Protocol for Nurse-Led Fundus Fluorescein Angiography Clinic

This protocol does not override the individual responsibility of health professionals to make appropriate decision according to the circumstances of the individual patient in consultation with the patient and /or carer. Health care professionals must be prepared to justify any deviation from this guidance.

SCOPE

The guideline outlines the minimum standard expected from clinical staff performing Fundus Fluorescein Angiography (FFA) as part of their duties within ophthalmology. The primary purpose of this policy is to ensure that practice is safe and based on best possible evidence. A separate guideline is available for ICG (awaiting revision). Anterior Segment Angiography is also considered separately.

This protocol is for use by the following staff groups:

- Ophthalmic Doctors.
- Ophthalmic Nurses.
- Medical photographers.

DOCUMENT HISTORY

Lead Author: Laura Knowles	Ophthalmic Nurse Practitioner
Approved by Ophthalmology Clinical Governance Committee	20th December 2018
Approved by Medicines Safety Committee on:	2nd September 2019
This is the most current document and should be used until a revised version is in place:	2nd September 2022

Key amendments to this guideline

Date	Amendment	Approved by: (name of committee or accountable director)
02/09/2019	Document approved for three years at Medicines Safety Committee	MSC

INTRODUCTION

- Covers the administration of Fluorescein dye for the purpose of fundus angiography.
- Provides details of minimum qualifications and training in order to perform this procedure.
- States that staff must adhere to Trust policy and procedures at all times and must update their knowledge and proficiency constantly.
- Applies to all sites in the Worcestershire Acute Hospitals NHS Trust (WAHT) where Fluorescein is administered.

Fundus Fluorescein Angiography (FFA) is currently the gold standard for diagnosis in Age Related Macular Degeneration (AMD). An FFA is a sequence of images captured of the fundus over a 10 minute period after injection of a fluorescein dye into a suitable peripheral vein. Sodium Fluorescein is a highly soluble, complex organic molecule. It has several physical and chemical properties that make it an excellent diagnostic tool. It is inexpensive, non-toxic, water soluble and a relatively inert organic plant resin.
Colour photographs **must** accompany the FFA as they yield important additional information on the composition of the macular lesion allowing interpretation of the FFA. Haemorrhage, pigment and exudate are easily distinguished from each other on colour images but are seen as dark areas on FFA.
Early phases of the angiogram must be captured as they are important for the visualisation of the choroidal phase and the early arterial phases, when pathology is better seen before obscuration of details by leakage and pooling of fluorescein dye.
Late images (6-10 minutes) are also important for distinguishing late leakage from drusen (which can take up fluorescein but which fade towards the end of the fluorescein run), RPE window defects and inactive scars. This is necessary to distinguish active from inactive pathology, which may be important for initiating or continuing treatment.
Stereo images may be used to identify the tissue compartment in which pathological features are seen e.g. RPE elevation, and/or elevation of the neurosensory retina.

Preparation:
It is extremely important to document a patient's medical history and obtain consent for the procedure. The history should elicit any fluorescein allergy noted at a previous exposure or previous anaphylaxis reaction. A record of the patient's current medications should be made. Blood pressure should have been recorded at the time of booking the investigation. While existing cardiovascular or renal disease is not a reason for withholding angiography, this information may prove useful in terms of subsequent patient management particularly in the event of an allergic reaction. For patients with renal disease, ***a reduced dose of 2.5ml*** of fluorescein dye is given (as per the recommendation of the Trust's Renal Consultant). If the patient is in the advanced stages of renal disease, the relevant blood tests should be requested and reviewed prior to the booking of the FFA.
If a patient is known to have a history of mild allergy from a previous fluorescein injection, such as itching, tingling, sneezing etc., the test may still be performed if it is considered important – but with appropriate precautions. These may include the administration of an appropriate drug, e.g. an oral antihistamine such as Chlorphenamine (Piriton) 4mg before the test, and giving ***a reduced dose of 2.5ml*** of fluorescein dye, and monitoring the patient for at least 60 minutes after the injection. If such a patient is using a betablocker drug, this should be discussed with a Doctor before the investigation begins.
Serious adverse reactions are extremely rare. However, it is essential that the facilities for resuscitation with a standard protocol should be available. If a patient has a minor allergic reaction, observation for at least 60 minutes is recommended before they leave the unit, as more severe life threatening reactions may take time to develop.

DETAILS OF PROTOCOL

PROCEDURE:

Consent, Prescribing and Documentation

- A Doctor or Registered Nurse, who has been trained in taking consent for this procedure must obtain written consent (in accordance with the Trust's Consent Policy) having explained the rationale, procedure and possible complications. This consent form must be placed in the patient's records and sent off for scanning into eZ notes at the end of the clinic. The patient should be given the underlying copy for their own records.

- The patient must be given the WAHT Fundus Fluorescein Angiography (FFA) information leaflet prior to the procedure. The patient should be asked to read the leaflet and any questions should be answered. If required, the leaflet should be read to them by a member of the nursing team or a relative.

- A Doctor or Nurse Practitioner must prescribe the Fluorescein dye and Sodium chloride 0.9% flush on the FFA booking request form: EZ Notes WR1410.

- The Nurse or Doctor must sign that they have administered the Fluorescein dye, complete the WAHT Peripheral Vascular Device (PVD form) and document any complications that may have arisen during the whole procedure.

- When this clinic is performed at WRH, a Doctor must be in the department due to the department being isolated from the main hospital.

- Any complications must be entered as an incident on DATIX according to Trust policy.

Contraindications and Cautions with respect to Fluorescein dye:

- Prior to administration the patient must be assessed by the Nurse, who checks the consent and ensures that there are no contraindications to the use of Fluorescein dye. Also, any cautions need to be evaluated before the decision is made to proceed.

- Contraindications - Significant Allergy to Fluorescein dye.

- Caution should be taken with patients with renal impairment. Patients with a history of renal impairment should be prescribed a reduced dose of dye (2.5ml). This is supported by the Specialist Consultant in Renal and General Medicine of the Trust.

- Cautions: Previous minor reaction to fluorescein dye. Also, if a patient has a predisposition to multiple allergies and if such patient is taking beta blocking medication. These patients are to be discussed with a Doctor prior to the investigation commencing.

- The Nurse should not proceed with the administration if they have any reservations about the suitability of the patient. In this case the patient should be referred to an appropriate Doctor for assessment.

EXCLUSIONS:

- Patients with previous anaphylaxis to intravenous Fluorescein.

CAUTIONS:

The following patients will only be accepted for an FFA if the Consultant requesting the investigation has documented that they are aware of the situation.

- Pregnancy.
- Breastfeeding.
- Children under the age of 16.

EQUIPMENT REQUIRED:

All drugs and equipment required must have their expiry dates checked before use.

- Fluorescein 10% dye for injection, 5ml vial (500mg per 5ml)
- Sodium chloride 0.9%, 3 x 5ml vials,
- Blunt filter needle,
- 5ml or 10ml syringes x2,
- Non-sterile gloves,
- Apron,
- Disposable tourniquet,
- Chloraprep,
- Venflon cannula (20g or 22g,)
- Cannula Dressing,
- Gauze,
- Micropore/Surgical tape,
- Vomit bowl,
- Water to drink
- Chlorphenamine 4mg tablets
- Oxygen,
- Anaphylaxis pack,
- Emergency and resuscitation drugs,
- Adequate space to manage a collapsed patient.

ADMINISTRATION OF INTRAVENOUS FLUORESCEIN

ACTION	RATIONALE
1. Ensure that information leaflet has been provided. Obtain a medical history, including allergies and renal function and check consent form is signed. Ensure that a baseline Blood Pressure reading has been recorded on booking (normally prior to the day of procedure).	To ensure allergies and medical conditions are documented, the patient is fit, understands FFA and has given consent. Ensures that patients who have hypertension have been assessed and treated and are fit to undergo the procedure.
2. Explain the procedure and the effects of the dye to the patient. Answer any questions.	To promote patient understanding and to alleviate patient concerns.
3. Instil dilating eye drops as prescribed. (On the request form).	To enable to photographer to obtain the best quality images. Advise patient in regards to disturbed vision and the effects of bright lights.
4. Hand hygiene as per Trust protocol.	Promote patient safety and prevention of transmission of infection.
5. Prepare the relevant equipment.	To ensure that everything required (and that may be needed) for the procedure is available.
6. Cannulate the chosen vein as per protocol for the insertion of cannula. Use Sodium chloride 0.9% as a flush to confirm the correct position of the cannula in the vein.	To provide safe venous access and allow the procedure to be performed. Pain on administration suggests extravasation.
7. Dispose of sharps as per Trust protocol.	To prevent needle stick injury.
8. Check pupil dilatation.	Administer an extra dose of Tropicamide 1% (if required) to obtain a good dilation. This gives the best chance to obtain high quality images and ensures that dilation remains sufficient under the bright lights from the camera.
9. Introduce the patient to the photographer and aid their positioning at the camera. The photographer will explain the next part of procedure to the patient.	To reassure the patient and ensure maximum comfort and compliance during the procedure.

10. Colour images of the fundus must be taken.	These yield important additional information on the composition of the macular lesion allowing interpretation of the FFA. Haemorrhage, pigment and exudate are easily distinguished from each other on colour images but are seen as dark areas on FFA .
11. The qualified nurse is to check the drug with another qualified nurse prior to injection, one of whom should be the registrant who administers the dye. Inject the dye as a stat dose, at a rate of 1ml per second, at the indication of the photographer, whilst observing the cannulation site.	Rapid injection of dye ensures a bolus dose, desirable for good photography. Observation of the cannula site for extravasation. Stop the injection immediately if this occurs.
12. Nurse to remain with the patient throughout the whole procedure.	To monitor any adverse effects from the injection. To provide reassurance for the patient and support for the photographer. To aid with positioning of the patient if needed.
13. The patient is accompanied to an appropriate area to wait for 30 minutes post dye injection.	To ensure no late onset allergic reactions occur and the patient is reassured while their vision has recovered from the dazzle of the bright lights.
14. Providing the patient is feeling well, remove cannula, apply pressure for 2-3 minutes and dress wound with sterile gauze and tape.	To minimise risk of bacteraemia and prevent a haematoma around the injection site.
15. Advise the patient in regard to the bright light and disturbed vision until their pupil dilation reduces. Also advise the patient of what adverse reactions to look out for, and how to deal with these issues if they arise.	To ensure the patient is educated when leaving the department.
16. Complete all relevant paperwork.	To ensure documentation is legible and in line with Trust policy

Monitoring Tool

How will monitoring be carried out?

CLINICAL AUDIT **-** to be carried out if concerns arise regarding variation in practice or adverse effects.

Who will monitor compliance with the guideline?

Deviations and untoward incidences to be reported on DATIX by staff concerned. Overview of the DATIX reports will be the responsibility of senior Nurses in the FFA team.

STANDARDS	%	CLINICAL EXPECTATIONS
Patient consented correctly.	100%	
Patient given the FFA information leaflet prior to procedure.	100%	
Procedure request form completed and signed by the Doctor.	100%	
Signed record of administration of FFA, completion of the Trust's PVD form, indicating the vein used and any complications.	100%	
DATIX incident report completed for any complications	100%	

REFERENCES

- Belena, J. M et al (2013**), Adverse reactions to Fluorescein during Medical Angiography.** JSM Ophthalmology, 1:1004.
- Nursing and Midwifery Council (2015). **Standards for Medicine https://www.nmc.org.uk/globalassets/sitedocuments/standards/nmc-standards-for-medicines-management.pdf** Accessed: 3/7/2018.
- Royal Cornwall Hospitals NHS Trust (2017). **CLINICAL GUIDELINE FOR- NURSE LED FUNDUS FLUORESCEIN ANGIOGRAPHY. https://doclibrary**rcht.cornwall.nhs.uk/DocumentsLibrary/RoyalCornwallHospitalsTrust/Clinical/Ophthalmology/NurseLedFundusFluresceinAngiographyClinic.pdf Accessed- 3/7/2018.
- Royal Liverpool and Broadgreen Univeristy Hospital Trusts (2011). **Fluorescein Angiography.** https://www.rlbuht.nhs.uk/departments/medical-specialisms/eyes-st-pauls-eye-unit/ Accessed- 3/7/2018.
- The Royal College of Ophthalmologists (2013). **Age related Macular Degeneration: Guidelines for management.** http://www.rcophth.ac.uk/wp-content/uploads/2014/12/2013-SCI-318-RCOphth-AMD-Guidelines-Sept-2013-FINAL-2.pdf Accessed 29/06/2018.

KEY INDIVIDUALS INVOLVED IN DEVELOPING THIS DOCUMENT:

NAME	DESIGNATION
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LAURA KNOWLES	OPHTHALMIC NURSE PRACTITIONER

This key document has been circulated to the following individuals for consultation:

Name and Designation
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Mrs J. Chhina, Consultant Ophthalmic Surgeon – Medical Retina Specialist
Mrs H. Sharma, Consultant Ophthalmic Surgeon –Medical Retina Specialist
Sister S. Ruck, Senior Sister – Countywide Ophthalmology
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Dr M. Ferring, Consultant in Renal and General Medicine
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This key document has been circulated to the following CD/Heads of Departments for comments:

Name and Designation
Mr M Woodcock, Clinical Director of Ophthalmology
Sister H. Hipkiss, Nurse Practitioner Manager and Ophthalmic ANP
Dr J. Gardner, Clinical Governance Lead for Ophthalmology

This key document has been circulated to the chair(s) of the following committee's / groups for comments:

Committee
Alison Smith Medicines Safety Committee

Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

		Yes/No	Comments
1.	**Does the policy/guidance affect one group less or more favourably than another on the basis of:**		
	• Age	No	
	• Disability	No	
	• Gender reassignment	No	
	• Marriage and civil partnership	No	
	• Pregnancy and maternity	No	
	• Race	No	
	• Religion or belief	No	
	• Sex	No	
	• Sexual Orientation	No	
2.	**Is there any evidence that some groups are affected differently?**	No	
3.	**If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?**	No	
4.	**Is the impact of the policy/guidance likely to be negative?**	No	
5.	**If so can the impact be avoided?**	No	
6.	**What alternatives are there to achieving the policy/guidance without the impact?**	No	
7.	**Can we reduce the impact by taking different action?**	No	

If you have identified a potential discriminatory impact of this key document, please refer it to Human Resources, together with any suggestions as to the action required to avoid/reduce this impact.

For advice in respect of answering the above questions, please contact Human Resources.

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	No
2.	Does the implementation of this document require additional revenue	No
3.	Does the implementation of this document require additional manpower	No
4.	Does the implementation of this document release any manpower costs through a change in practice	No
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	No
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval