

# Adverse Incident Reporting Intraocular Lens Defect



# Adverse Incident Reporting Intraocular Lens Defect

- Data contribution:
  - From all Malaysian Ministry of Health Facilities
  - Participation from the Universities and Private Sectors is encouraged
- Inclusion:
  - All cataract surgeries with intraocular lens (IOL) implantation
  - Unlimited time of post-operative period (eg, you can still notify IOL opacification of cataract surgery done many years ago. The patient may still keep the record of the IOL brand or other details of surgery)



Why do I need to notify?



Because your notification may save other patients from similar incident if the particular IOL results in opacification, contaminated, has manufacturing defect or wrongly labeled



What are the type/s IOI  
defect which I need to  
notify?

## Examples of the notifiable type of IOL defect

- Opacification
- Crack or Line on optic
- Deposit on optic/haptic
- Fracture or detachment of haptic
- Incorrect labeling of IOL
- Failure of injector



How to notify if I encounter  
problem during IOL implantation?  
How to notify if I notice IOL defect  
during slit lamp examination?

# Please click: <http://www.acrm.org.my/ned/>

Friday, April 10, 2015

## NED National Eye Database

Registries Performance Monitoring Service Monitoring and Surveillance

CSR	Retinoblastoma	Diabetic Eye	AMD	eKPI	eCUSUM	Monthly Census	IOL	Infectious Endophthalmitis	Outreach Programme Census
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### National Eye Database (NED)

The National Eye Database (NED) is a service supported by the Ministry of Health (MOH) as an approach to collect health information. It collects data on incidences and distributions, and evaluates risk factors as well as treatment outcome of visually threatening eye diseases such as cataract, diabetic retinopathy, glaucoma and contact lens related corneal ulcer. In the initial phase, NED will collect data on cataract surgery, status of diabetic retinopathy in new diabetic patients, contact lens related corneal ulcer and glaucoma patients. Besides disease registry, NED also collects monthly service census of MOH Ophthalmology departments. The census serves as an effort to monitor key performance indicators of each ophthalmology department in the MOH.

Information collected at NED will be very useful in assisting the MOH, Non-Governmental Organizations, private healthcare providers and industry in program planning and evaluation, leading to eye disease prevention and control as well as continuous improvement of ophthalmic service in the nation.

#### Registries

- [Cataract Surgery Registry](#)
- [Retinoblastoma Registry](#)
- [Diabetic Eye Registry](#)
- [Age Related Macular Degener](#)

#### Performance Monitoring

- [Key Performance Indicators \(KPI\) for Ophthalmology](#)
- [Monthly Ophthalmology service](#)
- [Adverse Incident Reporting for Intraocular Lens \(IOL\)](#)
- [Adverse Incident Endophthalmitis](#)
- [Outreach Programme Census](#)

Click here

**Sponsors**

**CONTACT US**  
**Manager,**  
The Manager  
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68100, Batu Caves  
Selangor.

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Website: <http://www.acrm.org.my>

Dropbox 3.2.9  
Up to date

10:48  
10/04/2015



# Who Where How?

- Paramedic/Optometrlist/Medical Officer/Master Trainee/Specialist/Head of Department – all can notify
- No need password
- You can even notify when you are at any outreach locations
- As long as you can get internet access
- Click the icon, complete the form and save

# Web Notification Form

Google+ | Inbox (12) - mohamadaziz | NED | National Eye Database (NI) | Mohamad Aziz

https://www.macr.org.my/ened/fwPage.jsp?fwbPageId=AdverseIncident\_IOLForm&fwbAction=Insert&appType=9

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## Adverse Incident Notification Form - Intraocular Lens (IOL)

### NEW- ADVERSE INCIDENT NOTIFICATION FORM - IOL DEFECTS

1 \*\* Date of notification

Save

#### Section A: Description of Adverse Event

1	Date of diagnosis of IOL defect	<input type="text"/>																												
2	Date of IOL implantation	<input type="text"/> <input type="checkbox"/> Estimated year <small>(If the exact date is not known, please enter 30/06/yyyy and tick the Estimated year checkbox)</small>																												
3 **	Type of incident	<table border="1"> <tr> <td><input type="checkbox"/> IOL Opacification</td> <td><input type="checkbox"/> Fine deposits on optic</td> <td><input type="checkbox"/> Early cataract formation subsequent to phakic IOL implantation</td> <td><input type="checkbox"/> Failure of IOL injector</td> </tr> <tr> <td><input type="checkbox"/> Crack on optic</td> <td><input type="checkbox"/> Fracture or detachment of haptic(s)</td> <td><input type="checkbox"/> Incorrect labeling of IOL, including IOL power</td> <td><input type="checkbox"/> Others, specify: <input type="text"/></td> </tr> <tr> <td colspan="4"><input type="checkbox"/> Lines on optic</td> </tr> </table>	<input type="checkbox"/> IOL Opacification	<input type="checkbox"/> Fine deposits on optic	<input type="checkbox"/> Early cataract formation subsequent to phakic IOL implantation	<input type="checkbox"/> Failure of IOL injector	<input type="checkbox"/> Crack on optic	<input type="checkbox"/> Fracture or detachment of haptic(s)	<input type="checkbox"/> Incorrect labeling of IOL, including IOL power	<input type="checkbox"/> Others, specify: <input type="text"/>	<input type="checkbox"/> Lines on optic																			
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4	Patient characteristics	<table border="1"> <tr> <td>a ** Age of patient at implantation:</td> <td><input type="text"/></td> </tr> <tr> <td>b ** Current age</td> <td><input type="text"/></td> </tr> <tr> <td>c ** Gender</td> <td> <input type="radio"/> Male    <input type="radio"/> Female    <input checked="" type="radio"/> Missing         </td> </tr> <tr> <td>d ** Ocular co-morbidity</td> <td> <table border="1"> <tr> <td><input type="checkbox"/> Glaucoma</td> <td><input type="checkbox"/> Uveitis</td> <td><input type="checkbox"/> Diabetic retinopathy</td> </tr> <tr> <td colspan="3"><input type="checkbox"/> Others, specify: <input type="text"/></td> </tr> </table> </td> </tr> <tr> <td>e ** Systemic co-morbidity</td> <td> <table border="1"> <tr> <td><input type="checkbox"/> Diabetes mellitus</td> <td><input type="checkbox"/> Renal failure</td> <td><input type="checkbox"/> Hypercalcemia</td> </tr> <tr> <td colspan="3"><input type="checkbox"/> Others, specify: <input type="text"/></td> </tr> </table> </td> </tr> <tr> <td>f ** Previous ocular surgery (besides cataract surgery)</td> <td> <table border="1"> <tr> <td><input type="checkbox"/> Glaucoma surgery</td> <td><input type="checkbox"/> Vitreoretinal surgery</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Others, specify: <input type="text"/></td> </tr> </table> </td> </tr> </table>	a ** Age of patient at implantation:	<input type="text"/>	b ** Current age	<input type="text"/>	c ** Gender	<input type="radio"/> Male <input type="radio"/> Female <input checked="" type="radio"/> Missing	d ** Ocular co-morbidity	<table border="1"> <tr> <td><input type="checkbox"/> Glaucoma</td> <td><input type="checkbox"/> Uveitis</td> <td><input type="checkbox"/> Diabetic retinopathy</td> </tr> <tr> <td colspan="3"><input type="checkbox"/> Others, specify: <input type="text"/></td> </tr> </table>	<input type="checkbox"/> Glaucoma	<input type="checkbox"/> Uveitis	<input type="checkbox"/> Diabetic retinopathy	<input type="checkbox"/> Others, specify: <input type="text"/>			e ** Systemic co-morbidity	<table border="1"> <tr> <td><input type="checkbox"/> Diabetes mellitus</td> <td><input type="checkbox"/> Renal failure</td> <td><input type="checkbox"/> Hypercalcemia</td> </tr> <tr> <td colspan="3"><input type="checkbox"/> Others, specify: <input type="text"/></td> </tr> </table>	<input type="checkbox"/> Diabetes mellitus	<input type="checkbox"/> Renal failure	<input type="checkbox"/> Hypercalcemia	<input type="checkbox"/> Others, specify: <input type="text"/>			f ** Previous ocular surgery (besides cataract surgery)	<table border="1"> <tr> <td><input type="checkbox"/> Glaucoma surgery</td> <td><input type="checkbox"/> Vitreoretinal surgery</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Others, specify: <input type="text"/></td> </tr> </table>	<input type="checkbox"/> Glaucoma surgery	<input type="checkbox"/> Vitreoretinal surgery	<input type="checkbox"/> Others, specify: <input type="text"/>	
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#### Section B: Action Taken

1 \*\* Action taken

None

Monitoring

# Web Notification Form

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https://www.macr.org.my/ened/fwbpPage.jsp?fwbpPageId=AdverseIncident\_IOLForm&fwbpAction=Insert&appType=9

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5 8	Lot No. / Serial No.	<input type="text"/>
5	IOL Expired date	<input type="text"/>
6	Distributor company	a Name <input type="text"/>
		b Contact address <input type="text"/>
		c Email <input type="text"/>
		d Contact no. <input type="text"/> H/P <input type="text"/>
<b>Section E: Reporting Centre and Person</b>		
1 **	Reporting person's name	<input type="text"/>
2 **	Position	<input type="radio"/> Doctor <input type="radio"/> Nurse <input type="radio"/> Medical Assistant <input type="radio"/> Others, specify
		<input checked="" type="radio"/> Missing Others, specify <input type="text"/>
3 **	Name of Facility	<input type="text"/> <input type="text"/>
4 **	Email	<input type="text"/>
5 **	Contact no	<input type="text"/> H/P <input type="text"/>
<b>Image Verification</b>		
1 **	Image Verification	
2 **	Type the characters you see in this image	<input type="text"/>
<input type="button" value="Save"/>		

Once you have completed the form, please click save



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This application supports Microsoft Internet Explorer 7.0 and above and Mozilla Firefox 8.0 and above.





Why do I need to complete all data fields as required in the form?

# Answer

- Complete data submission collected centrally by NED will allow sufficient planning and action to be taken
- Example:
  - Stop distribution of IOL which causes opacification
  - Inform IOL vendor to conduct more training if IOL is difficult to inject
  - Withdraw IOL from market if IOL is wrongly labeled



Your notification will automatically generate emails



Acknowledgement email  
to the reporting person



Email to NED manager in-  
charge who will call the  
reporting person to verify  
details



Email to NED chairman  
who will inform Head of  
Service if action is  
required

# Good Luck



To be continued...