Anatomy of an Infection Control Investigation

CASE STUDIES
ASC Surgery Center
DEF Surgery Center
ABC Surgery Center

The leadership of the ABC Surgery Center identified the following issues for review and evaluation:

INFECTIONS
- Eight (8) cases of possible endophthalmitis since the center opened eight (8) months ago

TRENDS
- Common threads: staff, autoclaves, OR, time of day, etc.
- Culture results

OUTSIDE VARIABLES
- Previous hospitalizations
- Recent illnesses
- Skin integrity
- Post-op patient compliance

PROTOCOLS EVALUATED
- Pre-op preparation
- OR set up
- Number of personnel
- Eye prep
- Instrument handling intraoperatively
- Instrument handling postoperatively
- Sterilization

SUPPLIES/EQUIPMENT FOCUS
- Reusable tubing
- Autoclaves

Infection Reported

A spreadsheet was developed to track information. The data was collected from the patients’ charts, the physicians’ office charts, and an onsite visit.

The center became aware of the infections and changed some of their processes, yet the infections continued. This report attempts to clarify what may have contributed to the infections.

**Investigation**

The following items were examined:

- Patient account number
- Date
- Case sequence number
- Case length
- Autoclave utilized
- Surgeon
- Circulator
- Scrub tech
- Additional staff
- Pre-operative eye drops
- Antibiotics administered
- Instruments: wrapped or flashed
- Culture results
- Hospitalizations prior to surgery
- Recent illnesses on or around surgery date
- Skin integrity on admission
- Type of procedure
- Outcome
- Miscellaneous

**CONCLUSIONS:**

There were no clear trends that could be directly associated to the infection rate. Following a summary of the data collected.
Date:

There was one infection per month, except for March 2003 and June 2003, when there were two per month.

Case Sequence:

- First case – 1
- Fourth case – 2
- Fifth case – 1
- Sixth case – 1
- Eighth case – 1
- Ninth case – 2

Autoclave Utilized:

- Autoclave 1 – 5 infections
- Autoclave 2 – 3 infections.

Autoclave 1 failed a vacuum test in June. After consulting the manufacturer, the center was advised that the autoclave could be safely used to flash instruments. Two of the infections occurred after the failure. The unit has since been sent back for repair. The repair report stated that there were numerous leaks in the vacuum system.

Circulator:

No trends were noted

Scrub Tech:

- L. Richards – 4
- Holloway – 4
- No trends were noted

Additional Staff:

Johnson, CRNA (present on all cases)
Pre-op Drops:

Orders were basically the same. Ocuflox was used on most cases. The two June cases used Zymar.

Instruments:

- Flashed – 5
- Wrapped – 3

Culture Results:

- Negative – 3
- Staph aureus coag. neg – 3
- Lactobacillus – 1
- Staph epidermidis – 1.

Patient Risk Factors:

- Patient resides in a nursing home - 1
- Patient was diabetic, manic depressive, had poor personal hygiene - 1
- Post-op corneal abrasion – 1

Type of Procedure:

All were phacoemulsification w/IOL; one (1) was a posterior chamber lens.

Outcome:

- Six reported good outcomes
- One continues to improve at the time of this report
- One was undetermined at the time of this report
Miscellaneous:

- All infections were identified 1 – 3 days post-operatively.
- Some patients had been seen by an optometrist post-operatively, prior to referral back to the ophthalmologist.
- Four of the patients were referred to retinal surgeons for treatment.
- Patients may have been non-compliant with instillation of drops post-op in 2 cases. On their follow-up call, they were reported to be confused and/or sleepy.
- The reusable phaco tubing was cultured with negative results.
- Reusable retrobulbar needles were used for injections on four patients.
- Steris Alcare foam is used between cases. Timed hand scrub is used at the beginning of the day.
- The instrument processing is thorough. The instruments and tubing are cleaned individually, and then flushed under pressure. No obvious problems or concerns could be identified.
- The instruments are not placed in an ultrasonic prior to manual cleaning.

Protocols

**Pre-op:**

Preparation was methodical using a consistent protocol for preparing the patients. The only variable identified was that some of the patients are blocked in pre-op, instead of in the OR. Some of the patients are blocked utilizing reusable retrobulbar needles. The patients often have to wait extended periods of time (greater than one hour) before transfer to the OR.

*Consider bringing the patients to the center at times that more closely match the time they will actually enter the OR. A CQI study could determine actual times, and admission times would be based on the results.*

**OR:**

In some cases, the blocks are done in the OR. The surgeon has two separate teams, and one tech scrubs to set up the case, while another assists the surgeon. The circulator preps the patient, then the tech drapes the patient. There was a lot of movement around the patient during the case, which could be minimized to reduce air movement. The patients are brought to the OR and wait more than fifteen (15) minutes, in many cases, prior to the start of their case.

*Review the time the patient is transferred to the OR. Could they be moved more closely to the actual surgery start?*
Number of Personnel:

The personnel are consistent and competent. Because it is a new facility there has been a lot of staff training during these eight months. When all of the staff training is complete, the number of personnel in the OR can be reduced.

Eye Prep:

The consistency of the prep could be improved. Alcohol is used as part of the prep, which is very unusual.

Reevaluate the prep procedure. Simplify the process and implement training and follow up to assure consistency in the implementation.

Instrument Handling:

There are more than 25 instruments on the cataract tray that must be decontaminated and sterilized after every case. This is unnecessary wear and tear on the instruments and unnecessary work for the staff.

Consider reducing the number of instruments on your basic cataract tray, keeping additional instruments sterile for use as needed.

Instrument Handling Post-Operatively:

All instruments were properly decontaminated prior to sterilization.

Sterilization:

- Counter-top autoclaves are used to sterilize the instruments. There have been problems with the autoclaves, and autoclave 1 was sent back following steam failure. This should be reported as part of the Safe Medical Device Policy adopted by the center.
- Reusable tubing is an acceptable option as long as it is used properly. At one point, the tubing was cultured with negative results.

PACU:

Care was consistent with one exception. Two patients were given post-op eye drops by an office assistant who also applied an eye patch and shield in PACU.
Conclusions:

After the data was collected and the site visit was concluded, the information was compiled in the spreadsheet and sent to the Clinical Director to ensure accuracy. PHI was redacted and several outside sources were consulted to review the data.

Sources that were consulted include:

- Joan Blanchard, RN, MSS, CNOR, CIC, Perioperative Nursing Specialist, Center for Nursing Practice, AORN
- Ramona Conner, RN, MSN, CNOR, Perioperative Nursing Specialist, AORN Center for Nursing Practice
- David S. George, MD, Ohio Valley Eye Physicians, PLLC, AAASC Board member
- Daniel J. Fleming, MD, Anderson Eye & Ear Associates, Associate Examiner, American Board of Ophthalmology
- Linda Spraley, RN, CRNO, AMO Clinical Application Technician

These sources all agreed that there was no single factor that they could identify that would have caused the infections. Below are items for your consideration:

- Hawthorne effect: Everyone in the center is aware of the infections, and behaviors have changed unconsciously. As a result, the infections have decreased or been eliminated.

- Foam scrub: Perform initial timed or counted stroke scrub. Repeat after breaks or bathroom visits. Use surgical foam between cases otherwise. Re-inservice the staff and physicians on application and use of the foam to assure proper application.

- Prep: Consider instilling a drop of iodine scrub solution to the eye cul-de-sac during the prep and at the conclusion of the case.

- Eyelashes: Ensure that they are isolated. Suggestion: use Tegaderm to hold back the lashes.

- Autoclaves: When a problem is identified with an autoclave (test failure, error message, etc), it must be taken out of use immediately until it can be inspected and serviced and proper function verified by a trained technician.

- If there is any doubt about the integrity of the wound, it should be tested with some pressure via a Weck-cel surgical spear.
No clear conclusions could be drawn from the information that was gathered. I understand that the autoclaves are being replaced. Obviously, if there are not further infections one would likely suspect the faulty vacuum seal was the culprit.

Awareness of the problem impacts human behavior and may contribute to a solution, which seems to be the case here. If you have any questions about this report, please feel free to contact me.

Respectfully submitted,

Progressive Surgical Solutions
### Anatomy of an Infection Control Investigation: Case Study #1 ABC Surgery Center

<table>
<thead>
<tr>
<th>Case #</th>
<th>MR+</th>
<th>Case+</th>
<th>Date</th>
<th>LOS (min)</th>
<th>Autoclave</th>
<th>Surgeon</th>
<th>Scrub</th>
<th>Circulator</th>
<th>CRNA</th>
<th>Preop gtts</th>
<th>Antibiotics at ASC</th>
<th>Antibiotics at home</th>
<th>Risk Fx</th>
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<td>36</td>
<td>2</td>
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<td>Stanf</td>
<td>Hawkins</td>
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<td>None</td>
<td>Postop. Corneal abrasion; optometry d/c/drops, applied amin. &amp; steroid. Pt. is diabatic, renal; depressive, unkempt body odor. App. of ev. of pt's personal hygiene</td>
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Other Considerations:
- Dr. #3 uses reusable retrobulbar needle for blocks in prep
- Staph. Coag. Neg. Normal flora, often the cause of nosocomial infections
- TASS - toxic anterior syndrome. Doctors feel that many of these cases may be cases of TASS other than bacterial endophthalmitis.
- Instrument processing is methodical. Place tubing in machines irrigated between each case. No ultrasonic machine is used.
DEF Surgery Center

After looking back it is noted that this is Dr. 6’s 5th incident of TASS. It was also noted that no other surgeon has had an incident of TASS in this facility. To better understand what has been occurring with these cases we went back and evaluated all of the previous incidents of TASS.

The first 2 incidents of TASS that had occurred were on 3/24/08. At that time the facility had only been open for about 5 months. This was Dr. 6’s second day operating at this facility. There were a total of 3 cases performed that day and on the second and third cases Dr. 16 requested to use his own instruments that he had brought to the ASC. At that time we did not have a policy in place for sterile processing instruments brought in from another facility. The instruments were unwrapped and used. The autoclave tape and chemical indicators were positive for meeting sterilization parameters. The follow up investigation was documented. In the absence of other findings, we concluded the instruments brought in from another facility were the probable cause. A new policy was created to address instruments that are brought in from the outside: All instrumentation that is brought in will be sterilized according to our policy and procedure before use in this facility.

The third case of TASS did not occur until 4/5/10, almost 2 years later. By this time Dr. 6 had performed multiple cases and we rarely used any of instruments from his tray. During the interim, the ASC had turnover in some lead positions, including, the lead tech, clinical director and charge nurse. Medicare implemented new conditions for coverage in May 2009, which resulted in changes to our decontamination and sterile processing procedure. The protocol at that time was: soak and wipe all instruments on the mayo stand after use with sterile water. The instruments were then transported to the Soiled Utility, covered. Handpieces were flushed with the quickrinse and instruments were soaked in the ultrasonic with an enzymatic cleaner. Everything was rinsed with distilled water. Instruments were sterilized in the Statim and transported to the OR covered. After the investigation some changes were made. The intra-op record was revised to include all information pertinent to an infection control investigation. This included lot numbers in more detail, and marking and numbering of all trays and instruments so we could trace what instruments were used for each case. We also numbered the phaco machines and handpieces so they could be traced as well. We changed the prep policy to include a drop of betadine in the eye prior to the prep for all cataract cases. We also took a look at the enzymatic cleaner. At that time we were using a cleaner that per manufacturer’s instructions was to be sprayed directly on the instruments. This was not how we were using this product; we were squirting it in the ultrasonic at the beginning of the day. We changed to a cleaning product that was made to go in an ultrasonic cleaner manufactured by the same company.
The fourth case of TASS happened about a month later 5/20/10. Since this was our 4th case of TASS with Dr. 6 we compared all cases to see if we could identify a trend. The changes from the previous case had been implemented for at least a month. One thing that stood out was that it was the first case of the day. Another thing to take into consideration was our technician staff. At this time we were having a significant amount of staff turnover and although they were all trained the same way, there may have been discrepancies in their performance. The investigation identified no obvious trends or conclusions. After eliminating what had already been done we tweaked our process a little. We had concern that the trays/handpieces were sitting in just the tray not wrapped and not sterilized at night. Leaving them open to exposure all night could allow time for particulate to dry on them or for them to be exposed to cleaning agents. So we changed our system and began to wrap all of our trays and handpieces at the end of day and sterilize them. As a result of the revisions to the CFC’s from Medicare we decided to look into the phaco tips that he was using. We were re-using the tips and per Medicare and manufacturers instructions we were not supposed to be doing that. We informed Dr. 6 and began to use a new phaco tip for every case.

The fifth case of TASS occurred 3/17/11. This is now our 5th case, with the same surgeon. No trend was identified from the last investigation. Staff was trained and competent in their duties and all of the previous changes had been implemented. After looking at all the cases and comparing them to each other we decided to compare Dr. 6 to other surgeons. What does he do differently? A couple of things were noteworthy. He is the only one who uses glass syringes, makes his own cystatome and the wire speculum. If sterilized appropriately we can’t see any reason for this to cause TASS. He is the only one who uses Vancomycin in his BSS. It is 500mg/ in 10ml of NS and then 0.4 ml is inserted into the BSS. After further investigation it was noted that many reports have shown no benefit of adding vanco into the BSS and that is could cause TASS (See attached articles). TASS can be caused by numerous agents, including medications injected in to the eye during surgery. The Vancomycin that we use is not preservative free and compounded by the nurse. This poses a lot of problems. First, the TASS taskforce in Utah recommends not using any medications in the eye unless they are preservative free. Second, since the nurse is compounding and mixing the Vancomycin, there is the possibility of error. Third, this Vancomycin is getting everywhere if it is mixed with the BSS; all the instruments, the lens, the BSS in a syringe used to seal the wound. That being said if the Vancomycin with preservatives was not mixed thoroughly enough or too much was added to the BSS it could potentially cause TASS. All of this was brought to Dr. 6 who decided to stop using Vancomycin in the BSS at this time.

We are planning another education day where this will be presented to the staff and reinforce the importance of all the steps we take here to prevent these type’s of incidences. We will share this study and information with our governing body, MAC, QAPI committee and Dr. 6. We will encourage feedback and evaluate any suggestions that are brought up. We will continue to monitor this closely and evaluate every quarter per our QAPI committee.

Note: There have been no further reports of TASS since discontinuing the practice of using Vanco in the BSS (4 years).