Investigation Report

Investigation of a complaint against the Northern Health and Social Care Trust & the Belfast Health and Social Care Trust

NIPSO Reference: 17834 & 21521

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The Role of the Ombudsman

The Northern Ireland Public Services Ombudsman (NIPSO) provides a free, independent and impartial service for investigating complaints about public service providers in Northern Ireland.

The role of the Ombudsman is set out in the Public Services Ombudsman Act (Northern Ireland) 2016 (the 2016 Act). The Ombudsman can normally only accept a complaint after the complaints process of the public service provider has been exhausted.

The Ombudsman may investigate complaints about maladministration on the part of listed authorities, and on the merits of a decision taken by health and social care bodies, general health care providers and independent providers of health and social care. The purpose of an investigation is to ascertain if the matters alleged in the complaint properly warrant investigation and are in substance true.

Maladministration is not defined in the legislation, but is generally taken to include decisions made following improper consideration, action or inaction; delay; failure to follow procedures or the law; misleading or inaccurate statements; bias; or inadequate record keeping.

The Ombudsman must also consider whether maladministration has resulted in an injustice. Injustice is also not defined in legislation but can include upset, inconvenience, or frustration. A remedy may be recommended where injustice is found as a consequence of the failings identified in a report.

Reporting in the Public Interest

This report is published pursuant to section 44 of the 2016 Act which allows the Ombudsman to publish an investigation report when it is in the public interest to do so.

The Ombudsman has taken into account the interests of the person aggrieved and other persons prior to publishing this report.

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SUMMARY

The complainant brought a complaint to this office about the care and treatment provided to her son (the patient) by the Northern Health and Social Care Trust (NHSCT). She said that despite a number of checks and tests performed after her son's birth, a serious eye condition was not discovered until he was seen at an Ophthalmology clinic run by the Belfast Health and Social Care Trust (BHSCT) in June 2014, nine weeks after birth.

The BHSCT Ophthalmologist who examined the patient at the clinic reported her concerns regarding the original checks for red reflex that were conducted at birth. Subsequently a Serious Adverse Incident (SAI) investigation was conducted by the NHSCT into the red reflex checks conducted at birth and at eight weeks. The complaint also focused on this SAI investigation. The complainant was concerned about the scope of the investigation, the weight given to the Ophthalmologist's comments in the SAI report, and how her final comments were taken into account.

The investigation of the complaint identified a number of failings in the care and treatment provided by NHSCT and BHSCT and in the way that the NHSCT conducted the SAI investigation.

In relation to the NHSCT, the investigation identified that the Neonatal Registrar and Enhanced Neonatal Practitioner failed to use eye drops to dilate the pupils at the red reflex check at birth and the Neonatal Registrar failed to mark the referral letter to the BHSCT Ophthalmology clinic as urgent and send this via fax.

In relation to the SAI, this investigation identified that the NHSCT failed to adequately communicate the scope and limitations of the SAI investigation, failed to adequately investigate all the issues within the scope of the SAI investigation appropriately, namely the eight week check with the GP, and failed to apologise to the complainant in line with the relevant standards.

The investigation identified that the BHSCT Specialist in Ophthalmology failed to triage the referral letter from the NHSCT Neonatal Registrar as urgent.

The failings identified caused a delay and as a result the patient received his surgery after the optimal time for performing this type of surgery. It was not possible to establish if this delay caused a loss of sight as the patient had other complications with his eyes.

I noted that a number of improvements have taken place as a result of learning from this incident, however I recommended that the NHSCT and BHSCT apologise to the complainant for the injustice arising from the failures identified in the report. I also recommended that the NHSCT share the SAI report with the patient's General Practitioner and the BHSCT to ensure that the learning from the SAI was appropriately shared.

THE COMPLAINT

1. The complaint concerned the care and treatment provided by the Northern Health and Social Care Trust (NHSCT) to the complaint's son who was born at 37 weeks +2 days gestational age weeks gestation. The complainant said that despite a number of checks and tests following birth, abnormalities were not discovered until the patient was seen at the Ophthalmology[1] clinic run by the Belfast Health and Social Care Trust (BHSCT) in Antrim Area Hospital (AAH) on 11 June 2014, nine weeks (corrected age[2]) after birth. After reviewing the patient at her clinic, the Consultant Paediatric Ophthalmologist reported the incident to the Consultant Neonatologist at AAH. It was subsequently decided to report this as an 'Interface Serious Adverse Incident' (SAI)[3], and the NHSCT were asked to lead on the investigation.

2. The SAI investigation was initiated at Level 2, as a Root Cause Analysis, to establish what had happened and if any lessons could be learned from the incident to improve future practice. When the SAI was completed the Root Cause Analysis report was shared with the individuals involved in the patient's care, the patient's parents, the Health and Social Care Board (HSCB), and the NHSCT Corporate Governance Department.

3. The complaint also focused on this SAI investigation. She complained about the scope of the SAI investigation, the weighting given to the Ophthalmologist's comments and how her final comments were considered.

Background

4. The patient, who is now deceased, was born with a genetic condition (COL4A gene mutation), bilateral cataracts and structurally abnormal eyes.

[1] A branch of medicine dealing with the diagnosis, treatment and prevention of diseases of the eye and visual system.
[2] Corrected age, or adjusted age, is a premature baby's chronological age minus the number of weeks or months he was born early. For example, a one-year-old who was born three months early would have a corrected age of nine months.
[3] An adverse incident is defined as, any event or circumstances that could have or did lead to harm, loss or damage to people, property, environment or reputation, arising during in an HSC organisation. An Interface SAI, involves two Trusts.

The Neonatal Registrar and the Enhanced Neonatal Nurse Practitioner (ENNP) had difficulty in conducting the red reflex assessment[9] at birth in the left eye and the patient also had bilateral subconjunctival haermorrhages[10]. The NHSCT consultant directed the Neonatal Registrar to request an appointment for the patient with Ophthalmology at Belfast Health and Social Care Trust (BHSCT). The Neonatal Registrar subsequently sent a referral letter requesting a routine appointment for the patient.

5. The Consultant Paediatric Ophthalmologist reviewed the patient on 11 June 2014 and it was discovered that the patient required urgent surgery. The Consultant Paediatric Ophthalmologist advised that '…*a child like this would really need cataract surgery considered before 8 or 9 weeks of age and he is now approaching the end of the age limit from which we can obtain any visual improvement*.' The BHSCT Consultant Paediatric Ophthalmologist alerted the NHSCT Consultant Neonatologist[11] that the referral letter should have been sent to her clinic as urgent due to the difficulties in obtaining a red reflex[12] during the examination at birth. She also explained that she was concerned that the red reflex examination was not conducted adequately and that a red reflex may not have been present at birth in either eye. The incident was reported to the Health and Social Care Board (HSCB) as an interface incident and NHSCT was requested to lead an investigation into the incident as an SAI.

6. As part of this investigation, this office sought Independent Professional Advice (IPA) from a Consultant Ophthalmic Surgeon on the issues the complainant raised. The advice from the IPA and the evidence on file was carefully considered. In order to fully investigate whether the care and treatment provided to the patient was appropriate and to maximise the opportunity of learning, it was decided that the discretion should be used to extend the scope of the investigation to include

.
[9] The red reflex test is a non-invasive test that can show early warning signs of serious eye conditions in children, it involves the examination of pupil reflections using an Ophthalmoscope.
[10] Bloodshot eyes.
[11] A subspecialty of pediatrics that consists of the medical care of newborn infants, especially the ill or premature newborn
[12] The red reflex test is a non-invasive test that can show early warning signs of serious eye conditions in children, it involves the examination of pupil reflections using an Ophthalmoscope.

the actions of BHSCT[13]. It was also determined to issue a single report of the investigation to both Trusts in order to provide a clear and full explanation to the family and the Trusts (including relevant health professionals) as to how I reached my conclusions. A single report also provides the best possible opportunity for learning from the investigation of this complaint given the interface issues involved in providing specialist services. The NHSCT and the BHSCT were informed of the decision to provide a composite report on 10 September 2019.

Issues of complaint

7. The issues of the complaint which I accepted for investigation NHSCT were:

   1. Whether the treatment and care provided to the patient at birth, before discharge and up to 23 June 2014, the date of his second surgery, concerning eye assessments was appropriate and reasonable?

   2. Whether the Serious Adverse Incident (SAI) investigation was conducted in accordance with the relevant SAI standards?

8. This office used discretion to extend the scope of the investigation to include the actions of BHSCT under the following issue of complaint:

   3. Whether the triaging of the letter of referral for the patient was carried out appropriately and in accordance with good medical practice?

9. The patient's journey involved both the NHSCT and BHSCT and therefore issue one and issue three are inextricably linked. I will therefore review both issues together.

INVESTIGATION METHODOLOGY

10. In order to investigate the complaint, the Investigating Officer obtained from the both the NHSCT and BHSCT all relevant documentation together with the Trusts' comments on the issues raised by the complainant.

[13] The BHSCT Ophthalmology service triaged the referral letter from the NHSCT prior to issuing an appointment for the patient on 11 June 2014.

After further consideration of the issues, I obtained independent professional advice (IPA) from a Consultant Ophthalmic Surgeon and Paediatric Ophthalmologist.

11. The information and advice which have informed my findings and conclusions are included within the body of my report. The IPA has provided me with 'advice'; however how I have weighed this advice, within the context of this particular complaint, is a matter for my discretion.

Relevant Standards

12. In order to investigate complaints, I must establish a clear understanding of the standards, both of general application and those which are specific to the circumstances of the case.

13. The general standards are the Ombudsman's Principles[14]:

    - The Principles of Good Administration

14. The specific standards are those which applied at the time the events occurred and which governed the exercise of the administrative functions and professional judgement of the Trust and individuals whose actions are the subject of this complaint.

15. The specific standards relevant to this complaint are:

    - Health and Social Care Board, Safety and Quality Reminder of Best Practice Guidance – '*How to Examine Newborns for Red Reflexes'*, issued 4 July 2017;

[14] These principles were established through the collective experience of the public services ombudsmen affiliated to the Ombudsman Association.

- Department of Health, Social Services and Public Safety '*Healthy Child, Healthy Future'* A Framework for the Universal Child Health Promotion Programme in Northern Ireland, dated May 2010 (Healthy Child guidance;
- Northern Health and Social Care Trust, *'Guideline for the Management of Absent Red Reflex in Babies*' (No date);
- Lloyd I c et al '*Advances in the management of congenital and infantile cataract'*. *Eye 2007 21 (10) 1301-0*;
- Journal of American Association for Paediatric Ophthalmology and Srabismus '*Duration of form deprivation and visual outcome in infants with bilateral congenital cataracts.'* Jain S et al. *2010 14(1) 31-4;*
- Lancet Child and Adolescent Health October 2018 *'Outcomes five years after primary lens implantation in children aged under 2 years with congenital cataract.'* Findings form the IOL under 2 UK and Ireland prospective inception coot study. Solebo at al*;*
- Belfast Health and Social Care Trust, '*Integrated Elective Access Protocol, Guidance for Staff*, Version 1.0, February 2010 (Triage protocol);
- Northern Health and Social Care Trust, Serious Adverse Incident Protocol, Checklist and template resource pack, August 2014 (SAI guidance);
- Northern Health and Social Care Trust, Appendix 11 to SAI guidance '*Being open'*- Communicating with Service users and/or their carers (Communication guidance);
- Health and Social Care Board '*Procedure for the Reporting and Follow up of Serious Adverse Incidents'*, November 2016 Version 1.1 (Procedural SAI guidance);
- General Medical Council, '*Good Medical Practice – Working with Doctor Working for Patients*', Published 25 March 2013, (GMC Code); and
- Nursing & Midwifery Council '*The Code*, *Standard of conduct, performance and ethics for nurses and midwives'* May 2008 (NMC Code).

16. I also examined the following evidence;

- Presentation, Author- Consultant Paediatric Ophthalmologist, '*The importance of the newborn red reflex check'* dated 25 August 2017

17. I have not included all of the information obtained in the course of the investigation in this report but I am satisfied that everything that I consider to be relevant and important has been taken into account in reaching my findings.

18. As part of the process, a draft copy of this report was shared with the complainant and the Trusts for comment on factual accuracy and the reasonableness of the findings and recommendations.

INVESTIGATION

Issue one: Whether the treatment and care provided to the patient at birth, before discharge and up to 23 June 2014, the date of his second surgery, concerning eye assessments was appropriate and reasonable?

Issue three: Whether the triaging of the letter of referral for the patient was carried out appropriately and in accordance with good medical practice?

Detail of Complaint

19. The complaint concerned the care and treatment provided to the patient, who had congenital bilateral cataracts and eyes that were significantly abnormal in structure. The complainant said that these abnormalities were not discovered until the patient was reviewed at the BHSCT Ophthalmology clinic in AAH 11 weeks (nine weeks corrected age) after birth. The patient underwent the standard red reflex check at birth, both the Neonatal Registrar and Enhanced Neonatal Practitioner (ENNP) recorded having difficulty obtaining the red reflex. The Neonatal Registrar sent a referral letter to the BHSCT Ophthalmology clinic and asked for the patient to be assessed due to Symmetrical Intrauterine Growth restriction (IUGR)[16], bilateral subconjunctival haemorrhages[17] as well as making reference to the difficulty in detecting a red reflex within the content of the letter.

[16] A type of intrauterine growth restriction where all foetal biometric parameters tend to be less than expected for the given gestational age.
[17] Bloodshot eyes

The letter was sent as routine and subsequently triaged as routine by a specialist in Ophthalmology at BHSCT.

20. The patient was visited by the health visitor on 9 May 2014. The notes in the Parent Child Health Record (PCHR)[18] detail that his upper eyelids were puffy and General Practitioner (GP) had no concerns. The patient also attended hospital for a number of blood transfusions after birth, and the complainant said that his eye problems were not discovered at these multiple appointments. The patient attended the appointment with the Consultant Paediatric Ophthalmologist at BHSCT on 11 June 2014. It was decided that the patient needed urgent surgery on both eyes. The Consultant Paediatric Ophthalmologist wrote to the Consultant Neonatologist in charge of the patient's care highlighting concern on how the red reflex check was conducted and the routine referral letter sent to the Ophthalmology clinic. It was subsequently decided that NHSCT should lead on an SAI investigation into this incident.

Evidence Considered

Legislation/Policies/Guidance

21. I considered the Healthy Child guidance and identified the following relevant extracts

> ***'By 72 hours***
>
> ***Action: Midwife/GP/maternity healthcare staff*****:** *Midwives, GPs and other maternity healthcare staff in hospital and home settings will provide a universal programme.*
>
> ***Activity***
>
> • *A comprehensive newborn physical examination to identify anomalies that present in the newborn will be carried out by a suitably trained and competent maternity healthcare professional. This includes clinical observation and assessment of the eyes, heart and hips (pathway to be reviewed) and testes for boys, as well as a general examination…'*

[18] The PCHR or 'red book' is a national health and developmental record given to parents/carers at a child's birth.

- *'Following identification of babies with health or developmental problems, early referral to specialist team, advice to parents on benefits that may be available, and invitation to join parent groups.*

Risk Factors: Appropriate Risk factors to be considered

Identify and review risk factors and respond within local guidance and regional guidelines, protocols and pathways.'

'Action: Midwife

At 8 weeks old

Action: GP. *A health review and first immunisation by the General Practice at 8 weeks.*

Venue: *Clinic*

Activity

- *A comprehensive physical examination by the GP with emphasis on the eyes, heart, hips in collaboration with health visitors, include DDH[19] age appropriate exam where this is currently carried out by the GP-(pathway to be reviewed) and testes for boys…'*

22. I considered BHSCT's policy on Triage which stated under prioritisation:

'The clinician should indicate clearly on the referral letter whether the case is urgent, routine or red-flag suspect cancer'

23. I considered the relevant sections of the GMC Code:

'7. You must be competent in all aspects of your work, including management, research and teaching.

8. You must regularly keep your professional knowledge and skills up to date.

15. You must provide a good standard of practice and care. If you assess, diagnose or treat patients, you must:

…

b. promptly provide or arrange suitable advice, investigations or treatment where necessary'

[19] Developmental Dysplasia of the Hip

24. I considered the relevant sections of the NMC Code:

28. You must have the knowledge and skills for safe and effective practice when working without direct supervisions

40. You must keep your knowledge and skills up to date throughout your working life.'

Clinical Records

25. I considered the patient's medical records for the period from birth to 11 June 2014. Relevant extracts are included in the table below.

Date	**Source**	**Commentary**	**Medical personnel**
25 March 2014	Infant Assessment	Beside 'Eyes'- two ticks	Midwife
26 March 2014	Infant Assessment	Beside 'Eyes'- two ticks	Midwife
26 March 2014	New born Assessment (Part 1)	The vision section has all risk factors circled as '*no*'	ST1[20]
27 March 2014	Infant Record of Management Care	*'Spoke to ophthalmology secretary. Fax a letter to partial booking for* (the Consultant Paediatric Opthamologist) *ext 334700.* (Consultant Paediatric Opthamologist)*will see letter + hopefully r/v on Wednesday'*	Neonatal Registrar
28 March 2014	Infant Record of Management Care	*Referral letter to* (Consultant Paediatric Opthamologist) *(tick) (copy in pt centre)*	Neonatal Registrar
28 March 2014	Referral letter to BHSCT Ophthalmology	Relevant extract regard red reflexes below;	Neonatal Registrar

[20] Speciality Trainee, first year.

		'The infant was noted to have a bruised face and bilateral subconjunctival haermorrhages present. Red reflexes were present in the left eye. The right eyes red reflex was difficult to detect due to the infant closing his eye during the assessment. No other eye abnormality was detected on inspection.'	
29 March 2014	New born Assessment (Part 2)	*"R*" '*Referred/Exam not Satisfactory'* for red reflex has been circled next to the section for 'Eyes' (including red reflex). A note stated "*red reflex L eye*." In the Details and Action box at the bottom of the sheet there is a comment *"Ophthalmology referral, eyes bloodshot. Difficult to see red reflex (L) eye."*	ST1/ENNP
29 March 2014	Infant Record of Management Care	*Red reflex L eye. Difficult to see red reflex. R eye- ophthalmology referral requested.'*	ENNP

9 May 2014	Parent Child Health Record (PCHR)	Under the section 'Significant Medical Conditions' notes state: *'Upper eyelids puffy- seen by GP- No concerns/puffy and bruised at delivery' 'Review eye apt- Antrim'*	Health Visitor

26. I reviewed a number of letters of correspondence about the patient's eyes between the different specialisms involved in the patient's care.

27. I considered the findings of the SAI report into the patient's care dated December 2016 which were as follows;
'1. Both eyes were swollen, bruised and bloodshot, affecting the quality of the examination.
2. Both the Specialty Doctor and the ENNP, report seeing a red reflex in the right eye during examination.
3. As the Specialty Doctor who made the referral observed a red reflex, she did not identify the referral to the Consultant Ophthalmology as being urgent.
4. The Specialty Doctor discussed the referral with the Consultant Paediatrician and faxed the referral through, but in the absence of this being marked as urgent it was triaged as a routine referral.
5. At the 8 week check for red reflexes the examination was not carried out and the Assessor recorded that a referral had already been made to the Consultant Ophthalmologist. '

28. I also considered the conclusion of the Root Cause Analysis report which identified:
'(Consultant Paediatric Opthamologist) s*tates that she does not believe that the red reflex would have been visible in the right eye at the time of the initial examinations. While the examination of the infant's eyes was clearly difficult both*

practitioners insist that they visualised the right red reflex during the initial examination. It is impossible to state definitively that the red reflex was not seen by either practitioner. It is important to add that the Neonatal Registrar had previously attended a course on the examination of the eyes in the newborn.'

29. In addition I reviewed the lessons learned from the SAI investigation which identified the following:

- *'Professionals who are examining eyes in new-born babies must be aware of the importance of detecting red reflexes.*
- *Where professionals are having difficulty examining new-born babies' eyes they must dilate the pupils.*
- *Where red reflexes are not detected in both eyes of a new-born, an urgent referral should be made to Consultant Ophthalmology Services.*
- *Professionals should be familiar with the process of referral to Regional Ophthalmology Services.*
- *Referrals should be familiar with the process of referral to Regional Ophthalmology Services.*
- *Referrals should clearly indicate the level of concern identified and when urgent, should be clearly marked as urgent.*
- *Professionals who are tasked with routine assessment of eyes should carry out this examination despite a previous referral being made to specialist services. The absence of red reflexes require an urgent follow up of referral.'*

NHSCT's response to investigation enquiries

30. NHSCT stated that *'…both the medical and nursing profession [ENNP and* Neonatal registrar] *recorded seeing red reflect in left eye and difficulty in seeing red reflex in left eye*[21] *(*sic) *due to the infant closing this eye during examination.* (The patient's) *eyes were swollen, bruised and bloodshot at the time of examination and this may have affected the quality of the examination'.* NHSCT further stated that the SAI team '…*recognised this is an area of learning and recommended that professionals who are examining eyes in new-borns must be*

[21] This is a quote from the Trust's response and appears to be an error. Medical records illustrate that there was difficulty in seeing the red reflex in the patient's right eye. See clinical records table at Paragraph 5.

aware of the importance of detecting red reflexes and where they are having difficulty examining the eyes they must dilate the pupils'.

31. In relation to the eight week check with the GP, NHSCT stated that '*The patient's eyes were not examined at the 8 week check with the GP in line with Regional Healthy Child Healthy Future recommendations and the assessor* [health visitor] *has recorded that a referral had already been made to the consultant Ophthalmologist. The SAI team recognised that this is an area of learning and recommended that professionals who are tasked with routine assessment of eyes should carry out this examination despite a previous referral being made to specialist services and that absence of red reflexes require urgent follow up.'*

32. NHSCT further explained '*In relation to apology to the family and serious issue of how late detection of cataracts can have detrimental effect on visual development, please see… detailed discussion the Consultant Neonatologist had with the parents in relation to this matter and his apology on behalf of the neonatal team.'*

33. NHSCT was asked whether it is within a midwife's role to check for a red reflex, NHSCT explained that midwives complete a check of infants at birth and a daily check whilst the infant remains in hospital. These checks do not include a red reflex check and are '*purely an observation by the midwife that the baby's eyes are in the correct place, appear to be open and shut in a normal pattern and there is no discharge.'* NHSCT explained that the national screening committee advise as good practice that all babies should have a physical examination within '*72 hours of delivery'* which includes a red reflex check. It stated that this is '…*usually performed in preparation for hospital discharge by a member of the paediatric team or by the midwife who has successfully undertaken training in the examination of the new-born infant…the examiner should use an ophthalmoscope and test for red reflex.'*

34. NHSCT also explained the checks performed by a health visitor include a physical examination but do not include a red reflex check as '…*health visitors are not trained in this procedure'*. NHSCT commented that on 9 May, the health visitor visited the patient and recorded that he had a review eye appointment at Antrim

hospital, that his '*upper eye lids appear puffy and that the GP is aware'.* NHSCT stated that during the hospital appointments when the patient was seen for blood transfusions between four and eight weeks, there were no concerns raised by the parents regarding the patient's eyes or pupil size. The Trust explained that '…*red reflex testing and pupil examinations would not generally be done in medical assessment.'*

BHSCT's response to investigation enquiries regarding Triage

35. BHSCT stated that the booking office in AAH received the referral letter on 4 April 2014. A BHSCT Associate Specialist Doctor triaged the letter and requested the patient to attend a routine joint paediatric appointment where he would be seen by both an ophthalmologist and an orthoptist. BHSCT stated that '*there are no markings on the letter that would suggest it had been sent by fax'.* BHSCT further explained that '*it is the understanding of the Belfast Trust's ophthalmology team that non-urgent referral letters were sent via internal mail in Antrim Area Hospital and therefore BHSCT assumes that the patient's referral letter was sent in the hospital's internal mail.'*

36. BHSCT stated the following '*It is the opinion of, Consultant Paediatric Ophthalmologist* that *the patient should have been referred urgently to her for a specialist ophthalmology opinion shortly after birth, ideally by direct telephone call.'* The Consultant Paediatric Ophthalmologist also advised that '*The patient's triage letter should have been triaged as urgent'.*

Relevant Independent Professional Advice

37. The Investigating Officer asked the IPA if it was possible to come to a conclusion as to the condition of the patient's eyes at birth and how evident any abnormalities should have been at birth. The IPA advised that it was *'…impossible to be sure that there was a dense central opacity[22] in the left eye (and probably the right eye) in the immediate neonatal period'*. However, the IPA advised that '*it is my opinion that there was probably some degree of opacity, particularly as both of the eyes*

[22] Corneal opacities are eye problems that can lead to scarring or clouding of the cornea, which decreases vision. The cornea is the clear, dome-shaped area that covers the front of the eye.

were noted to be structurally very abnormal with microphthalmia[23] and anterior segment dysgenesis[24].' The IPA further advised that '*COL4A1 mutations[25], while a rare cause of congenital cataract are known to also be causative of Axenfeld-Rieger abnormality[26]. This is a form of dygenesis[27] of the front of the eye (anterior segment) and it is the likely cause of the displaced lens[28] and pupil in the patient's case.'*

38. The IPA was asked whether due to difficulty in detecting the red reflex, the check should have been repeated to ensure an accurate result using eye drops. The IPA advised that it is dependent on protocols in place in each unit; however '*if there is difficulty (or doubt) in eliciting a red reflex then a prompt referral should be instigated to the ophthalmology team'.* Furthermore the IPA advised that '*examining eyes in a bright and busy ward environment can be challenging*', and '*the use of eye drops is simple and easy and can help make an examination easier for the non-expert.'* The IPA advised that *'…if there is doubt help should be sought from the ophthalmic team covering the neonatal unit.'*

39. The IPA was asked whether it should have been evident at birth that the patient's eyes were '*ectopic[29] and superiorly placed'* and if so, should this have led to an urgent referral. The IPA advised that identifying '*subtle displacement of the pupils of a neonate[30] is not, in my opinion, a skill which would be expected of a non-ophthalmologist'*. The IPA further advised that from reviewing the photographs provided '*The patient did have superiorly ectopic pupils but the degree is not so marked that it would be clearly obvious to a non-expert- particularly when the pupils have not been dilated'.* The IPA advised that if this sign had been identified, then it should have triggered an *'urgent referral'*

[23] An eye abnormality that arises before birth. In this condition, one or both eyeballs are abnormally small.
[24] A failure of the normal development of the tissues of the anterior segment of the eye. It leads to anomalies in the structure of the mature anterior segment, associated with an increased risk of glaucoma and corneal opacity.
[25] COL4A1 is a subunit of the type IV collagen and plays a role in angiogenesis. Mutations in the gene have been linked to diseases of the brain, muscle, kidney, eye, and cardiovascular system.
[26] Axenfeld-Rieger syndrome is primarily an eye disorder, although it can also affect other parts of the body. This condition is characterized by abnormalities of the front part of the eye, an area known as the anterior segment.
[27] Dysgenesis is an abnormal organ development during embryonic growth and development. Dysgenesis usually implies disordered development or malformation and in some cases represents the milder end of a spectrum of abnormalities.
[28] A dislocated lens is a lens that has moved out of position because some or all of the supporting ligaments have broken.
[29] In an abnormal place or position
[30] A newborn child

40. The IPA was asked whether there should have been an urgent referral. The IPA advised that '…*if the examining clinician on the neonatal ward is unable to elicit a red reflex then the referral should be urgent'.* The IPA advised that the management of dense congenital cataract[31] is *'time sensitive'* and advised that *'…visual outcomes for children who undergo surgery in the third month of life are poorer than those who undergo surgery in the second month'*. However, the IPA advised that '*this needs to be weighed against the risk of secondary glaucoma[32] which is much higher when surgery is carried out within the first two months of life and which is associated with poor results.'*

41. The IPA advised that although there is variability in the opinions of Paediatric Ophthalmologists, it is the '*general consensus that surgery should be performed by eight to ten weeks of age at the latest'*. The IPA advised that the patient's corrected age was '*just over 9 weeks'* when he was seen by Consultant Paediatric Ophthalmologist and '*his surgery was therefore carried our right at the tail end of this optimum period'.* The IPA advised that the patient's surgeries were carried out at nine and a half weeks and ten and a half weeks which *'…although not ideal is not too far outside the optimum period and in itself unlikely to be the major[33] impact on his subsequent visual development.'*

42. However, the IPA further advised that the patient had other *'systemic and developmental associated problems related to his COL4A1mutation which appear to have had a much more profound affect (sic) on his visual outcome than the slightly sub optimal timing of his procedures.* 'The IPA advised that the original referral letter *'should have been sent by fax and/or marked as urgent.[34]'*

43. The IPA was asked whether the patient's cataract and pupil defects should have been noted during examinations by other healthcare professionals prior to June 2014 during subsequent visits by health visitors, midwives and attendances at the hospital. The IPA advised that accurately examining the eyes of young infants is

[31] Refers to a lens opacity present at birth
[32] Glaucoma is a condition that damages your eye's optic nerve. It gets worse over time. It's often linked to a buildup of pressure inside your eye.
[33] IPA's emphasis
[34] IPA's emphasis

'*difficult and takes extensive training for even general ophthalmology trainees*' and stated '*it would not be a skill expected of non-ophthalmology healthcare professionals*.' The IPA advised that '*poor visual behavior may have been apparent but the absence of a red reflex (*without *the use of appropriate specialist equipment) would not be expected to be noted*.'

44. The IPA advised in conclusion that '*any infant who fails the red reflex test should have an urgent referral triggered…. And all units should thus have a robust system for prompt referrals'.* The IPA advised that although the referral letter was generated soon after birth, '*there was a lack of emphasis of the absence of the red reflex and it appears not to have been sent urgently (or faxed)'.* The IPA advised that this led to a '*delay in the patient receiving surgery'* and thus he had surgery *'perhaps two weeks later than would have been ideal'.* However, the IPA advised that this is '*unlikely to have had a major impact on his subsequent visual development. His eyes are structurally very abnormal and very small. He developed pupillary membranes [35] which required further operations and he also has concurrent neuro development problems. In my opinion these are the major factors underlying his subsequent poor visual development.'*

45. In relation to the triage of the referral letter performed by BHSCT, the IPA advised the referral letter did indicate that a red reflex was not obtained; however the letter was still triaged as *'routine'*. The IPA further advised *that 'one cannot assume that because the absence of a red reflex is not emphasised in the letter that it is unlikely to be abnormal'* and concluded that '*the triage system for such letters at Antrim Hospital should thus be improved.'* The IPA advised that the triage of the letter failed as the specialist did not '*fully recognise'* the information included in the letter regarding the difficulty in eliciting a red reflex.

Responses to Draft Report

NHSCT

46. The NHSCT did not have any comment to make regarding the draft report.

[35] Remnants of the mesodermal sheet carrying blood vessels that partially fill the anterior chamber during fetal development.

BHSCT

47. The BHSCT thanked the Office for sharing the draft report and advised that it had been shared with the Ophthalmology service.

48. The Associate Specialty Doctor provided a reflective response to the Office on the draft report. The doctor advised '*it concerned me greatly that, I had graded a neonate with this condition as 'routine'.* The doctor advised that the referral letter was '*unclear'* and '*at no time did it state that this was urgent or that there were absent or diminished red reflexes.'*

49. The doctor further advised '*I recall that the baby's name had not been added to the list of neonates to be seen each week. This is the list that identified the neonates with potential eye problems on the unit. An ophthalmologist attends the neonatal unit every Wednesday afternoon to examine these babies at risk. These two factors had lead me to believe this was a non-urgent referral. This all had to be decided upon in the space of minutes in a busy day of two clinics, a visit to the neonatal unit and administrative tasks. Unfortunately, in this instance, I made the wrong call but in my opinion, a reasonable one given the circumstances described above'.*

50. The doctor concluded '*I am sorry that I marked this as routine referral and in retrospect, wish I had made it urgent. I will certainly bear this case in mind in the future, to ensure that a similar situation does no arise again within my scope of practice'.*

The Complainant

51. The complainant stated that '*I think the report confirms the fact, that there were several missed opportunities for an earlier diagnosis and surgery options for* [her son]. She further stated that the '*the questions and doubts raised due to these failings will mean that the questions will never fully be answered as no-one is sure of the effect this may have had on* [her son].

52. The complainant also stated that she will always wonder if her son had been given the opportunity of having surgery two weeks earlier, '*would this have had*

even a small impact on his vision. Sometimes it's not all about the major impact as sometimes the smallest difference would have been massive to [him]. *Just because he had so many complex issues doesn't mean that he didn't deserve to be given the earliest change to help his vision, in fact to me it was more important because of how significant a small difference would have made to him.'*

53. The complainant acknowledged that the emphasis of the report was on '*learning'* but her '*emphasis is on how these decisions have affected us all and most importantly* [her son].' The complainant further stated that '*It is two years since we have lost our previous boy and through all his issues, he was a true blessing to our family, and we all miss him terribly,'*

Analysis and Findings

54. In relation to the complaint that the actions of the NHSCT contributed to a delay in the patient receiving surgery on his eyes, I considered the relevant clinical records from the patient's birth to the time of his second surgery on 23 June 2014. I note NHSCT stated that both the *'medical and nursing profession'* recorded seeing the red reflex in the patient's left eye and had difficulty in seeing the right eye due to its condition at birth. I note the letter from the Consultant Paediatric Ophthalmologist to the Consultant Neonatologist which states concern regarding the red reflex check as she believed that *'…it is probably unlikely that the red reflex was present in this child's left eye at birth.'*

55. I also reviewed the advice from the IPA which explained that *'…it is thus impossible to be sure that there was a dense central opacity in the left eye (and probably the right eye) in the immediate neonatal period. On balance of probabilities, it is my opinion that there was probably some degree of opacity, particularly as both eyes were noted to be structurally very abnormal with microphthalmia and anterior segment dysgenesis.'*

56. The SAI investigation and the IPA were both unable to determine if a red reflex was detected on the day of the examination following the patient's birth. However, I note the IPA advised that*' if there is a difficulty in eliciting a red reflex, a medical professional should use eye drops which can 'help make an examination easier*

for the non-expert'. In addition, the findings of the SAI investigation concluded in 'Lessons Learned' that professionals must dilate the pupils of new-born babies eyes if they are having difficulty examining them. I also note the NHSCT's comment that the SAI team had recognised the red reflex test at birth as *'an area of learning' and recommended that all professions conducting this test at birth should be aware of the importance of this test and must be aware to dilate the pupils.'*

57. The IPA also advised that if a clinician is unable to elicit a red reflex, then the referral should be marked as *'urgent'.* The IPA thus concluded that the original referral letter should have been *'sent via fax and marked as urgent'.* In addition, the Consultant Paediatric Ophthalmologist indicated the need for urgency for referral in her letter to the Consultant Neonatologist and the SAI investigation explained that referrals should *'clearly indicate the level of concern identified and when urgent, should be clearly marked as urgent'.* The report also advised that professionals should be *'familiar'* with the process of referral to Regional Ophthalmology Services.

58. I am unable to conclude if a red reflex was indeed elicited by the Neonatal Registrar or the ENNP before the patient was discharged from hospital after birth. However, I accept the IPA's advice that *'…the use of eye drops is simple and easy and can help make an examination easier for the non-expert.'* I note the GMC and NMC code which states that medical and nursing professionals must '…*regularly keep your professional knowledge and skills up to date'.* Therefore, I consider that not using eye drops to dilate the pupils given the difficulties experienced was a failure by the Neonatal Registrar and the ENNP in the care and treatment *provided to* (the patient).

59. I note the SAI investigation concluded that the letter was faxed to the BHSCT; however the BHSCT is unable to find any evidence that this was faxed to the ophthalmology department and I have not been provided with any evidence from the NHSCT that the letter was faxed. I thus accept the IPA's advice that the referral letter should have been faxed and marked as urgent. In addition, I also accept the advice of the IPA that although the letter was designated as routine,

the inclusion of information relating to the difficulty in eliciting a red reflex should have prompted the clinician to *'triage the letter as urgent'.* I acknowledge the response from the Associate Specialist doctor who triaged the referral letter. The response highlighted that the referral letter was not marked as urgent and that the patient was not listed as having potential eye problems. The Associate Specialist doctor also advised that due to a busy work schedule, letters had to be graded in '*the space of a few minutes'.* However I note the Associate Specialist's apology and learning identified as a result of this incident. I note the GMC code also states that medical professionals must '*promptly provide or arrange suitable advice, investigations or treatment where necessary'.* Therefore, I consider the NHSCT Neonatal Registrar should have marked the referral letter as urgent and faxed it to the BHSCT. I have considered the response to the draft report provided by the BHSCT Specialist in Ophthalmology and on balance I remain of the view that the Specialist should have triaged the letter as urgent. I consider these issues amount to a failure in the care and treatment provided to the patient.

60. As a consequent of these failings, I consider that the patient suffered the injustice of a loss of opportunity to have an earlier diagnosis and treatment. However, I accept the IPA's advice that the patient's operations were carried out at the *'tail end of the optimum period' for this type of surgery.* The IPA advised that the surgery should be conducted between eight and ten weeks and the patient's surgeries were conducted at nine and a half and ten and a half weeks (corrected age). It is important to note, that if the absence of a red reflex had been picked up at either of the two designated checks, the patient would have received his surgery perhaps two weeks earlier. The IPA explained regarding this timing that *'…although not ideal is not too far outside the optimum period and in itself unlikely to be the major impact on his subsequent visual development.'* I acknowledge the response from the complainant to the draft report and understand the complainant's perspective on my finding on the impact of delayed surgery on the patient. I understand and accept that even a minor change to the patient's sight would have been a success for the family and for the patient and would have made a difference in the patient's life. However, I am unable to determine the impact that an earlier surgery would have had on the patient. I accept the advice from the IPA that the patient did receive the surgery at the tail end of optimum

time period, which is unlikely to have majorly impacted his visual development. Furthermore, the IPA advised that the patient had other *'…systemic and developmental associated problems related to his COL4A1 mutation which appear to have had a more profound affect (sic) on his visual outcome than the slightly suboptimal timing of his procedures'.* I accept therefore that these failings were unlikely to have had a major impact on the patient's sight however I cannot state either that they would not have been of a benefit to the patient and note the complainant's views about the impact of even a minor positive change.

61. However, I consider that the complainant suffered the injustice of uncertainty as she will always question whether the patient's sight would have been improved if he had an earlier diagnosis and received the surgeries within the optimum time period, this is highlighted in the complainant's response to the draft report. I understand the complainant's frustration that the investigation has been unable to fully determine the impact on the patient. However, I trust that the complainant is reassured by the advice of the IPA.

62. The complainant also complained that the patient had a number of appointments with different specialties before his appointment with Consultant Paediatric Ophthalmologist on 11 June 2014 and believes that there were multiple missed opportunities to diagnose the patient's red reflex. I note the NHSCT's response which addresses the eight week check with the GP in line with the Healthy child guidance. NHSCT explained that the patient's eyes were not examined as the *'assessor'* [health visitor] had recorded that a referral had already been made to Ophthalmology. As the complaint is not against the GP, this examination is not within the scope of this investigation; however I am pleased to note that the SAI investigation has included a recommendation which addresses this; *'Professionals who are carrying out routine eye examination in new-born babies should continue to do so despite a referral already being made to Ophthalmology services. If red reflexes are not detected, the referral should be followed up as a matter of urgency.'*

63. Regarding the other checks that staff performed, I considered the response from NHSCT which stated that midwives and health visitors do not perform red reflex

checks during the standard checks on infants as they are not trained in this procedure. NHSCT also stated that red reflex testing and pupil examinations would not generally be carried out during the appointments for blood transfusions between four and eight weeks.

64. I accept the IPA's advice that that this would *'not be a skill expected of non-ophthalmology healthcare professionals'* and this examination is *'difficult and takes extensive training for even general ophthalmology trainees'.* I conclude that although the patient had a number of appointments with different health professionals between birth and 11 June 2014, these appointments were not specifically designated for checking red reflexes, nor were they performed by staff who were trained in this technique. I do not consider that there was failing on part of the NHSCT to diagnose the patient's eye problems at these appointments. Therefore I do not uphold this element of the complaint.

65. I have identified the following failings in care and treatment on the part of the NHSCT:

i. Failure of the Neonatal Registrar and ENNP to use eye drops; and

ii. Failure of the Neonatal Registrar to designate the referral letter as urgent and send via fax to BHSCT.

I identified the following failing in care and treatment on the part of the BHSCT

iii. Failure of the Specialist in Ophthalmology to triage the referral letter as urgent.

I consider these failures resulted in the patient experiencing the injustice of a loss of opportunity to have an earlier diagnosis and treatment and the complainant to have suffered the injustice of uncertainty.

Issue two: Whether the Serious Adverse Incident (SAI) investigation was conducted in accordance with the relevant SAI standards?

Detail of Complaint

66. The complaint focused on the SAI investigation jointly conducted by NHSCT and

BHSCT into the care and treatment provided to the patient. The complaint comprised of the following;

- The SAI investigation solely focused on the red reflex detection, The Complainant complained that the SAI investigation did not allude to or explain why other abnormalities were not discovered;
- The SAI concentrated on one occasion where the red reflex check was conducted. The complainant complained that all missed opportunities to diagnose The patient's condition should have been investigated during the SAI process;
- The complainant further complained that the SAI does not apologise or acknowledge the lack of care to the patient. In addition the Complainant complained that the consultant's opinion has been disregarded in the SAI investigation;
- The complainant complained that she communicated her concerns about the investigation during a meeting with members of the SAI investigation team in Coleraine in September 2016. The complainant complained that notes were not recorded during this meeting nor were comments at this meeting included in the final report; and
- The complainant complained that her comments were sent to the SAI investigation team and were attached to the final report; however the complainant complained that these were not addressed and appear not to serve a purpose.

67. Based on the concerns raised by the complainant, I decided that the investigation would look at the three points below;

i. The scope of the SAI investigation, how this was communicated to the complainant and whether this adequately dealt with the complainant's issues;

ii. The complainant's final comments on the investigation and how these were addressed in the SAI; and

iii. Whether the SAI investigation adequately addresses the Consultant Paediatric Ophthalmologist's comments on the red reflex test performed at birth.

Evidence Considered

Legislation/Policies/Guidance

SAI Investigation

68. I considered the SAI Procedural guidance from the HSCB which states:
'*SAI reviews should be conducted at a level appropriate and proportionate to the complexity of the incident under review. In order to ensure timely learning from all SAIs reported, it is important the level of review focuses on the complexity of the incident and not solely on the significance ofthe event.'*

The guidance also provides explanation of the purpose of an SAI investigation:
'The Key aim of this procedure is to improve services and reduce the risk of incident recurrence, both within the reporting organisation and across the HSC as a whole. The dissemination of learning following a SAI is therefore core to achieving this and to ensure shared lessons are embedded in practice and the safety and quality of care provided.'

69. I considered the SAI guidance the NHSCT provided during the investigation, in particular the following relevant sections;

'Aims of SAI process

- *Ensure the process works in partnership with all other statutory and regulatory organisations that may require to be notified of the incident or be involved in the investigation.*

Fact-Finding

- *Reports from GPs and any other contracted agencies involved, as appropriate.*

Notification of Incident process – Step 5 and step 6

- *Level 4 Officer to ensure the patient/family are notified that the incident has been reported as an SAI, the process explained and leaflet given. The contact should provide an opportunity for the relative to contribute to review/investigation process…'*
- ***Sharing Report with family and with staff***

'The decision as to how to share a final report with the appropriate family member/carer must be taken by the Investigation Team. The principle should be that a senior member of staff… will meet the family to share the report.'

Information about SAI investigation

70. I considered the terms of reference that were agreed for the SAI investigation, which were as follows;

- *'To undertake an investigation of the incident to identify specific problems or issues to be addressed.*
- *To consider any other factors raised by the incident.*
- *To identify and engage appropriately with all relevant services or other agencies associated with the care of those involved in the incident.*
- *To review the outcome of the investigation, agree recommendations, actions to be taken and lessons learned for the improvement of future services.*
- *To engage with family to identify concerns, explain investigation process and share outcomes from investigation.'*

71. I considered the letter from the Consultant Neonatologist to the complainant and her husband in which he refers to the SAI investigation:

*'This is a supplementary note just to put in writing about one part of our telephone conversation that I had with yourself, (*the complainant)*, outlining the report on 23 August 2014. This pertains to my mentioning to yourself about the initiation of the Serious Adverse Incident (SAI) Process. This is in relation to the bilateral cataracts detected in the patient at around 11 weeks of age* [9 weeks corrected age] *by* (Consultant Paediatric Ophthalmologist) *at her Ophthalmology Clinic. The process has been activated to look at the overall case, particularly with the issue regarding the possible late detection of the cataracts. I know I had discussed with you previously that there would be a careful analysis of the various aspects of the patient's management to date…Further information and meetings with yourselves will be set up in due course. I know this is a very brief note but the process will be explained in greater detail to you soon.'*

Notes of Meeting with the patient's parents 28 May 2015

72. I considered the notes of meeting with the patient's parents and the SAI investigation team on 28 May 2015. The minutes of the meeting state that:

'(The patient's parents) *were provided with a copy of the NHSCT leaflet which was discussed in full in terms of the process for investigation.*

The minutes also detail that;

'It was also explained to (the patient's parents) *that whilst a number of other professionals examined the patient following his birth and discharge from hospital, these examinations were not looking for cataracts and therefore not specifically examining for red reflexes. Professionals were also aware that a referral was already being progressed to RBHSC Ophthalmology department for* (the patient)*'*

73. I also considered the 'Adult Leaflet' which was presented to the patient's parents on 28 May 2015 at a meeting with the investigation team as recorded in the notes. Particularly the following section;

*'**What happens now?***

We want to work with you in reviewing these events and we would like to meet with you to talk you through the process and agree how we proceed. We will agree:

- *How much you wish to be involved*
- *What you would like the investigation to address*
- *Your experience*
- *How the report will be shared and the format- it is normal practice that all names will be removed to protect patient confidentiality*
- *How any learning will be progressed'*

I also considered '**The Process'** section particularly the following relevant points:

- *'At times other individuals may be interviewed such as your General Practitioner or other health care professionals'*
- *A written report will be shared with you while in draft form.*
- *'The final report, reflecting your comments will then be shared with the HSCB'*

74. I reviewed the Communication Guidance provided by NHSCT;

'There should be consideration and formal noting of the service user's and/or their carer's views and concerns, and demonstrate that these are being listened to and taken seriously'.

Interview with the Neonatal Registrar

75. As part of the SAI investigation, an interview was held with the Neonatal Registrar on 28 July 2015. During the interview, the Neonatal Registrar was asked to clarify the medical records which detail difficulty in detecting the red reflex. The Neonatal Registrar was asked if it was possible that she did not see the red reflex and responded stating that '…*although the eye was difficult to examine as it was red and the infant was opening and closing the eye she was sure she did see the red reflexed* (sic) *in both eyes.'*

Interview with ENNP

76. I reviewed the meeting note with the ENNP and the SAI investigation team. The ENNP explained that she had '*difficulty seeing the red reflex in the child's right eye but she spoke with the neonatal registrar and was aware referral had been made to Ophthalmology.'*

Root Cause Analysis report on the review of a Serious Adverse Incident

77. I considered the 'Parents Comments' section of the report;

'1. The process has not covered all the appointments/examinations/assessments that the patient experienced and how his eye and eyesight problems had other chances and opportunities to be discovered, or at least a concern raised. I feel that if they had investigated thoroughly there are more lessons that would/could have been learnt from this whole situation for more departments/staff. This is the extremely frustrating aspect.

2. The process itself is mechanical and practical but does not address how disappointed the family feel with the whole experience and there is no apology for what they went through.

3. When they submit this report is this the final copy and I am to be happy with that?

In response to (the complainant's) *comments the following information has been sent to via the Parent Support Officer:-*

The SAI was initiated as result of (Consultant Paediatric Ophthalmologist)*'s concern regarding the specific examination of the eyes for red reflex and subsequent referral following this examination. The focus of the SAI investigation, was to consider any learning from this incident. I'm sorry this has not met with* (the complaint's) *expectations. We acknowledge* (the complainant's) *concern that the learning*

investigation process is mechanical and practical, and understand the family's disappointment. We do apologise that this has been very difficult and stressful for the family.'

79. I reviewed the guidance the Trust issued as a response to the SAI investigation. This included;

- Guideline for the Management of Absent Red reflex in Babies (NHSCT)
- Safety and Quality reminder of Best Practice Guidance- 'How to Examine New-borns for Red Reflexes (HSC)'. This was issued to all relevant hospital and community staff, doctors training in relevant specialities, independent sector providers and GPs.
- PowerPoint presentation on red reflex testing which is part of the Antrim Paediatric Teaching programme.

80. I also reviewed the email from the Consultant Neonatologist which confirmed the following measures have been put in place;

'*1. At induction of doctors every 4 or 6 months there is red reflexes teaching at the cotside as part of explaining the newborn examination*
2. Midwives when undertaking the newborn examination training / refresher training are again shown how to do the red reflexes training
3. At 6 month intervals usually August / February The Consultant Ophthalmologist has been giving a teaching lecture / tutorial session regarding the importance of red reflexes examination to the medical / neonatal nursing and midwifery staff (all invited) with a PowerPoint presentation since 2015. '

NHSCT's Response to investigation enquiries

Scope of SAI investigation and communication of scope

81. The NHSCT acknowledged that it had '*not fully investigate*d' all earlier opportunities to diagnose the patient's eye problems. By way of explanation, the NHSCT indicated that staff had kept to the terms of reference of the SAI that had been agreed. This was following concerns expressed by the Consultant Paediatric Ophthalmologist who saw the patient on 11 June 2014 at the outpatient clinic in AAH. The NHSCT explained that *'…the focus of the SAI investigation was on the new born examination within 72 hours and the 6-8*

week examination, which are the two examinations identified through national screening guidelines that examination for red reflexes should take place.'

82. The NHSCT stated that the scope for the SAI investigation was explained to the patient's parents during a clinic appointment with the Consultant Neonatologist in July 2014 and at the first meeting with SAI Investigation team on 28 May 2015. At this meeting the patient's parents were supplied with an information leaflet outlining the SAI process. The minutes state that the leaflet was '…*discussed in full in terms of the process for investigation'.* The minutes also comment on why The patient's eyes were not examined during other appointments and why the absence of red reflexes were not picked up***, 'It was also explained to*** the patient's parents *that whilst a number of other professionals examined the patient following the birth and discharge from hospital, these examinations were not looking for cataracts and therefore did not specifically examine for red reflexes. Professionals were also aware that a referral was already being progressed RBHSC Ophthalmology department for* (the patient)*.'*

Whether the SAI investigation adequately addresses the Consultant Paediatric Ophthalmologist's comments

83. NHSCT stated in relation to this comment that '…*both medical and nursing* [Neonatal Registrar and ENNP] *profession recorded seeing red reflect in left eye and difficulty in seeing red reflex in right eye due to the infant closing this eye during examination.* (The patient's) *eyes were swollen, bruised and bloodshot at the time of examination and this may have affected the quality of the examination.* NHSCT explained that the SAI team recognised that this was an '*area of learning'* and '…*recommended that professionals who are examining eyes in new-borns must be aware of the importance of detecting red reflexes and where they are having difficult examining the eyes they must dilate the pupils.'*

84. NHSCT further stated that the opinion of Consultant Paediatric Ophthalmologist was '*not disregarded'* but reiterates that the focus of the investigation was on '*learning and not to apportion blame'.* NHSCT explained that '*the investigation*

team felt that this was the opinion of one Consultant and that if this were challenged other Consultants may have a differing view. The investigation team felt this was out with their remit'.

The Complainant's final comments on the investigations and how these were addressed in the SAI

85. NHSCT explained that during the meeting on 19 September 2016, (Doctor) discussed all issues raised by the complainant. It stated that it was agreed at the end of the meeting that the complainant would put all her concerns in writing and the investigation team would address these and include them in the final report. The complainant's comments were received in writing on 20 October 2016 and a response was sent to advise that the investigation team was seeking advice on how to proceed and would get back with a response as soon as possible. The complainant's comments were included in the final report along with the response to the investigation.

Response to the Draft report

86. The BHSCT nor NHSCT did not have any comments to add regarding the findings under this head of complaint.

87. The complainant did not make any comment regarding the findings under this head of complaint.

Analysis and Findings

Scope of SAI investigation, communication of scope and whether investigation adequately dealt with the complainant's issues

88. The complainant said that the SAI investigation solely focused on red reflex detection. It did not investigate why other abnormalities were not discovered or why the patient's condition was not detected at other appointments, and therefore did not adequately deal with the concerns she had raised.

89. In relation to the scope of the SAI investigation, I reviewed NHSCT's response which stated that the scope of the SAI investigation was triggered by the

incident flagged by the Consultant Paediatric Ophthalmologist and thus the SAI was to investigate the red reflex check following birth and the eight week check as outlined in the relevant guidance at Appendix three to this report. I note that NHSCT stated that the terms of reference were explained to the complainant at a meeting with the SAI investigation team on 28 May 2015. I considered the notes of the meeting with the patient's parents in which it was stated that they were provided with a copy of the NHSCT leaflet and the process of investigation was '…*discussed in full'.* The notes also document that the Consultant Neonatologist explained to the complainant that other checks which the patient underwent were not specifically designed for red reflex checks and therefore would not have picked up the absence of red reflexes or eye abnormalities. Having reviewed the Trust's explanation as to the rationale for limiting the investigation to these checks, along with the advice from the IPA, I consider the scope of the investigation was correct, in that, it focused on the two instances where the patient's red reflex should have been checked according to the Healthy Child guidance. Therefore I do not uphold this element of the complaint.

90. On review of whether the scope was fully investigated by the SAI team, I reviewed the guidance provided on what an investigation should entail along with the terms of reference within the SAI report. The terms of reference for the investigation are general and do not specifically state what would be specifically investigated; however the description of the incident and findings both make reference to the eight week check by the GP. Furthermore, the NHSCT stated that the focus of the SAI was on '*new born examination within 72 hours and the 6-8 week examination.'* The SAI investigatory guidance directs users to collect all relevant medical information from GPs and any other contracted agencies involved. I also examined the guidance on the relevant bodies to share the report with, it states that the report should be shared with all '*responsible healthcare professionals'*. I note that the Adult leaflet shared with the complainant states that GP practitioners may be interviewed as part of the investigation.

91. Therefore, in these circumstances, I would expect the SAI team to have obtained the records from the GP surgery involved in order to accurately investigate this check. I note the SAI report made comment about the exam undertaken by the Health Visitor at the patient's home; however, I cannot find any evidence that the SAI investigation team contacted the GP to confirm if a red reflex assessment was conducted at the GP surgery. As part of the investigation, I confirmed with the NHSCT that the GP practice was not contacted as part of the investigation. Therefore, it is not clear how the SAI investigation team made a finding on the eight week check without consulting the relevant bodies i.e. the GP surgery.

92. The first principle of Good Administration states that public bodies must '*Get it Right'* by following policy and guidance. I consider the NHSCT failed to adequately consult with the GP practice during the course of the SAI investigation and therefore failed to comply with the SAI policy and the Principles of Good Administration. As a consequence of this maladministration, I consider that the complainant experienced the injustice of frustration as she expected the NHSCT to thoroughly investigate all instances where the patient's eye problems could have been diagnosed. I therefore uphold this element of the complaint.

93. With regards to the communication of the scope of the SAI investigation, I am unable to determine that it was clearly communicated to the complainant that the SAI investigation would only focus on the red reflex checks at birth and at 6-8 weeks. The meeting notes lack detail and thus do not provide evidence that NHSCT explained that the SAI investigation would only focus on the red reflex checks per guidance and would not look at other eye abnormalities or other medical appointments that the patient attended. It is evident that this is what was expected from the complainant's comments on the SAI investigation which stated that '*the process has not covered all the appointments/examinations/assessments that the patient experienced and how his eye and eyesight problems had other chances and opportunities to be discovered, or at least concern raised.'*

94. I note the guidance provided in a leaflet to the complainant which details that the SAI investigation requires their input as to what they would like the investigation to address. I also note the terms of reference of the SAI investigation which state the aim to '*engage with family to identify concerns'* and *'explain investigation processes.'* The importance of communication and engagement with family members during an SAI investigation have also been examined in the recent report by Mr Justice O'Hara in The Inquiry into Hyponatremia related deaths.[36] In considering the complaint, I have had regard to the second principle of Good Administration. It requires public bodies to be '*customer focused'* which stipulates that public bodies must '*inform customers what they can expect'*. I consider the NHSCT failed to adequately communicate the scope and limitations of the SAI investigation to the complainant and thus failed to meet the requirements of the SAI policy and failed to comply with the second principle of Good Administration, which constitutes maladministration. As a consequence of the maladministration, I consider that the complainant experienced the injustice of frustration, as the final report did not deliver on her expectations as to the scope of the SAI investigation. I therefore uphold this element of her complaint.

95. It is worth noting the output from the SAI investigation, namely the documentation that has been produced and shared as a result. I am pleased to note that the guidance has instructed staff (see paragraph 46) on the importance of red reflex assessments in babies at birth and eight weeks, and that this should be conducted despite an existing referral in place. Furthermore, it provides detailed guidance on how the red reflex examination should be conducted and specifically advises that staff should use eye drops. Furthermore, I am also pleased to note that there is regular training in place for all staff who conduct this type of examination as confirmed by the consultant neonatologist.

96. In relation to the complainant's comments regarding an apology, I reviewed the Root Cause Analysis report in conjunction with the SAI investigatory

[36] http://www.ihrdni.org/Vol3-08-Current.pdf

procedures, it does not state that the Root Cause Analysis report should include an apology to the family. I also reviewed the procedural SAI guidance which states the main purpose of an SAI investigation is to '*improve services'.* However I note that the SAI investigatory procedures reference appendix 11 which state that service users should receive both verbal and written apologies. The guidance states that a written apology should '…*clearly state the Trust is sorry for the suffering and distress resulting from the incident.'*

97. I note NHSCT referred to the clinic letter which outlined an apology provided in person from the Consultant Neonatologist to the patient's parents at a meeting on 2 July 2014 (see Appendix 6). I am unable to find any evidence of a written apology to the complainant following completion of the SAI investigation. The Principles of Good Administration state that public bodies must work to put it right. The fifth principle of Good Administration highlights that Public Bodies must acknowledge mistakes and apologies where appropriate. I consider that a lack of a written apology to the complainant following completion of the SAI process is contrary to the fifth principle and the SAI investigatory procedures, which constitutes maladministration. I consider that the maladministration identified caused the complainant to experience upset and frustration, as she has stated that she feels she has not yet received a proper apology for the NHSCT's failings. As stated in the complainant's response to the draft report, '*lives have been affected and influenced by the actions and decisions made'* and therefore an apology to the family of the patient was important step in the SAI process. I therefore uphold this element of the complaint.

The complainant's final comments on the investigations and how these were addressed in the SAI

98. The complainant said that her final comments were not adequately addressed in the SAI investigation. I reviewed the guidance from NHSCT which explains that the report should be shared with family at the end of the investigation. I also considered the information leaflet provided to the complainant which states that the final report will be shared reflecting their comments. I consider that NHSCT did act in accordance with these guidelines

and reflected the complainant's comments within the report and also provided an answer to these comments.

99. I note that the complainant was invited to a meeting to discuss the report before the final report was issued. The investigation has established that notes were not recorded of this meeting and it was agreed that the complainant would email her comments. I note the NHSCT principles of communicating with service users whereby '…*there should be consideration and formal noting of the service user's views and concerns….. And demonstrate that these are being listened to and taken seriously'.* I also note the third Principle of Good Administration which requires that '*good and proper records'* must be taken by public services. I consider the lack of a record of this meeting a failure amounting to maladministration however I do not consider that the complainant suffered an injustice as her comments were included within the final report in accordance with the NHSCT guidance. Therefore I do not uphold this element of the complaint. However, it would be my expectation that the NHSCT remind relevant staff involved in the SAI process of the importance of keeping accurate records of meetings with service users.

Whether the SAI investigation adequately addresses Consultant Paediatric Ophthalmologist's comments

100. The complainant said that the SAI investigation did not address the consultant's opinion on the patient's eyes. I have noted that the investigation team interviewed the physician who completed the red reflex assessment on the patient as part of the investigation. I note that the doctor was specifically asked if it was possible that she did not see the red reflex and was asked to clarify her notes in the medical records. I reviewed NHSCT's response which explained that the Consultant Paediatric Ophthalmologist's opinion was '*not disregarded*' but the purpose of the investigation was on learning and '*not to apportion blame'.* I also note the IPA's comments which conclude that it is '…*impossible to be sure that there was a dense central opacity in the left eye (and probably the right eye) in the immediate neonatal period. On the balance of probabilities,*

it is my opinion that there was probably some degree of opacity, particularly as both of the eyes were noted to be structurally very abnormal…'

101. On review of the evidence available to me, I accept that the Consultant Paediatric Ophthalmologist's comments were included in the SAI investigation and adequately addressed. I consider that the meetings with both the Neonatal registrar and ENNP highlight that the comments were taken into account during the investigation as both professionals were asked to recount the red reflex examination. I also note the IPA's advice that it is '*impossible to be sure'* of the condition of the patient's eyes at birth. I consider that the SAI investigation could not determine if the red reflex was or was not present at birth and therefore the inclusion of the Consultant Paediatric Ophthalmologist's comments was sufficient for the purpose of the investigation. Therefore I do not uphold this element of the complaint.

102. I have identified a number of areas of maladministration on the part of the NHSCT.

I. Failure to adequately communicate the scope and limitations of the SAI investigation;
II. Failure to adequately investigate part of the scope of the SAI investigation, namely the eight week check with the GP; and
III. Failure to apologise to the complainant in line with guidance.
IV. Failure to make a record of the meeting with the complainant prior to the SAI report being finalised

I am satisfied that this maladministration caused the complainant to sustain the injustice of frustration and upset

CONCLUSION

The complainant brought a complaint to this Office about the actions of the NHSCT. As part of the investigation of that complaint, I also considered the actions of the BHSCT staff in relation to triaging of the referral letter to the Ophthalmology Service for the patient.

NHSCT

The investigation found failures in the care and treatment provided to the patient in relation to the following matters;

- Failure of the Neonatal Registrar and ENNP to use eye drops to dilate pupils; and
- Failure of the Neonatal Registrar to mark the referral letter as urgent and fax to BHSCT.

BHSCT

The investigation found a failure in care and treatment in respect of;

- The failure of the Specialist in Ophthalmology to triage the NHSCT referral letter as urgent.

I have found that these failings resulted in the patient suffering the injustice of not receiving a diagnosis sooner and consequently not having his operation within the optimal timeframe. However, it is not possible to determine if this had an impact on the patient as he received the operations just outside the optimum time period and the IPA has noted that this is unlikely to have had a major impact on the patient's sight. However, I do consider that these failings caused the complainant to suffer the injustice of uncertainty.

I found the following failings in the way that the SAI investigation was conducted by the NHSCT;

- Failure to adequately communicate the scope and limitations of the SAI investigation;
- Failure to adequately investigate part of the scope of the SAI investigation, namely the eight week check with the GP; and
- Failure to apologies to the complainant in line with guidance.
- Failure to make a record of the meeting with the complainant prior to the SAI report being finalised

I consider these failings amount to maladministration. I am satisfied that these failures caused the complainant to suffer the injustice of frustration and upset.

The investigation did not find a failure by the NHSCT care and regarding the:

- Care and treatment provided to the patient from other specialities

The investigation did not find maladministration regarding the following;

- Consideration of the complainant's final comments on the SAI investigation; and
- How the SAI investigation addressed the Consultant Paediatric Ophthalmologist's comments.

Recommendations

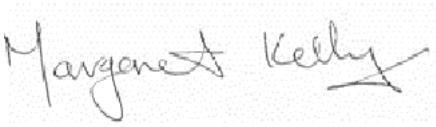
I welcome the learning already identified regarding the importance of the red reflex check, how this should be conducted and how urgent referrals should be instigated. I am pleased to note that this has been documented in Best Practice guidance which has been shared with all relevant staff and bodies including GP practices.

I recommend the NHSCT should within **one month** of the date of this report:

a. Provide the complainant with a written apology in accordance with NIPSO 'Guidance on issuing an apology' (June 2016), for the injustice of uncertainty, frustration and upset identified as a result of the maladministration and failures in care and treatment identified in this report;
b. Shares the SAI report with the patient's GP practice;
c. Remind staff involved in SAI investigations of the importance of;
    - Adequately communicating the scope of an SAI investigation to complainants and ensuring this is understood at the beginning of an investigation;
    - Providing complainants with both a verbal and written apology;
    - Communicating and sharing any relevant findings with all bodies involved; and
    - Taking notes and keeping records of all meetings with complainants in line with the Principles of Good Administration.

I recommend the BHSCT should within **one month** of the date of this report:

a. Provide the complainant with a written apology in accordance with NIPSO 'Guidance on issuing an apology' (June 2016), for the injustice of uncertainty, frustration and upset identified as a result of the failure in care and treatment identified;
b. Should ensure that the Specialist in Ophthalmology involved with the triage process within Ophthalmology is aware that any difficulties in obtaining a red reflex should instigate an urgent appointment for the patient.



MARGARET KELLY
OMBUDSMAN **September 2020**

APPENDIX ONE

PRINCIPLES OF GOOD ADMINISTRATION

Good administration by public service providers means:

1. Getting it right

- Acting in accordance with the law and with regard for the rights of those concerned.
- Acting in accordance with the public body's policy and guidance (published or internal).
- Taking proper account of established good practice.
- Providing effective services, using appropriately trained and competent staff.
- Taking reasonable decisions, based on all relevant considerations.

2. Being customer focused

- Ensuring people can access services easily.
- Informing customers what they can expect and what the public body expects of them.
- Keeping to its commitments, including any published service standards.
- Dealing with people helpfully, promptly and sensitively, bearing in mind their individual circumstances
- Responding to customers' needs flexibly, including, where appropriate, co-ordinating a response with other service providers.

3. Being open and accountable

- Being open and clear about policies and procedures and ensuring that information, and any advice provided, is clear, accurate and complete.
- Stating its criteria for decision making and giving reasons for decisions
- Handling information properly and appropriately.
- Keeping proper and appropriate records.
- Taking responsibility for its actions.

4. Acting fairly and proportionately

- Treating people impartially, with respect and courtesy.
- Treating people without unlawful discrimination or prejudice, and ensuring no conflict of interests.

- Dealing with people and issues objectively and consistently.
- Ensuring that decisions and actions are proportionate, appropriate and fair.

5. Putting things right

- Acknowledging mistakes and apologising where appropriate.
- Putting mistakes right quickly and effectively.
- Providing clear and timely information on how and when to appeal or complain.
- Operating an effective complaints procedure, which includes offering a fair and appropriate remedy when a complaint is upheld.

6. Seeking continuous improvement

- Reviewing policies and procedures regularly to ensure they are effective.
- Asking for feedback and using it to improve services and performance.
- Ensuring that the public body learns lessons from complaints and uses these to improve services and performance.