Sandwell and West Birmingham Hospitals NHS
NHS Trust

Investigation report following a never event.
Wrong eye injection in BMEC out patients 25/10/2018

Patient RXK Numbers	RXK4763419
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Report Author Job Title	Consultant, Intensive Care Medicine and Anaesthesia
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Chief Executive approval	
Non-Executive Director, Vice Chair, Lead for Quality & Safety approval	

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Executive Summary

Incident 163444	**Never Event – retained gauze Gynaecology patient**	
Incident date 21/10/2018	**Department/Ward** Ophthalmology	**Lead Investigator** Dr J Bleasdale

Incident synopsis

Patient A attended for one in a long course of bilateral injections she had started in 2015 for wet macular degeneration. The planned procedure was right intra vitreal injection

The Injector and Care Assistant completed the positive patient identification checks with the list and the electronic patient record (Medisoft) but failed to check the consent and list with Medisoft together. Patient A stated that she was expecting to have her left eye injected and, distracted by this assertion from the patient, a stressful list and without a double check from the Care Assistant the Injector injected the left eye as requested by the patient, not the right eye as planned.

The error was recognised almost immediately, a full clinical assessment of the eye undertaken confirming no harm and an apology and reassurances given to Patient A

Incident investigation synopsis

The *Standard Operating Procedure (SOP) For Intra Vitreal Injections BMEC (version 11)* was not followed.

The Care Assistant trusted the Injector to be correct and was not sure how to check the procedure on Medisoft.

It was a very disrupted list with many changes and repeated interruptions

The provision of lucentis®, on the day, for the injections is cumbersome and generates a distraction

Near misses are not reported

Root Cause:

Failure to follow Standard Operating Policy

What have we done to prevent the incident from occurring again?

a. Sign on outside of door and doors locked internally when injecting.
b. All Injectors and HCAs met with Mr Chavan and Mr Nessim to go through the correct process.
c. "Hard stops" to be reiterated to staff in Huddles/QIHD – ok for all to challenge.
d. All Injectors and Care Assistants been retrained on how to access management plan on Medisoft
e. All injectors and assistants to go through audit of practice to assure the Directorate of safe and consistent practice
f. Template for all clinicians to use for completing the management plan in Medisoft has been implemented to create a standard approach to documentation aiding understanding by the injectors and care assistants.

1 Introduction

This report will present the findings of a never event review meeting held on 10th January 2019, investigating the circumstances leading up to a never event when a patient, having one of a series of intra-ocular injections, was injected in the wrong eye.

2 Investigation terms of reference

- To clarify and review the treatment and care provided for Patient A in the out patients of the Birmingham and Midland Eye Centre (BMEC) on 25th October 2018.
- To review and confirm whether the care provided was in line with Trust policies, procedure and guidance
- To identify a root cause for the never event.

Lead Investigator: Dr John Bleasdale; Consultant, Intensive Care Medicine and Anaesthesia
Support: Peter Hughes, Interim Patient Safety Manager

Clinical team: The clinical team involved were a doctor undertaking the injections (Injector) and a Health Care Assistant (Care Assistant)

Information sources referred to as part of the investigation included;

- Report of the local Table Top Review meeting (TTR)
- Standard Operating Procedure (SOP) For Intra Vitreal Injections BMEC (version 11)
- Individual discussion with those involved and investigating locally
- A round table discussion chaired by Dr John Bleasdale and attended by;
    - Mr M Nessim (Consultant Governance Lead)
    - Laura Young (Directorate Lead Nurse, Ophthalmology)
    - Mr R Chavan (Medical Retina Lead)
    - Dr S Nair (Injector)
    - D Pag-Ong (Care Assistant)

3 Investigation

3.1 Background

The outpatient clinic in the Birmingham and Midland Eye Centre completes over 11,000 eye injections per year. These are undertaken in 12 half-day lists per week, with up to 15 cases on each list. On the 25th October 2018 the morning injection list that Patient A attended had 13 patients on and 2 "walk ins" who attended on the day.

3.2 Summary of events

Patient A attended for an injection of lucentis® into the vitreous of her right eye, this was to be just one in a course of bilateral injections she had started in 2015 for bilateral wet macular degeneration.

The Injector and Care Assistant completed the positive patient identification checks with the list and the electronic patient record (Medisoft). The Care Assistant then continued with other essential list administrative tasks and did not confirm the consent with the Injector. The Injector checked the consent and list with Medisoft alone as the Care Assistant was unsure how to find the relevant information in the Medisoft management plan. Patient A stated that she was expecting to have her left eye injected and, distracted by this assertion from the patient and without a second person checking the correct side, the Injector injected the wrong eye.

The error was recognised at the "sign out". Patient A and the Consultant Lead for Medical Retina were informed immediately; a fundal examination and Optical Coherence Tomography (OCT) scan were completed demonstrating that no harm had been caused. An apology and full explanation was given to Patient A and the duty of candour process was commenced.

3.3 List organisation

Some, though not all, patients requiring lucentis® treatment often need a series of multiple injections into both eyes. The consent process for these injections requires consent forms for each eye. The documented consent is for a course of treatment, not an individual injection, and can be valid for several years (this is nationally accepted practice endorsed by the Royal College of Ophthalmologists). These two consent forms are added to the patient record.

If a patient requires both eyes to be treated the normal process is for the first three injections into both eyes to be done at the same visit at monthly intervals. Following the third injection OCT scans are undertaken. The scans are reviewed by one of the medical team and a recommendation for the frequency of continuing injections, for each eye, is recorded in the Medisoft Management Plan. (The frequency of future injections may not be the same for both eyes). All further injections are followed by an OCT scan which is then reviewed and recommendations for the timing of ongoing injections recorded in Medisoft.

To compile a clinic list of injections the Booking Team consult Medisoft, determine when a patient next needs an injection and which eye needs injecting. This is done by reviewing the OCT report recommendation and the previous injection schedule, both viewed on the same Medisoft screen. This list is then used to arrange delivery of the lucentis® (on a named patient basis) to the injection clinic and by the Care Assistant to prepare on the day for the procedures.

3.4 Confirming the correct side

On the day of the list the Care Assistant checks the list and prints the appropriate consent form, stored in Medisoft, for the side as listed. Where possible the consent forms are printed off in advance for the majority of the patients.

When a patient enters the injection room the *Standard Operating Procedure (SOP) For Intra Vitreal Injections BMEC (version 11)* determines the safety checks as:

> "*4.4 Safety Checks Performed – use of WHO checklist and stamp. This must be undertaken with both the injector and the assistant following the Positive Patient Identification Process.*
>
> - *Sign in WHO check-list initial part by HCA or nurse (as appropriate) with the Injector (doctor/ specialist nurse).*
> - *Positive ID details check and place patient ID sticker on the WHO checklist.*
> - *Allergy check.*
>
> *Both injector and assisting nurse checking the patients ID on notes and the Medisoft.*
>
> - *Both confirm side of injection and drug for injection from management plan in the notes and Medisoft*."

3.5 Late changes to the list

The injection lists are often changed at very late notice (3 or 4 changes on the day) and it is an almost normal occurrence for patients to "walk in" on the day. It is because of this that some patient's consent forms are not printed off until the day of the list.

Lucentis®, stored in the fridge, is prescribed and administered on a named patient basis. The Care Assistant needs to check the drugs against the list, return to pharmacy any that are not needed and arrange further supplies to be delivered for the new additions to the list. Each dose of lucentis® requires a "Blueteq" form to be completed prospectively before Pharmacy will dispense the drug. The Care Assistants spend a significant part of their time ensuring these forms are completed, transported to Pharmacy and then chasing delivery of the drug to the clinic to ensure the list runs to time.

3.6 SOP for Intra Vitreal Injections

The *Standard Operating Procedure (SOP) For Intra Vitreal Injections BMEC (version 11)* was reviewed and found to be a satisfactory process for ensuring the correct, planned procedure is completed if all the steps are followed. The practice in other eye centres was discussed and though, as is expected, there is some variation in the approach to organising intra vitreal injection lists the system adopted at BMEC was in keeping with that developed by many others.

3.7 Risk culture in BMEC

It became clear during the review meeting that there have been previous episodes when the consent and listed procedure do not match the Medisoft management plan and that these events are managed on the day in accordance with the *Standard Operating Procedure (SOP) For Intra Vitreal Injections BMEC (version 11)*

> *"4.6 ….defer procedure and seek advice"*

These never event near misses are not being reported and discussed at local governance meetings.

4 Findings

4.1 Good practice

- The error was recognised immediately
- Full clinical assessment of the eye undertaken confirming no harm
- Full explanation and reassurances given to Patient A
- Lead for Medical Retinal informed immediately
- Duty of Candour phase 1 completed
- The *Standard Operating Procedure (SOP) For Intra Vitreal Injections BMEC (version 11)* is adequate to prevent further events if followed correctly and is in keeping with similar standards at other eye centres

4.2 Variance in practice

- Not following Standard Operating Procedure
    - No two person check of listed procedure with management plan in Medisoft
- Care Assistant "trusted" doctor to be correct and didn't question operative side
- Care Assistant was not sure how to use Medisoft to find and check that the correct procedure had been listed

4.3 Contributory factors

- Very disrupted list with changes and repeated interruptions
- Clinic Assistant preoccupied with administrative tasks
    - catching up with changes in the list
    - ensuring adequate supplies of lucentis®
- Injector disturbed by stressful list (disruption and knocks at the door)
- Injector not questioning the patients assertion that she was due to have her left eye treated

4.4 Root cause:

Failure to follow Standard Operating Procedure

5 Recommendations

5.1 From Directorate TTR

a. *Sign required on outside of door – eg "Do not disturb, injections in progress".*
b. *Re-audit of HCA staff to ensure they understand the SOP, expectation to call a hard stop and how to read the Medisoft Management Plan*
c. *Observers to be cleared by Mr Chavan, ie dates, times – no random interruptions.*
d. *Ensure all consent forms scanned onto Medisoft.*
e. *Create learning tool of processes to follow.*
f. *All Injectors and HCAs to meet with Mr Chavan and Mr Nessim to go through the correct process.*
g. *"Hard stops" to be reiterated to staff in Huddles/QIHD – ok for all to challenge.*
h. *Consent forms to be checked against Patient Management Plan.*

5.2 From never event review meeting

a. Review requirement for a second, qualified nurse to check consent and list with Medisoft as stated in the SOP to enable the first Clinic Assistant to manage the list
b. Review provision of lucentis® for injection lists to ensure that an adequate supply of the drug is available at the start of the list
c. Report and discuss near miss events through local governance structure (and SWBH Theatre management Board) to develop a more healthy risk culture and share learning.

6 Actions

	Action	By Whom	By When	Evidence/ Measure	Date Achieved
A: Empowerment of staff					
A1	"Hard stops"/challenging to be reiterated to all staff during Huddles/QIHD. Staff will always be supported when calling a hard stop.	Lead injector OPD Manager Mr Chavan	25.10.18 OPD Huddles – ongoing QHID – 13.11.18	Email QIHD minutes	25.10.18
A2	Implement additional signage on doors – Injections in Progress – DO NOT DISTURB	OPD Manager	12.11.18	Sign in situ	12.11.18
B: Education					
B1	Learning tool to be created – to ensure SOP is followed in a standard way/required to follow	Mr Chavan, Mr Nessim and Lead Injector	13.11.18	QIHD minutes	13.11.18 Training pack updated
B2	All injection staff to have training on how to access/read Management Plan	Mr Nessim/Mr Chavan	13.11.18	QIHD minutes	13.11.18
B3	Doors to be locked internally when injection is taking place	Lead Injector	12.11.18	audit	12.11.18
C : Audit					
C1	All injectors and assistants to go through annual audit of practice to assure the Directorate of safe and consistent practice	Mr Chavan, Mr Nessim and Lead Injector	16.12.18 and then regular yearly audit	Report back to SMT by 23.12.18 Then annually	
C2	Review of practice within other departments	Laura Young	30.12.18		
D: Risk mitigation and governance					
D1	Review requirement for a qualified nurse for Medisoft checking	Mr Nessim Mr Chavan Laura Young DGM		QIHD minutes	
D2	Encourage near miss reporting and discussion at local governance meetings	Mr Chavan, Mr Nessim Laura Young		QIHD minutes TMB minutes	
D3	Review supply of lucentis® for injection lists	Mr Chavan, Mr Nessim Laura Young Divisional Pharmacy Lead		Meeting minutes	

7 Learning

The findings will be shared with the specialty through shared learning events and educational sessions.
Consideration will be given to whether there are similar practices within other specialties within the Trust and advise those areas to review and amend to prevent a similar occurrence.

8 Conclusion

The root cause was failing to follow an agreed and disseminated standard operating procedure. This was contributed to by the disrupted nature of the list.