Public Health England

NHS

Incidents in the Screening Programme

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EQA

- Clinical details may indicate case is not an antenatal case
- Recommend that where possible EQA samples are tested to maximise learning opportunities

Themes:

- Incorrect results or information returned
- IT/software
- Sampling
- FOQ

Interpretation and reporting errors

- Results read incorrectly and reported, missed by second check
  - Hb S carrier reported as other variant
  - Hb C x 2 and 1 x Hb AS reported as no Hb variants detected
  - Beta thalassaemia carrier reported as possible alpha thalassaemia
- Request for testing baby's biological father not added to report comment, missed by second check
- Failure initiate mechanism for referral to counsellors, missed by second check
- Wrong HPLC plot attached to FOQ – SS but patient normal – this was reported as a training issue

IT:

Rules based reporting

- Rules implemented
- Issue not highlighted until clinical incident
- All rules should be tested for all the scenarios they cover
- Ensure failsafe procedures
- Ensure constant monitoring and checking of rules

Data transmission

- Failure of data to transfer between systems
  - Relevant request information
  - Results

Sampling and identification

- Samples received x2 labelled with same identifier
- Electronically printed labels
- Detected by laboratory
- Several cases:

  Positive result - Beta thalassaemia carrier (x2), Hb C

  Different blood groups

  What action needs to be taken?

- Father with previously normal results now a beta thalassaemia carrier
- Father results assigned to son's records

FOQ review

- Ensure that FOQ forms are reviewed
- Egg and sperm donors in high prevalence areas
- Enquiries about BMT to help line
- Mechanism for dealing with declines

- **FOQ incidents**:
- Incorrect information on FOQ form
  - father designated not high risk but actually unknown
- Father testing requested by lab but mother not high risk
- Donor egg recorded on form – not dealt with appropriately by laboratory (x2)
- Sickle test not requested on FOQ

Missed screening

- Sample processing transferred to hub
- Samples not processed for a variety of reasons
- - transit/transport issues
- - requesting/process issues
- Issues with return of results to midwifery
- When centralizing/transferring processes ensure:
  - responsibility agreed for all QA processes (failsafe) and KPI/data returns
  - audit is carried out
- A number of incidents reported with delayed or lost samples

Hb A_2

- Instrument bias observed with Hb A_2
- More than one site, more than one manufacturer
- Both high and low bias observed
- Difficulty resolving problems with the manufacturers in a timely fashion
- Despite efforts from the laboratory
- Actions:
  - report to programme QA/lab advisers
  - review and recall
  - test results at an alternate site
  - exchange samples with alternate site

- Hb A_2 action value not used

- Hb A_2 at borderline
- Hb A_2 3.8%, MCH 26.4 pg (South East Asian)
- Checked at second laboratory Hb A_2 3.6%
- Reported at possible beta thalassaemia carrier
- Test baby's biological father
- Father not involved in pregnancy and no contact (Southern Europe)
- Conversations with haematologist and counsellor
- Woman progresses to PND
- PND sample Hb A_2 3.4%, MCH 27.1pg

- Hb A_2 and iron deficiency
- Baby's father result
- Hb A_2 - 2.8%, Hb 141 g/L, MCH 24.9pg

- Confusion created when reported as beta thalassaemia could not be excluded in the absence of a ferritin result

Manufacturers unable to provide consumables

Thank you