

Report

To,
The Municipal Commissioner, Ahmedabad

Respected Madam,

An Independent inquiry committee has been constituted on 14th March, 2016 by the Municipal Commissioner & Chairman, AMC MET comprising of Dr. Shashank Patel, Dr. Bharat Ghodadra and Dr. Mariam Mansuri to investigate the incident in detail and submit findings including suggestions about the incident happened at the L.G. Hospital i.e. 4 patients acquiring infection after cataract surgery by PHACO technique on 11th March, 2016.

We have submitted our preliminary report on 18th March, 2016 upon your request in which we have stated as under:

A) Qualified ophthalmic surgeons performed cataract surgery as per standard protocol and observed necessary care.

B) patients who reported with severe ocular complain and found post operative endophthalmitis had been diagnosed immediately and treated immediately as per the standard protocol of care. At the same time considering the possibility of infection after cataract surgery in other cases operated on the same day they were tried to be contacted by the Professor & Head Dr. Beena Desai for early diagnosis and even management.

C) On examining the data and the record of fumigation & sterilisation submitted by hospital authority, we found that sterilisation of operating instruments, fumigation of operation theatre and its Micro biology tests have been done as per standard protocol.

D) On prima facie we do not find any short fall or lacunae in any procedures of standard protocol of cataract surgery by treating medical and paramedical staff members. However considering the serious complication of post operative bacterial endophthalmitis, there is an urge to find out the source of infection. The post operative & infection after cataract surgery is multi factorial. This includes standard sterilization protocols, standard aseptic and antiseptic precautions in operating room and during surgery. It also includes the immunity activity of patients. We can only reduce the bacterial load in the operating environment and in operative procedure. However to reduce it completely is beyond the possibility and capability.

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After submitting interim report we have further visited L.G. Hospital on 29th March & 12th April, 2016 in order to find out all possible causes of eye infections during and after ocular surgery, We had suggested hospital authorities to collect swabs for microbiology test from operation theatre, microscopes and phaco machine & tubes, surgical furniture, surgical instruments, intraocular injections and fluids, surgical gloves etc. The details are as under:

Sr.	Particulars
1	Fluid from patients' eye
2	Swab from patients' eye
3	Blood from patients' eye
4	Sterilium – Navagilon Hand Rub
5	Chlorhexidine Solution from Gujarat Pharma Lab Pvt. Ltd.
6	Spirit
7	Povidone - Iodine
8	Shadowless Lamp (Right)
9	Foot Step -2
10	OT Table - 1
11	Drum Stand - 2
12	Phaco Drum
13	A.C. Venti
14	Chalazion DCR Drum
15	Xray View Box
16	Cataract Drum Inside
17	Drum Stand - 3
18	Drum Stand - 8
19	Emergency Drum
20	Pt Foot Step - 1
21	PK Drum
22	Table Drum
23	Evisceration Drum
24	Phaco HBsAg +Ve Drum
25	Plastic Sheet Drum
26	Microscope -2 Magnification knob - 2 White
27	Microscope - 1 Handle knob - 2
28	Seating Stool - 1
29	Quantum Phaco Machine
30	Drum Stand - 1
31	Microscope - 1 Handle Knob - 1
32	GA Trolley - 1
33	Formaline Chamber - 3
34	Seating Stool - 3
35	Surgeon Seating Table Black
36	Formaline Chamber - 2

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37	Patient Head Ring - 1
38	Sink
39	Drum Stand - 6
40	Oertli Foot Pedal
41	Surgeon Seating Table Blue
42	Phaco Drum Inside
43	Saline Stand
44	Microscope -1 Magnification knob - 1
45	Cataract Drum Outside
46	Zeiss New Microscope No. 1
47	Dressing Drum
48	Patient Head Ring - 2
49	Sheet Drum
50	Microscope -2 IPD Knob - 1
51	Drum Stand - 5
52	Floor
53	Microscope - 1 Magnification Knob -2
54	Wall
55	Microscope - 2 Magnification Knob
56	Tap
57	Microscope - 1 IPD Knob
58	Formalin Chamber - 1
59	Soap Dish
60	Drum Stand - 4
61	Phaco Oertli Machine
62	Paint Swab Drum
63	Debrillator
64	OT Table No. 2
65	Microscope Handle Knob
66	Microscope - 2 Magnification Knob - 2
67	Oertli Phaco Cassette
68	GA Trolley - 2
69	Microscope -2 IPD Knob
70	Drum Stand - 7
71	Phaco Tubing Solution
72	Visco
73	Hydro Solution (BSS)
74	Drum Stand - 1
75	Drum Stand - 2
76	Drum Stand - 3
77	Drum Stand - 4
78	Drum Stand - 5
79	Drum Stand - 6
80	Drum Stand - 7

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R. S. Shinde

81	Drum Stand - 8
82	OT Table - 1
83	OT Table - 2
84	F.Ch. - I
85	F.Ch. - II
86	F.Ch. - III
87	Dyentum Phaco Machine
88	Catankt Drum
89	Oriental Phaco
90	Pla Sheet Drum
91	Emergac Drum
92	Table Drum
93	Daom Handle
94	Anawin Drug
95	Inj. Lingo + Adrine Drug
96	Inj. Ligozi Drug
97	F.Plus Drops
98	Inj. Hylaronidase
99	Paracain Drug
100	Ocular Jelly
101	Scrubbing Water
102	Tubing Solution
103	Aspiration Canula Solution
104	Phaco Probe Solution
105	Irrigation Canula Solution
106	Microscope - 1 Eye Piece
107	Microscope - 1 Lens
108	Microscope - 2 Eye Piece
109	Microscope - 2 Lens
110	Microscope - 2 IPD
111	Microscope - 2 Handle
112	Operation Trolley No - 1
113	Operation Trolley No - 2
114	Operation Trolley No - 3
115	Operation Trolley No - 4
116	Operation Trolley No - 5
117	Operation Trolley No - 6
118	Phaco Tubing
119	Irrigation Needle Tip (Hydro)
120	Viso Needle Tip
121	Inj. Geramycine
122	Aspiration Candle Tip Attachment
123	Phaco Probe Tip
124	Phaco Probe Tube Attachment

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125	I.A. Canualla Tube Attachemnt
126	Instrument Drum
127	Gloves Drum
128	Visco
129	Syringe 10 cc
130	Syringe 5 cc
131	Syringe 2 cc
132	Operation Table -1
133	Operation Table - 2
134	Inj. Daxona
135	Needle No. 24
136	Needle No. 20
137	Needle No. 26.5
138	IV Set
139	Side Port Blade
140	Crescent Blade
141	Keratome Blade
142	Equasol Solution
143	I.A. Canula Tip Irrigation
144	Chlorhexidine Solution from Gujarat Pharma Lab Pvt. Ltd. Batch No. 15313 Mfg. 11-2015 (Loose)
145	Chlorhexidine Solution from Gujarat Pharma Lab Pvt. Ltd. Batch No. 15313 Mfg. 11-2015 (Seal Pack)

The hospital authority has collected the swabs and sent for microbiology tests. The microbiology reports are attached as Annexure to the report.

Reports of various swabs did not show presence of any micro organisms. However moderate growth of Acenetobacter Spp. was found from the swabs of knob of the Operating microscope – 1 and Scanty growth of Pseudomonas was found from Liquid antiseptic solution used for holding chittle forceps in eye operation theatre. Therefore we suggested the authority to check the unused bottle of the same batch of the antiseptic solution for the microbiology tests. The microbiology report of the unused antiseptic solution named: Chlorhexidine Solution from Gujarat Pharma Lab Pvt. Ltd./Batch no: 15313 manufacture ITC November, 2015 also showed scanty & significant growth of the Pseudomonas organisms(which was also isolated from the vitreous tap from the post operative patients)

The knob of the microscope is been sterlized by formalin vapour by putting it in formalin chamber. As per protocol formalin content of formalin chamber shall be checked and replaced by at least fifth day; also the swab from the formalin chamber shall be sent for culture at least once in a week. On detailed inquiry from Operation Theatre the records for changing the formalin tablets in

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the formalin chamber was not available. The record of the report of the culture swab from formalin chamber was also not available with OT staff.

The antiseptic solution which is kept to hold the chittle forceps shall be changed by OT staff everyday as per protocol; also the swab from the antiseptic solution shall be sent for culture atleast once in a week. On detailed inquiry from Operation Theatre the records for changing the antiseptic solution everyday was not available. The record of the report of the culture swab from antiseptic solution was also not available with OT staff.

However hospital do not have microbiology reports for the samples collected on the day of eye surgery. Therefore we can not comment on the sterilization of pre operative environment in OT.

As per literature postoperative endophthalmitis is a multi factorial eye infection. The possible factors responsible for post operative eye infection can be related to patient , operation room infrastructure, intra operative & post operative medicine & medical/paramedical staff.

- The standard protocol for sterilisation of operating instrument and fumigation of operating theatre is found satisfactory as per record. But Hospital do not have microbiology reports for the samples collected on the day of eye surgery hence the growth of the microorganism which was found in swabs collected from the knob of the operating microscope-1 and antiseptic solution after the incidence could be the possibility for the cluster infections after cataract surgery.
- The procedure for **cataract surgery** has been performed by qualified ophthalmic surgeon.

Suggestions:

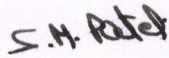
- We are submitting the guideline issued by Government of Gujarat under National Programme for control of Blindness for your perusal which may help the institute to prevent such catastrophe.
- We also suggest the hospital to format the customised checklist for eye surgeries.
- To form infection control committee under the flagship of microbiology department at the hospital level for effective control of infection.
- We also suggest to have a rapid and modern sterilization system to be placed separately for Ophthalmic OT in their own OT.

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M. M. Marani

13/8/2018

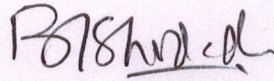
We sincerely thank Municipal Commissioner for keeping faith in us and appoint us as team of expert. We sincerely thank the patients and their relative for their co operation for our investigation in spite of their stressful conditions. We also thank the hospital staff and other concerned authority for their kind co operation during our investigation and observation.



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