



Collecting a patient specific intraocular lens

Clinical Protocol Summary

Outlines the processes for collecting a patient specific intraocular lens power in adults undergoing cataract surgery

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Ratified: 12th December 2014

Version History

Version	Date Issued	Brief Summary of Change	Author
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2.0	January 2013	Update guideline	Martin Watson Melanie Hingorani Michael Miller
3.0	December 2014	Update guideline	Martin Watson Melanie Hingorani Ronald Kam Vincenzo Maurino
		Group responsible for review and updating of guidelines	Director of Cataract Service
		Date for review/update of guidelines	December 2017

For more information on the status of this document, please contact:	
Policy Author	Martin Watson, Melanie Hingorani
Policy Owner	Cataract Service Lead
Department	Cataract
Accountable Director	Medical Director and Clinical Director for Surgical Services
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Ratified by	Clinical Governance Committee
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Checklist for the review and approval of Clinical Guidelines

1. Purpose

Cataract extraction is the most commonly performed surgical procedures in the NHS and the aim of the surgery is to improve vision and to enhance the patient's quality of life. An intraocular lens (IOL) is inserted during cataract surgery, after removal of the natural lens. Implantation of the correct IOL is essential to achieve a good visual outcome and predicted post-operative refraction.

Selection of the correct power of intraocular lens relies on careful biometry (see *Intra Ocular Lens Measurement Guideline*), consideration of all patient specific factors in selection of the IOL by a clinician (*Guidelines for selection of intraocular lenses in adults*) and ensuring the IOL provided to the surgeon is that selected (this protocol).

The objectives of this protocol are:

- To ensure consistent management throughout the Trust of patients undergoing cataract surgery
- To ensure all patients attending for cataract surgery will have the correct patient specific IOL implanted
- To ensure that the maximum number of patients achieve their desired refractive outcome following surgery
- To reduce unplanned post-operative refractive outcomes
- To prevent 'Serious Incidents' (SI) and 'Never events'

2. Scope

- This protocol has been developed for all staff involved in the process of collecting a patient specific IOL to the point of implantation
- This applies to all patients booked for cataract extraction with IOL in one or both eyes.
- The lens collection procedure can be undertaken by doctors, theatre nurses, ODA's (Operating Department Assistants) and support workers (HCA's).

3. Explanation of Terms Used

Serious Incidents

'all events which cause death or serious harm or may impact on an organisation's ability to deliver on-going healthcare services'

Never Events

'a serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented'

In relation to cataract surgery these include:

- wrong site surgery
- wrong implant/prosthesis
- misidentification of patients
- retained foreign object post-procedure

Insertion of the wrong IOL becomes a 'Never Event' if further surgery is required i.e. IOL exchange, refractive surgery or if there is a complication directly related to the insertion of the wrong IOL.

4. Procedure

Ward

The **admitting doctor** must check the biometry data (following *Guidelines for selection of intraocular lens power in adults*) and complete the IOL selection sheet (Appendix 1), signing and dating this in the space provided as 'IOL selected by:'. Please note that in some cases, particularly at the satellite sites, the IOL selection sheet is completed prior to the day of surgery either at the initial consultation or a few weeks before. Under these circumstances the admitting doctor should carefully recheck that the IOL selection sheet is completed correctly with the appropriately selected IOL documented.

Before sending the patient to theatre, the **admitting ward staff** must complete the 'Before sending the patient to theatre checklist' in the *Patient assessment and treatment record* (Appendix 2). This includes checking the biometry is in the notes with the correct patient identification and correct side (left or right eye) and that this matches the correct side/eye marking and the side/eye on the consent form, and that the IOL selection sheet has been completed and signed.

Theatre

The **theatre staff member** receiving the patient into the anaesthetic room will check the patient (see *Reception and checking of the patient into the operating department 2012*).

The IOL power and lens has 2 safety checks (Surgical safety checklist, Appendix 3)

1st Check

As part of the Surgical Safety Checklist, the 1st Check is carried out at the 'SIGN IN' by the staff member receiving the patient. This includes checking the IOL selection sheet is completed and that the IOL is available.

As part of this they must check that:

- Name and hospital number on the biometry, the consent form, the notes and the IOL selection sheet corresponds to the patient.
- The side/eye marked on the patient matches the side indicated on the biometry sheet, the IOL selection sheet, the consent form and the theatre list
- The IOL selection sheet is completed with the IOL power written in the box provided and the lens model ticked or written if another type of lens is required i.e specific toric IOL
- The IOL selection sheet is signed and dated in the space 'IOL selected by:'

If a minus lens is to be used then the word 'minus' should already be written in the correct box.

The **operating surgeon** should also check the biometry data and 'IOL selection sheet' and confirm with a member of theatre staff that the IOL written down should be the one collected.

Before the patient is anaesthetised, the theatre staff must be certain that the

SELECTED IOL IS AVAILABLE. This should then be PHYSICALLY IN THEATRE WITH THE PATIENT AT THE TIME OUT STAGE.

The 'SIGN IN' part of the 'surgical safety checklist' is completed to confirm this is done.

Only one lens at a time is permitted into the theatre.

2nd Check

The 2nd check is at the **TIMEOUT** on the Surgical safety checklist where the **theatre staff member**, **scrub nurse** and **operating surgeon** visually and verbally check that they have the correct patient; that the correct operation is about to be performed on the correct eye; and that the lens model and power are correct for that eye.

The check involves three components:

- Identity check: details on patient bracelet are read out and confirmed with the
 patient (if able to e.g LA) that these are correct. They must match the details on
 the front of the notes, consent form, 'IOL selection sheet' AND biometry.
 Allergies are also confirmed at this stage.
- Eye check: the correct eye; 'Left' or 'Right' for the correct procedure on the consent form and lens choice written on the correct side of the IOL selection sheet.

Lens check: the notes must be held up with the IOL selection sheet and biometry printout visible next to each other simultaneously on facing pages. The power and model of the handwritten IOL choice on the correct side of the IOL selection sheet must match the IOL choice for the same eye on the biometry print-out on the facing page. The IOL box is then opened and a lens sticker is pasted on the "Paste IOL sticker here during timeout" box on the 'IOL selection sheet'. The lens power and model on the sticker must match the handwritten IOL choice immediately above it on the 'IOL selection sheet' and the chosen IOL on the correct side of the biometry printout on the facing page.

3. If no discrepancies are identified in the checks above, the lens is then opened and placed on the scrub nurses trolley.

The **TIMEOUT** part of the Surgical Safety Checklist is completed to confirm this is done. This includes ticking the box on the 'IOL selection sheet' to confirm that 'The surgeon verbally confirms:'

The surgeon verbally confirms:
> handwritten IOL & sticker match facing biometry
> correct side of biometry page matches operated eye
> all documents match patient and operated eye

At the end of surgery the **theatre staff member** attaches an implant identification label onto the patient's clinical records, theatre lens record and also enters this onto the computer Galaxy system patient record.

Inserting the correct lens is a team responsibility. It is crucial that, if any theatre staff members have any concerns as to the consistency of the paperwork or the correct selection of lens model or power, they must inform the operating surgeon and the scrub nurse immediately. It is also important the surgeon respects and supports any team member who raises a concern and does not continue with implanting the IOL until this has been resolved.

In the event of the surgeon needing to reassess and recalculate the power of another lens to the original lens selection, i.e. for vitreous loss, capsule tear, then the **theatre staff member** returns the original lens within its packet and opened box to the theatre coordinator, drawing a line across the previously recorded details indicating lens return. The unused IOL or IOL packaging must be removed from theatre before the next patient arrives in theatre. The procedure as set out above is followed for selection of an alternative lens prior to implantation. On the IOL selection sheet, the original lens power and model is crossed out and the new lens power and model written instead. The new lens sticker is either placed over the original lens sticker or instead of the original lens sticker if this can be removed.

If a lens is faulty or has been opened and not used, these lenses may be returned to the manufacturer. The lens and packaging are to be saved. Lens sticker to still be placed on lens record sheet for audit trail

5. Duties

- 5.1 Service Directors, the Director of Nursing and Allied Health Professions and Managers/Nurse Managers/Matrons are responsible for ensuring that this protocol is distributed and implemented within their areas of responsibility, to ensure that their staff are aware of the content and its procedures to follow in practice.
- 5.2 The consultant in charge must ensure adequate supervision of the trainee in IOL selection and insertion.
- 5.3 Doctors selecting the IOL and performing cataract surgery must read and understand this protocol and report any incidents as per the Trust's Incident Reporting Policy.
- 5.4 The ultimate responsibility to insert the correctly planned IOL lies with the operating surgeon. The surgeon must stop and take action if any member of staff raises a concern about the correct patient, side or IOL.
- 5.5 Theatre staff are responsible for ensuring the appropriate paperwork and checks are completed and that they look for and bring to attention any possible inaccuracy, discrepancy or mistake to the surgeon as soon as possible

6 Training

6.1 At departmental induction, new members of theatre staff will receive a period of training and new theatre staff will be assessed against the relevant Trust Competency according to standard operating procedures. Staff are accountable to their employer to follow their contract of duty and to their regulatory and professional bodies. Support workers are accountable to their employer to follow their contract of employment to undertake tasks delegated to them under the supervision of a registered practitioner.

7 Stakeholder Engagement and Communication

- 7.1 This document has been developed by the Cataract Service and Consultants within the Cataract Service.
- 7.2 Theatre and satellite managers have also had an opportunity to review this document.

8 Approval and Ratification

- 8.1 The guideline has been approved by the Cataract Service meeting, the Cataract Service Lead and will be approved by the Clinical Audit and Effectiveness Committee.
- 8.2 The guidelines will be ratified by the Clinical Governance Committee.

9 Dissemination and Implementation

- To all consultants and medical staff and to all incoming trainees on the service induction day and general trainee induction.
- Via departmental/service specific Clinical Governance days
- For theatres, the staff will be informed through departmental meetings and the daily role call meetings in the mornings by the theatre coordinators when there are changes to the protocols and competencies.
- To all ward managers
- This guideline is available on the intranet and also circulated to all managers and theatre sister.
- Communication via Chief Executives newsletter to all staff

10 Review and Revision Arrangements

10.1 The guideline will be reviewed by the Policy Owner/Author every three years or earlier if required due to further Never Events or changes in technology or Royal College Guidance.

11 Document Control and Archiving

- 11.1 The current and approved version of this document can be found on the Trust's intranet site. Should this not be the case, please contact the Head of Clinical Governance.
- 11.2 Previously approved versions of this document will be removed from the intranet by the Head of Clinical Governance and archived. Any requests for retrieval of archived documents must be directed to the Head of Clinical Governance or Risk and Safety team.

12 Monitoring compliance with this Policy

12.1 The Trust will use a variety of methods to monitor compliance with the processes in this document, including the following methods:

Measurable Policy Objective	Monitoring/ Audit method	Frequency of monitoring	Responsibility for performing the monitoring	Monitoring reported to which groups/ committees, inc responsibility for reviewing action plans
Adherence to processes in policy	Audit using undercover live monitoring of the protocol in theatres Audit of randomly selected notes for evidence of completion of the Surgical safety checklist and IOL selection sheet Serious Incidents and Never events reporting IOL exchange procedures derived from theatre computer management system	At the discretion of the Cataract Service Director	Audit of compliance is expected among all consultants and trainees under their supervision in clinics and theatres. Head of Clinical Governance Cataract Service Director	Management Executive

In addition to the monitoring arrangements described above the Trust may undertake additional monitoring of this policy as a response to the identification of any gaps, or as a result of the identification of risks arising from the policy prompted by incident review, external reviews or other sources of information and advice.

This monitoring may include commissioned audits and reviews, detailed data analysis or another focussed study, for example. Results of this monitoring will be reported to the committee and/or individual responsible for the review of the process and/or the risks identified.

Monitoring at any point may trigger a policy review if there is evidence that the policy is unable to meet its stated objectives.

13 Supporting References / Evidence Base

- Jackson T (2008) Moorfields Manual of Ophthalmology .China :Elsevier
- Morrin J (2005) Working Protocol for the selection and collection of intraocular lens requested in theatre Moorfields Eye Hospital NHS Foundation Trust.
- National patient safety Agency (NPSA) (2005) Safer Patient Identification.

- National patient safety Agency (NPSA) (2005) Correct Site Surgery.
- HSC 2001/023 Good Practice in consent
- The Royal College of Ophthalmologists 2012/EACT/002 external review from the Royal College of Ophthalmologists following 'Never Events' at the Moorfields NHS Trust.
- Guidelines for selection of intraocular lens power in adults Local guidelines, updated October 2012

14 Supporting Documents

- IOL Measurement (Adult) Guideline
- Guidelines for selection of IOL in adults

Biometry check: performed after printing biometry				
•	ct setting (optical or ultrasound)			
Correct formula Target	refraction (if different from emmetropia)			
AL X22mm, use SRXCT AL \$22mm, use Hoter O	Signed:			
Right eye	Left eye			
Target Ref: Emmetropia, OR (0 to -0.5D)	Target Ref: Emmetropia, OR (0 to -0.50)			
□ Discussed with patient	□ Discussed with patient			
IOL Model: AcriSert (SN60WF) Multi-plece (MA60AC) Other:	IOL Model:			
IOL Power (diopter): Pred. Ref.	IOL Power (diopter): Pred. Ref:			
Please write minus If minus IOL:	Please write minus if minus IOL:			
Paste IOL sticker here during 'Timeout'	Paste IOL sticker here during 'Timeout'			
Incision / LRI: Superior	Incision / LRI: Superior			
Angle:*	Angle:			
-				
IOL selected by: Sloned: Date:	IOL selected by: Signed: Date:			
The surgeon verbally confirms: > handwritten IOL & sticker match facing biometry > correct side of biometry page matches operated eye > all documents match patient and operated eye	The surgeon verbally confirms: > handwritten IOL & sticker match facing blometry > correct side of blometry page matches operated eye > all documents match patient and operated eye			

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Admitting Consultant						
Reason for Admission						
Location:			PA	TIENT S	TICKER	
Anaesthetic: LA / GA / LAS / LA	AÇ.					
Date of Surgery:						
Languages spoken:		Telephone A	ssessment		Yes 🔲	No 🗆
Absolute exclusion cri	teria for local anaesthe	esia				
Have you had a heart attack in					Yes	No
Have you had a stroke in the la					Yes	No
If any answer yes Refe Have you had a heart attack in Have you had a stroke in the la Do you have sickle cell disease Are you pregnant (female patil Are you on domiciliary oxygen Do you have obstructive sleep Observations Pulse rate (bpm) Blood pressure Blood sugar	the last 6 months? ast 6 months? rents) and will you be more than 2 represented the months?	:3 weeks on date o	f surgery?	Height Weight BMI	Yes Yes Yes Yes Yes Yes Yes Yes	No No No No No No
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Visual Acuity Right VA Tests (please tick) ECG	uawith glassesph	Liver Thyroi Biometry: Ye Pentacam: Y Special lens Theatre Mar	Name of Signature Dates. Dates: No lores: No lores: No lores: Aphylaxis if it is aph	For to Anaes If Nurse / HO IT, T, T, D IT the mailed to: Co any:	INR Militrasound Dept:	RSA swab 🔲 Yes 📗 No 🛄
Visual Acuity Right VA Tests (please tick) ECG Bloods: FBC Blood results checked: Yes Date: Action taken if abnormal: Specify patient's ALLERGIES Latex Allergy: Type 1: Yes WEH205 Checklist before send Is it the right patient with corre Patient consent is valid and sign	with glassesph	Liver Thyroi Biometry: Ye Pentacam: Y Special lens Theatre Mar	Name of Signature Dates. Dates: No lores:	Fer to Anaes If Nurse / HO IT, T, T, D IT, D IT	INR Militrasound Dept:	RSA swab 🔲 Yes 📗 No 🛄
Visual Acuity Right VA Tests (please tick) ECG	with glassesph	Liver Thyroi Biometry: Ye Pentacam: Y Special lens Theatre Mar	Name of Signature Dates: Dates	For to Anaes If Nurse / HO If I (I (INR Militrasound Dept: \ onsultant Surgec	RSA swab 🔲 Yes 📗 No 👊

Moorfields Eye Hospital NHS Foundation Trust Surgical Safety Checklist TIME DUT SIGN OUT Allergies? Surgeon / theatre nurse verbally confirms with team: Ward handover Anaesthetist Has the patient (or Have any specimens been labelled (including guardian)* confirmed patient's name) / Not applicable? patient's identity, procedure, Surgeon, anaesthetist (if present) and scrub Has it been confirmed that instruments swabs nurse to check patient and consent form and site and consent (including and sharps counts are complete (or not type of anaesthesia)? applicable)? What is the patient's name / Hospital number? Is the surgical site marked? ☐ What procedure and site are planned? Surgeon and anaesthetist (if present) Is consent form signed and Are there any special instructions regarding Yes Is non-operative eye protected? do details match patient's care of the patient for recovery and / or the Yes / Not applicable identity band? Allergies? Surgeon to confirm: Are there any specific equipment requirements? Important Notes: □ No □ Yes Are there any non routine steps you want the Is the patient starved? *Children (<16yrs of age). Form must be completed for all patients and filed in. team to know about? Yes/NA Intraocular lens sheet patient records adjacent to consent form. If intraocular lens to be implanted 3. Omit shaded questions if list has no anaesthetic completed? Surgeon to confirm: If yes confirm This form is designed to raise the question not record data. Relevant information must be recorded ☐ Intraocular lens power and type Chosen lens / Theatre nurse to confirm: elsewhere in the patient's records. available Lens choice matches Int ar lens sheet Is the anaesthesis machine and medication checking Yes Chosen lens / implant ava complete? Nurse / ODP: ☐ No☐ Yes ☐ Has sterility of the instrumenta Are there any confirmed (including indicator re Are there any specific issues or o including VTE If yes is appropriate equ Yes Are the following required to reduce surgical infection? Name of ward staff. Antibiotic prophylaxis Signature Name of theatre staff. 2nd check 1st check If intraocular lens to be implanted Surgeon to confirm: Intraocular lens sheet ☐ Intraocular lens power and type Yes/NA completed? Theatre nurse to confirm: If yes confirm: Lens choice matches Intraocular lens sheet Chosen lens / implant ☐ Chosen lens / implant available available

Equality Impact Assessment

The equality impact assessment is used to ensure we do not inadvertently discriminate as a service provider or as an employer.

To be completed and attached to any procedural document when submitted to the

appropriate committee for consideration and approval.

propriate committee for consideration and	<u>approval</u>	
	Yes/No	Comments
Does the policy/guidance affect one group less or more favourably than another on the basis of:		
• Race	No	
 Ethnic origins (including gypsies and travellers) 	No	
Nationality	No	
• Gender	No	
Gender reassignment	No	
• Culture	No	
Pregnancy and maternity	No	
Marriage and civil partnership	No	
Religion or belief	No	
Sexual orientation including lesbian, gay and bisexual people	No	
• Age	No	
Disability (e.g. physical, sensory or learning)	No	
Mental health	No	
Is there any evidence that some groups are affected differently?	No	
If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	N/A	
Is the impact of the policy/guidance likely to be negative?	No	
If so can the impact be avoided?	N/A	
What alternatives are there to achieving the policy/guidance without the impact?	N/A	
Can the impact be reduced by taking different action?	N/A	
	Does the policy/guidance affect one group less or more favourably than another on the basis of: Race Ethnic origins (including gypsies and travellers) Nationality Gender Gender Culture Pregnancy and maternity Marriage and civil partnership Religion or belief Sexual orientation including lesbian, gay and bisexual people Age Disability (e.g. physical, sensory or learning) Mental health Is there any evidence that some groups are affected differently? If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable? Is the impact of the policy/guidance likely to be negative? If so can the impact be avoided? What alternatives are there to achieving the policy/guidance without the impact? Can the impact be reduced by taking	Does the policy/guidance affect one group less or more favourably than another on the basis of: Race Race No Ethnic origins (including gypsies and travellers) No Gender No Gender Culture Pregnancy and maternity Religion or belief Sexual orientation including lesbian, gay and bisexual people Age Disability (e.g. physical, sensory or learning) Mental health Is there any evidence that some groups are affected differently? If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable? If so can the impact be avoided? No No No Religion or belief No

If you have identified a potential discriminatory impact of this procedural document, please refer it to the director of corporate governance, or the human resources department, 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 the director of corporate governance (ext. 2306)

Please ensure that the completed EIA is appended to the final version of the document, so that it is available for consultation when the document is being approved and ratified, and subsequently published.

Checklist for the Review and Approval of Clinical Guidelines

To be completed (electronically) and attached to any document which guides practice when submitted to the appropriate committee for approval or ratification.

Title of the document:

Policy (document) Author:

Policy (document) Owner:

		Yes/No/ Unsure/ NA	Comments
1.	Title		
	Is the title clear and unambiguous?	Yes	
	Is it clear that this document is a Clinical Guideline?	Yes	
2.	Scope/Purpose		
	Is the target population clear and unambiguous?	Yes	
	Is the purpose of the document clear?	Yes	
	Are the intended outcomes described?	Yes	
	Are the statements clear and unambiguous?	Yes	
3.	Development Process		
	Is there evidence of engagement with stakeholders and users?	Yes	
	Who was engaged in a review of the document (list committees/ individuals)?	Yes	
	Has the policy template been followed (i.e. is the format correct)?	Yes	
4.	Evidence Base		
	Is the type of evidence to support the document identified explicitly?	Yes	
	Are local/organisational supporting documents referenced?	Yes	
5.	Approval		
	Does the document identify which committee/group will approve/ratify it?	Yes	

		Yes/No/ Unsure/ NA	Comments
	If appropriate, have the joint human resources/staff side committee (or equivalent) approved the document?	Yes	
6.	Dissemination and Implementation		
	Is there an outline/plan to identify how this will be done?	Yes	
	Does the plan include the necessary training/support to ensure compliance?	Yes	
7.	Process for Monitoring Compliance		
	Are there measurable standards or KPIs to support monitoring compliance of the document?	Yes	
8.	Review Date		
	Is the review date identified and is this acceptable?	Yes	
9.	Overall Responsibility for the Document		
	Is it clear who will be responsible for coordinating the dissemination, implementation and review of the documentation?	Yes	
10.	Equality Impact Assessment (EIA)		
	Has a suitable EIA been completed?	Yes	
Committee Approval (Clinical Audit and Effectiveness Committee) If the committee is happy to approve this document, please complete the section below, date it			

Committee Approval (Clinical Audit and Effectiveness Committee)						
	ee is happy to approve this document the Policy (document) Owner	nent, ple	ase complete the section below, date it			
Name of Chair	Melanie Hingorani	Date	12 th December 2014 (Chair's approval at CGC, CAEC approval January 2015)			
Ratification by Management Executive (if appropriate)						
If the Management Executive is happy to ratify this document, please complete the date of ratification below and advise the Policy (document) Owner						
Date:						