Report on a QI Project Eligible for Part IV MOC

Implementing Surgeon Use of a Patient Safety Checklist in Ophthalmic Surgery

Instructions

Determine eligibility. Before starting to complete this report, go to the UMHS MOC website [ocpd.med.umich.edu], click on "Part IV Credit Designation," and review sections 1 and 2. Complete and submit a "QI Project Preliminary Worksheet for Part IV Eligibility." Staff from the UMHS Part IV MOC Program will review the worksheet with you to explain any adjustments needed to be eligible. (The approved Worksheet provides an outline to complete this report.)

Completing the report. The report documents completion of each phase of the QI project. Final confirmation of Part IV MOC for a project occurs when the full report is submitted and approved.

An option for preliminary review (recommended) is to complete a description of activities through the intervention phase and submit the partially completed report. (Complete at least items 1-16 and 27a-b.) Staff from the UMHS Part IV MOC Program will provide a preliminary review, checking that the information is sufficiently clear, but not overly detailed. This simplifies completion and review of descriptions of remaining activities.

Questions are in bold font and answers should be in regular font (generally immediately below the questions). To check boxes electronically, either put an "X" in front of a box or copy and paste "☒" over the blank box.

For further information and to submit completed applications, contact either:
Grant Greenberg, MD, UMHS Part IV Program Lead, 763-936-1671, ggreenbe@med.umich.edu
R. Van Harrison, PhD, UMHS Part IV Program Co-Lead, 763-1425, rvh@umich.edu
Ellen Patrick, UMHS Part IV Program Administrator, 763-936-9771, ellpat@umich.ed

Report Outline

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QI Project Report for Part IV MOC Eligibility

A. Introduction

1. **Date** *(this version of the report):* September 17, 2015

2. **Title of QI project:** Implementing surgeon use of a patient safety checklist in ophthalmic surgery

3. **Time frame**
   a. **Date physicians begin participating (may be in design phase):** August 5, 2014
   b. **End date**: June 30, 2015

4. **Key individuals**

   a. **QI project leader** *[also responsible for attesting to the participation of physicians in the project]*
   Name: Jennifer S. Weizer, MD
   Title: Associate Professor of Ophthalmology and Visual Sciences
   Organizational unit: Dept. of Ophthalmology and Visual Sciences
   Phone number: 734-936-9503
   Email address: jweizer@umich.edu
   Mailing address: Kellogg Eye Center, 1000 Wall St., Ann Arbor, MI 48105

   a. **Clinical leader to whom the project leader reports regarding the project** *[responsible for overseeing/"sponsoring" the project within the specific clinical setting]*
   Name: Michael Smith-Wheelock, MD
   Title: ACU Director/ Associate Professor of Ophthalmology and Visual Sciences
   Organizational unit: Dept. of Ophthalmology and Visual Sciences
   Phone number: 734-615-1472
   Email address: mswhe@med.umich.edu
   Mailing address: Kellogg Eye Center, 1000 Wall St., Ann Arbor, MI 48105

5. **Approximately how many physicians were involved in this project categorized by specialty and/or subspecialty?** All surgical ophthalmology faculty members (56 total, 34 of whom are eligible to receive part IV MOC credit)

6. **Will the funding and resources for the project come only from internal UMHS sources?**
   ☒ Yes, only internal UMHS sources
   ☐ No, funding and/or resources will come in part from sources outside UMHS, which are: _____

The Multi-Specialty Part IV MOC Program requires that projects engage in change efforts over time, including at least three cycles of data collection with feedback to physicians and review of project results. Some projects may have only three cycles while others, particularly those involving rapid cycle improvement, may have several more cycles. The items below are intended to provide some flexibility in describing project methods. If the items do not allow you to reasonably describe the methods of your specific project, please contact the UMHS Part IV MOC Program office.

B. Plan

7. **General goal**

a. Problem/need. What is the "gap" in quality that resulted in the development of this project? Why is this project being undertaken?

Incidents (such as wrong-sided surgery and wrong implant) have been reported in the ophthalmologic literature that might have been avoided by using a checklist in the operating room. However, no established guidelines exist regarding the use of checklists in ophthalmic surgery. The systematic use of checklists has been demonstrated to reduce the occurrence of unsafe events.

Currently no standard checklist is used by our ophthalmic surgeons and operating room staff. Marking of the surgical site and a time-out prior to surgery were expected by policy but not enforced prior to this project. No data was collected concerning the marking and time-out prior to this project. Therefore, this project is being undertaken in an attempt to improve patient safety by developing and instituting use of a safety-oriented checklist for ophthalmic surgeons and operating room staff.

b. Physician's role. What is the physician's role related to this problem?

Physicians are the central actors in the surgical checklist process and are responsible for ensuring that it occurs prior to and during each surgery.

c. Project goal. What outcome regarding the problem should result from this project?

The goal of this project is to improve patient safety by monitoring and potentially improving surgeon adherence to using a safety-oriented checklist in the operating room.

8. Patient population. What patient population does this project address.

This project includes all patients undergoing ophthalmic surgeries performed in the operating rooms of the University of Michigan Kellogg Eye Center and Livonia Surgery Center.

9. Which Institute of Medicine Quality Dimensions are addressed? *[Check all that apply.]*

☒ Safety	☐ Equity	☐ Timeliness
☒ Effectiveness	☐ Efficiency	☒ Patient-Centeredness

10. What is the experimental design for the project?

- ☒ Pre-post comparisons (baseline period plus two or more follow-up measurement periods)
- ☐ Pre-post comparisons with control group
- ☐ Other: _____

11. Baseline measures of performance:

a. What measures of quality are used? If rate or %, what are the denominator and numerator?

We developed a checklist based on information from other sources and internal discussion of points at which safety checks should occur and what they should involve. The six components of the checklist are presented in the Appendix at the end of this report.

The measures are adherence to each of the six components over the course of a surgical procedure: pre-op, pre-brief, pre-anesthesia verification, time-out, positive surgeon response to intraocular lens (IOL), and debrief. However, data on performance of the first five components is recorded on the debrief form, so information regarding performance on those components is available only when a debrief occurs and the electronic debrief form is completed. Therefore, the measure of documentation of debrief for all surgical patients is presented first, followed by other measures of performance available for surgical patients for whom debrief and documentation on the debrief form occurs.

<u>Debrief</u>

Denominator: number of surgical patients

Numerator: number of these patients for whom debrief was performed and documented on the debrief form.

Measures with the denominator of number of surgical patients who had a debrief form completed.

Pre-op
Numerator: number of these patients for whom at least one component was performed and documented on the debrief form.

Pre-brief
Numerator: number of these patients for whom at least one component was performed (4 components for non-cataract patients, an additional 5 components for cataract patients) and documented on the debrief form.

Pre-anesthesia verification
Numerator: number of these patients for whom this component was performed and documented on the debrief form.

Time out (after draping)
Numerator: number of these patients for whom at least one component was performed and documented on the debrief form.

Measure with the denominator of surgical patients undergoing IOL implantation (i.e. during cataract surgery; not all surgical patients) who had a debrief form completed

Positive response from surgeon when announcing IOL at time of opening package
Numerator: number of these patients for whom this component was performed and documented on the debrief form.

b. Are the measures nationally endorsed? If not, why were they chosen?
No. There are no national guidelines regarding the use of a standardized checklist in ophthalmology in the U.S. These measures and checklist items were chosen based on previous incident reports at our institution as well as review of the literature.

c. What is the source of data for the measure (e.g., medical records, billings, patient surveys)?
The source of the data is the electronic debrief form completed by the circulating nurse at the completing of each surgical case. This data collection process was initiated at the beginning of the baseline observation period and continued to be performed through and beyond the end of the QI project.

d. What methods were used to collect the data (e.g., abstraction, data analyst)?
A data analyst collected the data from each debrief form.

e. For what time period was the sample collected for baseline data?
The sample baseline data were collected from August 5, 2014 to August 11, 2014.

12. Specific performance objectives

a. What was the overall performance level(s) at baseline? *(E.g., for each measure: number of observations or denominator, numerator, percent. Can display in a data table, bar graph, run chart, or other method. Can show here or refer to attachment with data.)*

Checklist Performance Measures	Baseline 8/5-11/14
N surgical patients	114
Of these patients:	
Debrief documented	90%

N surgical patients with debrief documented	103
Of these patients:	
Pre-op documented	87%
Pre-brief documented	90%
Pre-anesthesia documented	90%
Time-out after draping documented	90%
N cataract patients with debrief documented	55
Of these patients	
Positive response to IOL announcement documented	2%

b. Specific aim: What was the target for performance on the measure(s) and the timeframe for achieving the target?

From baseline performance ranging from 2% to 90% across the measures, the target was 100% in all areas of checklist adherence by June 30, 2015.

c. How were the performance targets determined, e.g., regional or national benchmarks?
No national performance targets exist for checklist performance in ophthalmic surgery. We set the targets at our aspirational level of 100%.

13. Data review and identifying underlying (root) causes.

a. Who was involved in reviewing the baseline data, identifying underlying (root) causes of the problem(s), and considering possible interventions ("countermeasures") to address the causes? Briefly describe:

- **Who was involved?**
  All departmental faculty were involved.

- **How?** *(e.g., in a meeting of clinic staff)*
  All departmental faculty discussed the checklist elements in grand rounds presentations. The actual checklist draft was circulated electronically to all faculty. The faculty was presented with the project and checklist during a faculty meeting. The results of the baseline data was distributed to faculty electronically.

- **When?**
  The actual checklist draft was circulated electronically to all faculty in December 2013. The faculty was presented with the project and checklist during a faculty meeting in June 2014 prior to the start of the baseline data collection period. The results of the baseline data was distributed to faculty electronically in August 2014.

b. What were the primary underlying/root causes for the problem(s) that the project can address?
(Causes may be aspects of people, processes, information infrastructure, equipment, environment, etc. List each primary cause separately.)

1) lack of standardized process
2) inconsistent enforcement of OR protocols,
3) non-standardized information infrastructure with regards to OR protocols
4) the busy surgical environment found in operating rooms that likely contributes to inconsistencies in adhering to OR protocols.

C. Do

14. Intervention(s).

a. Describe the interventions implemented as part of the project.
To institute active use of a surgeon operative checklist for patient safety for each surgical case, the intervention consisted of several linked components:

- education about the importance and effectiveness of checklists,
- developing a standard checklist tool
- training surgical teams in the use of the checklist
- posting the checklist in each OR to ensure all members of the operative team could reference and adhere to its elements
- training circulating nurses to record performance reliably
- providing feedback of performance to checklist protocol by sharing data

15. Who was involved in carrying out the intervention(s) and what were their roles?

All physicians and OR staff were responsible for conducting the checklist process.

- The data analyst analyzed the baseline data and reported it electronically to the surgical faculty.
- The surgical faculty gave suggestions and feedback via electronic communication regarding the analysis and possible improvements for the future.
- Dr. Weizer met with the OR nursing staff on October 3, 2014 during their service meeting to discuss using the checklist and recording adherence to its categories. The OR charge nurse then posted the checklist in each OR.
- The surgical faculty used the checklist for reference and adherence.
- The circulating nurses recorded the adherence to the checklist on each case's debrief form.

16. The intervention was initiated when? (For multiple interventions, initiation date for each.)
September 10, 2014

D. Check

17. Post-intervention performance measurement. Did this data collection follow the same procedures as the initial collection of data described in #11: population, measure(s), and data source(s)?

☒ Yes ☐ No – If no, describe how this data collection

18. Performance following the intervention.

a. The collection of the sample of performance data following the intervention occurred for the time period:

October 15, 2014 – December 15, 2014.

b. What was post-intervention performance level? *(E.g., for each measure: number of observations or denominator, numerator, percent. Can display in a data table, bar graph, run chart, or other method. Can show here or refer to attachment with data.)*

Checklist Performance Measures	Baseline 8/5-11/14	Post-Intervention 10 /15-12/15/14

N surgical patients	114	1,135
Of these patients:		
Debrief documented	90%	71%
N surgical patients with debrief documented	103	802
Of these patients:		
Pre-op documented	87%	85%
Pre-brief documented	90%	85%
Pre-anesthesia documented	90%	85%
Time-out after draping documented	90%	85%
N cataract patients with debrief documented	55	478
Of these patients		
Positive response to IOL announcement documented	2%	86%

c. Did the intervention produce the expected improvement toward meeting the project's specific aim (item 12.b)?
Following the intervention the performance and documentation of debriefings decreased meaningfully and the performance of other activities decreased modestly for most of the other activities. However, for cataract patients the response to IOL announcement greatly increased. All of the performance measures remain substantially below our target of 100%.

E. Adjust – Replan

19. Review of post-intervention data and identifying continuing/new underlying causes.

a. Who was involved in reviewing the post-intervention data, identifying underlying (root) causes of the continuing/new problem(s), and considering possible adjustments to interventions ("countermeasures") to address the causes? Briefly describe:

- **Who was involved?**
  All departmental faculty were involved.

- **How?** *(e.g., in a meeting of clinic staff)*
  The results of the post-intervention data were distributed to faculty and the circulating OR nurses electronically. The surgical faculty gave suggestions and feedback via electronic communication regarding the analysis and possible improvements, such as incentivizing the circulating nurses to fill out the debrief forms for each case, for the future.

- **When?**
  The results of the baseline data were distributed to faculty and the circulating OR nurses electronically in December 2014. The participating physicians reviewed the data, assessed the underlying causes, and considered plans for improvement in December 2014 and January 2015.

b. What were the primary underlying/root causes for the continuing/new problem(s) that the project can address? *(Causes may be aspects of people, processes, information infrastructure, equipment, environment, etc. List each primary cause separately. How the intervention(s) address each primary underlying cause will be explained in #20.c.)*

1) The meaningful decrease in the percentage of debriefs that were documented is likely due to a "methodological artifact" – the initiation and novelty of the documentation process (completion of

the electronic debriefing form by the charge nurse at the end of surgery). Documentation began with the initiation of baseline data collection when the responsibility for collecting data was new and everyone was oriented to its performance. The baseline data collection period was only six days during which the process was still novel. The documentation process was no longer novel two months later when the post-observation period began. No negative consequences occurred if documentation was not performed at the end of procedure, so everyday pressures in the busy surgical environment found in operating rooms could result in forgetting or distractions that resulted in the debriefing form not being completed.

2) The small decrease in the performance of activities in the checklist likely also reflect a "methodological artifact" of the comparison with a baseline performance when documenting elements on the checklist was novel. With documenting the checklist less frequently performed, performing specific activities could also be performed a little less frequently due to the pressures of the busy surgical environment.

3) For cataract patients the substantial increase (from 2% to 86%) in "positive response to IOL announcement" reflects the introduction of this new expectation. Expectations for other items on the checklist were already in place, reflected in the high rates of performance at baseline.

F. Redo

20. Second intervention. What additional interventions/changes were implemented?

- Education and reinforcement to improve documentation. Dr. Weizer met with the OR nursing staff on March 19, 2015 during their service meeting to discuss and reinforce use of the checklist and recording adherence to its categories.
- Incentive for performing documentation. The circulating nurses were each offered a $5 coupon for each week of the 9-week upcoming data collection period that s/he completed all of his/her debrief forms.
- Individual feedback to surgeons. Individual surgical faculty received summaries of their rates of adherence to the checklist elements (from completed debrief forms) across patients on which they performed surgery. This called to their attention deficits in performance on their surgical cases.
- Heightened attention. Given the busy surgical environment found in operating rooms, which likely contributes to inconsistencies in adhering to OR protocols, focus was placed on enforcing the multiple time-outs designated on the checklist by all surgical team members.

21. The second intervention was initiated when? (For multiple interventions, initiation date for each.)
December 22, 2015

G. Recheck

22. Post-second intervention performance measurement. Did this data collection follow the same procedures as the initial collection of data described in #11: population, measure(s), and data source(s)?

☒ Yes ☐ No – If no, describe how this data collection

23. Performance following the second intervention.

a. The collection of the sample of performance data following the intervention(s) occurred for the time period:

March 23, 2015 – June 1, 2015

b. What was the performance level? *(E.g., for each measure: number of observations or denominator, numerator, percent. Can display in a data table, bar graph, run chart, or other method. Can show here or refer to attachment with data.)*

Checklist Performance Measures	Baseline 8/5-11/14	Post-Intervention 10 /15-12/15/14	Post-Adjustment 3/21-6/1/15
N surgical patients	114	1,135	1,283
Of these patients:			
Debrief documented	90%	71%	82%
N surgical patients with debrief documented	103	802	1,050
Of these patients:			
Pre-op documented	87%	85%	97%
Pre-brief documented	90%	85%	97%
Pre-anesthesia documented	90%	85%	97%
Time-out after draping documented	90%	85%	97%
N cataract patients with debrief documented	55	478	581
Of these patients			
Positive response to IOL announcement documented	2%	86%	98%

c. Did the second intervention produce the expected improvement toward meeting the project's specific aim (item 12.b)?
For all of the measures other than "Debrief performed," the adjustments resulted in appreciable increases that are close to the target of 100%. While performance on "Debrief" also improved, it is still substantially below the target of 100%.

H. Readjust

24. Review of post-second intervention data and identifying continuing/new underlying causes.

a. Who was involved in reviewing the data, identifying underlying (root) causes of the continuing/new problem(s), and considering additional possible adjustments to interventions ("countermeasures") to address the causes? Briefly describe:

- **Who was involved?**
  All departmental faculty were involved

- **How?** *(e.g., in a meeting of clinic staff)*
  The results of the post-adjustment data were distributed to faculty and the circulating OR nurses in a departmental grand rounds and electronically. The surgical faculty were given the opportunity to provide suggestions and feedback via electronic communication regarding the analysis and possible improvements for the future.

- **When?**
  The results were distributed in August 2015.

b. What were the primary underlying/root causes for the continuing/new problem(s) that the project can address? *(Causes may be aspects of people, processes, information infrastructure, equipment, environment, etc. List each primary cause separately.)*

1) The most likely reason why the debrief forms were only completed 82% of the time is the time pressure on circulating nurses to complete paperwork during and between our relatively short ophthalmic surgery cases. While education, reinforcement, and a small incentive (with recognition) improved performance by 11 percentage points, competing time pressure remain a meaningful problem.

2) When performance was documented, it was very high (97% – 98%), almost reaching the goal of 100%. The busy surgical environment found in operating rooms likely contributes to a few inconsistencies in adhering to OR protocols.

If no additional cycles of adjustment are to be documented for the project for Part IV credit, go to item #24.
If a few additional cycles of adjustments, data collection, and review are to be documented as part of the project to be documented, document items #20 – #23 for each subsequent cycle. Copy the set of items #20 – #23 and paste them following the last item #23 and provide the information. When the project to be documented for Part IV credit has no additional adjustment cycles, go to item #24.
If several more cycles are included in the project for Part IV credit, contact the UM Part IV MOC Program to determine how the project can be documented most practically.

I. Future Plans

25. How many subsequent PDCA cycles are to occur, but will not be documented as part of the "project" for which Part IV credit is designated?
No more formal PDCA cycles will be performed. When documented, performance (97% – 98%) was as practically close to the ideal of 100% as can be expected. We will continue to try to encourage and increase completion of the debrief form at the end of each case and can still gather data on checklist adherence rates, but other quality improvement priorities will take precedence in the future

26. How will the project sustain processes to maintain improvements?
The checklists will continue to be posted in each ophthalmology operating room with an expectation that they are utilized for every OR case.

27. Do other parts of the organization(s) face a similar problem? If so, how will the project be conducted so that improvement processes can be communicated to others for "spread" across applicable areas?

As the ophthalmology department continues to expand its surgery centers outside of Kellogg Eye Center and Livonia, the operating room checklist will be posted in each of those new ORs.

The process of a standardized checklist will be shared with the Director of Clinical Quality in the Office of Clinical Affairs for dissemination to other surgical specialties for them to consider applying in their respective areas.

28. What lessons (positive or negative) were learned through the improvement effort that can be used to prevent future failures and mishaps or reinforce a positive result??

The physicians supported financially incentivizing the nurses to complete the debrief forms, which likely accounted for the increase from 71% to 82% between the post-intervention and post-adjustment phases. Perhaps offering more than $5 per week or finding other incentives would lead to even better adherence with debrief form completion.

J. Physician Involvement

Note: To receive Part IV MOC a physician must both:

a. Be actively involved in the QI effort, including at a minimum:
- *Work with care team members to plan and implement interventions*
- *Interpret performance data to assess the impact of the interventions*
- *Make appropriate course corrections in the improvement project*

b. Be active in the project for the minimum duration required by the project

29. Physician's role. What were the minimum requirements for physicians to be actively involved in this QI effort? *(What were physicians to do to meet each of the basic requirements listed below? If this project had additional requirements for participation, also list those requirements and what physicians had to do to meet them.)*

a. Interpreting baseline data and planning intervention:
All departmental faculty discussed the checklist elements in grand rounds presentations. The actual checklist draft was circulated electronically to all faculty. The faculty was presented with and discussed the project and checklist during a faculty meeting in June 2014 prior to the start of the baseline data collection period. The results of the baseline data was distributed to faculty electronically in August 2014.

b. Implementing intervention:
All physicians were ultimately responsible for conducting the checklist process. The surgical faculty gave suggestions and feedback via electronic communication regarding the data analysis and possible improvements for the future. The surgical faculty used the checklist for reference and adherence for each surgical case.

c. Interpreting post-intervention data and planning changes:
The results of the post-intervention data were distributed to all departmental faculty electronically. The surgical faculty gave suggestions and feedback via electronic communication regarding the analysis and possible improvements, such as incentivizing the circulating nurses to fill out the debrief forms for each case, for the future.

d. Implementing further intervention/adjustments:
The physicians supported offering the circulating nurses a $5 coupon for each week of the 9-week upcoming data collection period that s/he completed all of his/her debrief forms. Rates of adherence to the checklist elements on the debrief form at the conclusion of each surgical case were reported to the surgical faculty. Given the busy surgical environment found in operating rooms, which likely contributes to inconsistencies in adhering to OR protocols, physicians placed focus was placed on enforcing the multiple time-outs designated on the checklist by all surgical team members, since the physicians were ultimately responsible for each checklist's completion.

e. Interpreting post-adjustment data and planning changes:
The results of the post-adjustment data were distributed to all faculty in a departmental grand rounds and electronically. The surgical faculty gave suggestions and feedback via electronic communication regarding the analysis and possible improvements for the future.

30. How were reflections of individual physicians about the project utilized to improve the overall project?

The feedback received from the faculty led to numerous electronic discussions whose goal was to improve checklist adherence. Their feedback was also presented to the circulating OR nurses in order to build consensus and improve OR team checklist adherence rates.

31. How did the project ensure meaningful participation by physicians who subsequently request credit for Part IV MOC participation?

All surgical faculty had their checklist adherence data collected, analyzed, and reported back to them. They had the opportunity to give feedback, suggest changes, and improve their own adherence to the checklist categories. Each faculty member was asked to give feedback, and many communicated their thoughts and suggestions for improvement.

K. Sharing Results

32. Are you planning to present this QI project and its results in a:

☒ Yes ☐ No Formal report to clinical leaders?

☒ Yes ☐ No Presentation (verbal or poster) at a regional or national meeting?

☒ Yes ☐ No Manuscript for publication?

L. Project Organizational Role and Structure

33. UMHS QI/Part IV MOC oversight – this project occurs within:

☒ **University of Michigan Health System**

- **Overseen by what UMHS Unit/Group?**

  Kellogg Eye Center, Department of Ophthalmology

- **Is the activity part of a larger UMHS institutional or departmental initiative?**

  ☒ No ☐ Yes – the initiative is:

☐ **Veterans Administration Ann Arbor Healthcare System**

- **Overseen by what AAVA Unit/Group?**

- **Is the activity part of a larger AAVA institutional or departmental initiative?**

  ☐ No ☐ Yes – the initiative is:

☐ **An organization affiliated with UMHS to improve clinical care**

- **The organization is:**

- **The type of affiliation with UMHS is:**

  ☐ **Accountable Care Organization type** *(specify which):*

  ☐ **BCBSM funded, UMHS lead Collaborative Quality Initiative** *(specify which):*

  ☐ **Other** *(specify):*

APPENDIX

OPHTHALMIC SURGERY CHECKLIST

Pre-Op:

- Patient Verification
- Surgery site marked

Pre-Brief:

- Type of anesthesia
- Special devices/instruments discussed
- Allergies
- Confirm patient marked correct eye so that mark is visible under drape
- For cataract surgery only:
    - Surgeon confirmed microscope and phaco settings
    - Surgeon written IOL (intraocular lens) power on board (axis for Toric)
    - IOL measurements available (Toric posted)
    - Only primary IOL on counter
    - Confirm IOL on desk matches white board and IOL printout

Pre-anesthesia verification

Time-out (after draping):

- Name/side surgery/operation
- IOL power (if applicable)
- Allergies
- Antibiotics
- Fire risk

Positive response from surgeon when announcing IOL at time of opening package (cataract surgery only)

De-brief