training, action for staff who repeatedly have samples that need repeating and highlighting this to line managers. From September 17 staff responsible for each avoidable repeat sample is sent a letter with details of the reason for the rejection and e-learning training and education details. We have seen an improvement within the community since this local strategy was implemented. The comprehensive action plan locally devised with specific training requirements to be fulfilled and signed off by the line manager continues for recurrent offenders. Regular attendance by the Lab manager to the community forum meetings, updates, key issues and quality of blood are discussed. This is well received by the maternity staff; neonatal unit staff are invited but have not attended.

Local refinement of lab data to discard Airedale samples is also essential in reporting accurate KPI data. The avoidable repeat data is now refined and more reliable. Bradford Midwives have been instructed to clearly mark samples as 'RAE' in order for the lab to allocate repeats correctly.

There are established links between the newborn Screening laborotory and the named people in the Community office for the request of repeat samples for babies under the age of 28 days, the same links apply between Child health records department (CHRD). A process map is followed for repeat sampling and a individual proforma is commenced and completed when repeat samples are requested. The same process is used for samples received in the laborotory that are not fit for purpose.

All births are notified electronically to CHRD, any baby that does not have a completed screening result by 14 days of age has a sample requested, as per recommendations from QA report.

Babies remaining on the missing list for 3 weeks are added to an escalation list by the CHRD department. This list is then sent to the screening –coordinator for immediate action.

The bloodspot failsafe system is now accessed and actioned regularly .

Audits/Reports completed

Escalation Bloodspot Screening Risk Report provided by Emma Whiteley (Child Health Information Systems Assistant)

Conclusions and Recommendations

The avoidable repeat data is now refined and more reliable however requires continuous monitoring Avoidable repeats performed in the hospital setting (NNU, TCU and postnatal wards) has not improved and requires a multi-disciplinary focused approach.

Section 7: Newborn and Infant Physical Examination

Clinical Arrangements, Management of Results and Failsafe Processes

The named person responsible for co-ordination of the New-born Physical Examination screening programme is Dr Sunita Seal, (Consultant Neonatologist/ Clinical lead).

All babies are routinely examined, by trained personnel. In this trust the New-born Physical Examination is usually undertaken by paediatric or trained midwifery staff. This is largely a midwifery led service, which is excellently received and given priority cover.

The examination does provide an opportunity to examine the baby in the presence of the mother and father and any anxieties expressed by the parents can be addressed.

The Personal Child Health Record booklet is given to parents by the New-born hearing screeners at the time of the hearing screen.

Bradford NHSFT Policy and arrangements include:

- Process to ensure examinations are performed <72 hours (include babies being discharged in/out of area)
- Clinical referral pathways for hearts, hips, eyes and testes
- Policy in NICU/transitional care

The NSC recommends that trusts have a data management system that links records of individuals within the target populations with their current screening status and their screening results and facilitating audit and performance monitoring of the screening programme against national standards.

The use of the NIPE SMART system is now established and well accepted by staff. This has resulted in excellent KPI data for NP1. Timely feedback from Sheffield children's hospital for referrals for DDH (developmental dysplasia of the hips) continues to be an issue.

Despite the use of SMART, obtaining accurate annual report data has been problematic due to practitioner's inconsistency in recording screen positives and referral dates

Number of babies eligible for screening by the organisation in the reporting period	5545
Number of babies who screen positive for abnormality of the eye	18
Number of babies who are seen by consultant ophthalmologist/paediatric ophthalmology service within 2 weeks of age	Unable to provide data at present as not documented on SMART
Number of babies who have identified risk factors for developmental dysplasia of the hips	254
Number of babies who screen negative for developmental dysplasia of the hip but have risk factors who have ultrasound scan of the hips by 6 weeks of age	Unable to provide data at present as not documented on SMART
Number of babies who screen positive for bilateral undescended testes	17
Number of babies who screen positive for bilateral undescended testes who are assessed by a consultant paediatrician/ associate specialist within 24 hours	Unable to provide data at present as not

of the examination	documented on SMART
Number of babies who screen positive for a cardiac abnormality	Unable to provide data at present as not documented on SMART
Number of babies referred for assessment of potential cardiac abnormality	63

Audits completed

Submission of KPI NP1 / NP2 data quarterly

Conclusions and Recommendations

- Timely feedback from Sheffield children's hospital is required for referrals for DDH or consideration of alternative referral arrangements
- Some daily administration time to monitor the SMART system would be invaluable in identifying babies that need to be prioritized for their examinations, transfers to other hospitals prior to the examination, identifying babies that may have missed an examination and a failsafe for babies to be recalled who are discharged home without an examination (6 hour discharges) and capturing home deliveries.
- Develop and agree a robust SOP with the NIPE clinical lead, for recording screen positives and follow up of outcomes for the NIPE screening elements.

Section 8: Newborn Hearing Screening Programme

Clinical Arrangements, Management of Results and Failsafe Processes

The named person responsible for co-ordination of the Newborn Hearing Screening Programme is Pushpa Mistry. Rob Gardner is Team Leader (Consultant Clinical Scientist, Head of audiology Services). We are a member of the Trust Steering Group and audit data is shared with maternity unit.

The aim of the NHSP is to identify permanent moderate, severe and profound deafness and hearing impairment in newborn babies.
Early identification of hearing impairment gives children a better chance of developing speech and language skills, and of making the most of social and emotional interaction from an early age. The earlier a baby is identified as having hearing impairment or deafness, the better the outcomes for the family. It empowers parents of children with a permanent congenital hearing loss to make informed choices about early communication and support options.

Hearing screening is offered to all babies born or resident in Bradford and is carried out by 9 NHSP trained screeners who are specifically employed to carry out the screen. The aim is to complete the screen prior to but as close to discharge as possible. A suitable time to screen is negotiated with the parent and wherever possible the parent is present.
If the screening process cannot be completed as an inpatient, an outpatient appointment, at a convenient time for the parent is arranged.

There are separate protocols for well babies, and for those who have spent over 48 hours in SCBU, and clear nationally agreed care pathways for the screening and referral process for NHSP.

Management of Results and failsafe Processes

There is an established link between the Birth Notification Process and the NHSP national database S4H (Smart 4 Hearing) which allows the number of births on a daily basis to be identified. These birth notifications are crossed checked with the birth register books in labour ward and birth centre to ensure no babies are missed. Also, regular weekly lists from Child Health inform the programme of any movements in (i.e. babies moving in from abroad) that are eligible for the screen (up to 3 months old).
All hearing screening data is uploaded electronically to S4H.

Trust Summary Data (for a more detailed breakdown please see appendix)

All hearing screening providers must meet and report on key performance indicators, or KPIs, set and reviewed by the national screening team. Below is a table summary:-

KPI	Bradford Average – from Performance Report 15/06/18
NH1 – Screen completed by 4 weeks. Standard >=97%	99.8%
NH2 – referral to seen within 4 weeks. Standard >=90%	98.5%

Conclusion and Recommendations

The programme consistently achieves both key performance indicators NH1 and NH2.
For NH2, Bradford was mentioned as one of 9 sites nationally that had a performance rate of over 95% for 4 or more quarters in year 2015/16 – which is exceptional.
The aim of the programme is to continue to meet these KPIs.

Please refer to Appendix 2 for detailed data on The Hearing Screening Programme

Section 9: Diabetic eye screening in pregnancy

Diabetic Eye Screening in Pregnancy

Bradford women with pre-existing Diabetes attend the joint antenatal clinic as soon as the pregnancy is confirmed and then at 1-4 weekly intervals, as appropriate. The planning and care during the pregnancy will involve a multidisciplinary team including the Obstetrician, Diabetes physician, Diabetic Nurse Specialist (DNS), Diabetes Specialist Dietitian and Diabetes specialist midwives (MW).

Retinal assessment

Eye screening by retinal photography is offered twice in pregnancy, at booking (8-12 weeks) and between 24-28 week gestation. Increased frequency of assessment may be advised (6 or 8 weeks) if any concerns. Women with retinopathy present at first assessment will be referred to Ophthalmology department; women with retinopathy observed later will be referred according to clinical judgement.

All newly pregnant women with diabetes are referred to the Opthalmology Service in Bradford by NHS.net email. Paper reports are given to the woman, sent to the GP and uploaded to System One. Women are seen within six weeks of referral and results are obtained by accessing System One.

Section 10: Training and Education

It is recommended that all health care professionals involved in the provision of antenatal and newborn screening undertake regular educational updates.

The use of National e-learning modules, resources and signing up to the screening blog are promoted at induction and mandatory training sessions.

CPD training for screening was reintroduced into the monthly mandatory midwifery days at the beginning of 2017. This 60 minute session is attended annually by all midwives, healthcare assistants and midwifery support workers and delivered by the screening co-ordinator. This is a key message session concentrating on local screening issues and pathways which is very well received by staff and evaluates well.

The previously held screening study days evaluated well and gave staff an opportunity to fulfil CPD requirements. Consideration should be given to recommencing these, possibly as a half day programme. It should be recommended that all community midwifery staff attend.

The Leeds laboratory manager attends midwifery forum meetings twice a year; neonatal unit staff are also invited. Updates about the key issues and importance of quality newborn bloodspots are discussed.

The screening coordinator delivers regular training on the induction programmes for new midwives, support staff, neonatal medical staff and the obstetric registrars. These are very practical sessions concentrating on operational aspects of screening. NSC resources are utilised as well as local resources.

Midwives and support staff moving from hospital settings into community settings are seen individually or in small groups on an ad hoc basis. The aim is to instil confidence in their new role in relation to screening and improve KPI data eg. avoidable bloodspot repeat rate and correct completion of Down's, Edwards' and Patau's forms. A leaflet published locally is provided detailing the operational aspects, updates and issues for each screening programme.

Online NT training is recommended annually and CEMT21 training recommended 2 yearly staff is encouraged to access this as per recommendations for sonographers.

NIPE e-learning resource is recommended annually however completion is not monitored.

A training needs analysis would help identify the specific needs of the staff but due to time constraints we have been unable to achieve this. We plan to do this in the future.

Newborn Hearing Screening Programme

Prior to carrying out unsupervised screening NHSP training involves:

- Local induction – safeguarding, infection control, information governance etc.
- NHSP e-learning units 1-7
- Practical training - including equipment protocols (delivered by the NHSP Co-ordinator)
- Supervised screening
- NHSP competency assessment
- National IT system training

- Attend observed structured clinical examination (OSCE) within 3months of employment

Conclusions and Recommendations

The Trust should continue to develop antenatal and newborn screening education and ensure staff engagement in this training. The focus of the training should support the improvement of standards mainly to:

- Reduce inaccurately completed blood forms,
- Reduce the avoidable repeat rate for newborn bloodspot and
- Highlight the importance of 'test tracking results'.

Consideration of half day screening study days, possible mandatory for community staff

Appendix 1

Index of key performance indicators

ID1	Antenatal infectious disease screening – HIV coverage
ID2	Antenatal infectious disease screening – timely assessment of women with Hep B
ID3	Antenatal infectious disease screening – hepatitis B coverage
ID4	Antenatal infectious disease screening – syphilis coverage
FA1	Fetal anomaly screening – completion of laboratory request forms
FA2	Fetal anomaly screening – ultrasound coverage
ST1	Antenatal sickle cell and thalassaemia screening – coverage
ST2	Antenatal sickle cell and thalassaemia screening – timeliness of test
ST3	Antenatal sickle cell and thalassaemia screening – completion of FOQ
NB1	Newborn blood spot screening – coverage (CCG responsibility at birth)
NB2	Newborn blood spot screening – avoidable repeat tests
NB3	Newborn blood spot screening – coverage (movers in)
NH1	Newborn hearing screening – coverage
NH2	Newborn hearing – time from screening outcome to attendance at an audiological assessment appointment
NP1	Newborn and infant physical examination – coverage (newborn)
NP2	Newborn and infant physical examination – timely assessment of developmental dysplasia of the hip (DDH)

Appendix 2

Bradford review of NHSP reports for year 2017/18 (01/04/17 to 31/03/18)

3. NHSP Performance Report: Standards and KPIs (by Screening Site)

Produced on 15/06/18

				BRA_Bradford Royal Infirmary Maternity Unit		Total (Unique Records)	
Std	Objective	Acceptable	Achieveable	#	%	#	%
1	The proportion of babies eligible for newborn hearing screening for whom the screening process is complete by 4 weeks corrected age (hospital programmes-well babies, NICU babies) or by 5 weeks corrected age (community programmes-well babies). (NH1)	≥ 97%	≥ 99.5%	5536/5546	99.8%	5536/5546	99.8%
2	Well baby referrals from OAE 1 hospital	≤ 30%	≤ 25%	1328	25.3	1328	25.3
2	Well baby referrals from OAE 1 community	≤ 15%	≤ 13.5%	N/A	N/A	N/A	N/A
3	Total Referrals - Hospital	≤ 3%	≤ 2.5%	268	4.8	268	4.8
3	Total Referrals - Community	≤ 1.6%	≤ 1.3%	N/A	N/A	N/A	N/A
4	The proportion of babies with a no clear response result in one or both ears or other result that require an immediate	>=97%	>=99%	267/268	99.3	267/268	99.6

	onward referral for audiological assessment who are offered audiological assessment within the required timescale.						
5	The proportion of babies with a no clear response result in one or both ears or other result that require an immediate onward referral for audiological assessment who receive audiological assessment within the required timescale. (NH2)	>=90%	>=95%	264268	97.5	264/268	98.5
	Additional Information For Internal Monitoring						
	Total babies			5547		5547	
	Total well babies			5246		5246	
	Total NICU babies			301		301	
	Screens offered			5546	100.0	5546	100.0
	Screens completed by 3 months			5547	100.0	5547	100.0
	Screens declined			0	0.0	0	0.0
	Well baby referrals from OAE2 hospital			373	7.1	373	7.1
	Well baby referrals from OAE2 community			N/A	N/A	N/A	N/A
	NICU with bilateral NCR at OAE			36	12	36	12
	NICU bilateral referrals from AABR			8	2.7	8	2.7
	NICU unilateral referrals from AABR			7	2.3	7	2.3
	Total bilateral referrals			94	1.7	94	1.7

	(including NICU)						
	Total unilateral referrals (including NICU)			173	3.1	173	3.1
	Total Incomplete referrals			0	0.0	0	0.0

Note: Standards 4 & 5 exclude babies who have not reached 4 weeks post screen / 44 weeks GA
Babies born or resident outside of England have been excluded from the report.
Babies who start their screen in one facility and complete it in another will be counted in each facility they are screened in but only once in the site total
Babies who start their screen in one site and complete it in another site will be counted in both sites