Anatomy of an Infection Control Investigation

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Objectives

• Describe the steps of a postop infection investigation
• Describe the considerations important to a postop infection investigation and analysis

Financial Disclosure

• Regina Boore is the principal of Progressive Surgical Solutions, LLC.
Infection Surveillance

416.51(b) Standard: infection control program

...The program is...

(3) Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately corrective and preventive measures that result in improvement.

Surgical Site Infection (SSI)

- Center for Disease Control (CDC)
- National Health Safety Network (NHSN)
- SSI event instructions

State Based Reporting Requirements

<table>
<thead>
<tr>
<th>To NHSN</th>
<th>To State Database</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorado, Massachusetts, Nevada, New Hampshire, New Jersey, Texas</td>
<td>Missouri</td>
</tr>
</tbody>
</table>
SSI Definitions

Superficial
- Within 30 days
- Involves only skin and subcutaneous tissue of the incision
- At least one of the following:
  - Purulent drainage
  - Positive culture
  - Deliberately opened incision w/+ culture of not cultured AND
    - Pt has at least one of the following:
    - Swelling, redness, heat
  - SSI Dx by surgeon

Deep Incisional
- Within 30 or 90 days
- Spontaneous dehiscence or deliberately opened w/+ culture or no culture AND
  - At least one of the following:
    - Fever (>38°C), localized pain, tenderness
    - Abscess or other evidence of infection involving deep incision
  - Deep incision SSI Dx by surgeon

Organ/Space SSI
- Within 30 or 90 days AND
  - Involves body part excluding skin incision, fascia or muscle that is opened or manipulated during surgery AND
  - At least one of the following:
    - Purulent drainage from the organ/space
    - + culture of the organ/space
    - Abscess or other evidence of infection involving the organ/space
  - Dx of organ/space SSI by surgeon
Endophthalmitis

- Endophthalmitis is an infectious intraocular inflammation in response to the introduction of:
  - Bacteria
  - Fungus
  - Trauma
  - Other

TASS

- Toxic Anterior Segment Syndrome is a non-infectious inflammatory intraocular response caused by introduction of a toxic agent during and anterior segment surgery.

Identification

- It is critical to differentiate TASS from endophthalmitis because treatments are different and treatments are not interchangeable.
Signs and Symptoms

**TASS**
- Sudden onset 12-24 hr postop
- Hypopyon
- Minimal pain
- Variable IOP
- Culture gram stain negative
- Improve w/topical and/or PO steroids

**Endophthalmitis**
- Onset 3-7 days postop
- or blurred vision
- Often involves PC
- AC flare (75%)
- Can be gram stain positive or negative
- Tend to occur individually
- Does not resolve with steroids alone – requires aggressive Tx with antibiotics, steroid and possible surgery

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**TASS Contributing Factors**
- Irrigants
- Preservatives in ophthalmic solutions
- IOLs
- Improperly diluted, mixed or dosed intraocular medication
- Residual viscoelastic in the AC
- Endotoxins
- Improper or inadequate instrument decontamination and sterilization

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**Endophthalmitis Contributing Factors**
- Inadequate prep of lids and conjunctiva
- Blepharitis or conjunctivitis
- Prolonged surgical time
- Vitreous loss
- Lacrimal duct obstruction
- Previous AC surgeries
- Cataract wound abnormalities (leakage)
### Infection Investigation

#### Gather the data – Preop

<table>
<thead>
<tr>
<th>Pt risk factors</th>
<th>Other pt risk factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preop antibiotics</td>
<td>Surgical order</td>
</tr>
<tr>
<td>OOS</td>
<td>Block</td>
</tr>
<tr>
<td>Staff</td>
<td>Medications (lot #s)</td>
</tr>
<tr>
<td>Hand hygiene</td>
<td>IC practices</td>
</tr>
</tbody>
</table>

#### Gather the data – Intraop

<table>
<thead>
<tr>
<th>OR</th>
<th>Antibiotics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff</td>
<td>Prep</td>
</tr>
<tr>
<td>Visitors</td>
<td>Technique breaks</td>
</tr>
<tr>
<td>Irrigant, additives</td>
<td>Block</td>
</tr>
<tr>
<td>Medications (lot #s)</td>
<td>OVD (lot #)</td>
</tr>
<tr>
<td>Phaco machine</td>
<td>LDS</td>
</tr>
<tr>
<td>Surgical hand hygiene</td>
<td>Hand hygiene</td>
</tr>
<tr>
<td>Intracameral injection</td>
<td></td>
</tr>
</tbody>
</table>

#### Gather the data – Sterile Processing

<table>
<thead>
<tr>
<th>Instrument tray #, use of the day</th>
<th>Reusable tubing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilizer</td>
<td>Staff</td>
</tr>
<tr>
<td>Process monitors</td>
<td>Decontam process</td>
</tr>
<tr>
<td>Rehousing</td>
<td></td>
</tr>
</tbody>
</table>
## Infection Investigation

### Gather the data – Other

<table>
<thead>
<tr>
<th>Medications (lot #)</th>
<th>Shield/dressing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotics</td>
<td>PO Staff</td>
</tr>
<tr>
<td>Housekeeping</td>
<td>Staff illnesses</td>
</tr>
<tr>
<td>C&amp;S report</td>
<td>Medical Record</td>
</tr>
<tr>
<td>Surgeon report</td>
<td>Peer review</td>
</tr>
</tbody>
</table>

## Analysis

- Trends
- Human factors
- Process factors
- Equipment issues
- Controllable factors/issues
- Uncontrollable factors/issues

## Action Plan

- For each factor/issue
  - Opportunity for improvement
  - Plan for prevention or recurrence
  - System changes to reduce the likelihood of human error
  - Re-evaluation

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Reporting

• IC Committee, MAC, GB
• Per state requirements
• CMS reporting likely to be coming

Reporting TASS

Nick Mamalis
Intermountain Ocular Research Center
John A. Moran Eye Center
University of Utah
Salt Lake City, Utah 84132
Email nick.mamalis@hsc.utah.edu
P 801-581-6586
F 801-581-3357

Case Study #1

• A newly developed ASC has 8 reported SSIs within 8 months
• See graph
• See analysis
Case Study #2

- ASC has 3 reported SSIs within 2 months
- See graph
Case Study #3
- ASC reports 5 cases of TASS over 3 years for the same surgeon
- See TASS Investigation Summary

Conclusions
- Ongoing Surveillance
- Thorough investigation
- Peer review
- Internal and external reporting
- Investigations may build on each other

Questions?
- regina@pss4asc.com

thank you!
# Anatomy of and Infection Control Investigation

## Case Study #1

<table>
<thead>
<tr>
<th>MR #</th>
<th>Date</th>
<th>Case #</th>
<th>LOS(min)</th>
<th>Surgeon</th>
<th>Scrub</th>
<th>Circulator</th>
<th>CRNA</th>
<th>Preop gtts</th>
<th>Antibiotics at home</th>
<th>Antibiotics at ASC</th>
<th>Instrument Processing</th>
<th>Culture</th>
<th>Procedure(s)</th>
<th>Risk Fx</th>
<th>Complications</th>
<th>Outcome</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>427726981</td>
<td>10/9/02</td>
<td>8</td>
<td>36</td>
<td>3</td>
<td>Richards</td>
<td>Woods</td>
<td>Johnson</td>
<td>2.5% Neosyn., 1% Mydriacyl, 1% Cyclogel, Ocufox</td>
<td>Ocuflox</td>
<td>None</td>
<td>Staph aureus coh neg</td>
<td>Neg</td>
<td>CEBIL</td>
<td>Postop. Gernal abrasion; optometrist d/c'd drops, applied omentum &amp; shield. Pt. is diabetic, manic depressive, unkempt, body odor. Apparent lack of personal hygiene</td>
<td>None identified</td>
<td>Mac Degen. Lives in assisted Living facility since husband's death</td>
<td>None identified</td>
</tr>
<tr>
<td>42682555</td>
<td>12/13/02</td>
<td>4</td>
<td>17</td>
<td>2</td>
<td>Richards</td>
<td>Hawkins</td>
<td>Johnson</td>
<td>2.5% Neosyn., 1% Mydriacyl, 1% Cyclogel, Ocufox</td>
<td>Ocuflox &amp; Acular</td>
<td>Ocufox</td>
<td>RISS</td>
<td>Neg</td>
<td>CEBIL</td>
<td>Postop. Gernal abrasion; optometrist d/c'd drops, applied omentum &amp; shield. Pt. is diabetic, manic depressive, unkempt, body odor. Apparent lack of personal hygiene</td>
<td>None identified</td>
<td>Mac Degen. Lives in assisted Living facility since husband's death</td>
<td>None identified</td>
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<tr>
<td>428241028</td>
<td>1/3/03</td>
<td>23</td>
<td>23</td>
<td>2</td>
<td>Richards</td>
<td>Scott</td>
<td>Johnson</td>
<td>2.5% Neosyn., 1% Mydriacyl, 1% Cyclogel, Ocufox</td>
<td>Ocuflox</td>
<td>Ocufox</td>
<td>Wrapped</td>
<td>Neg</td>
<td>CEBIL</td>
<td>Postop. Gernal abrasion; optometrist d/c'd drops, applied omentum &amp; shield. Pt. is diabetic, manic depressive, unkempt, body odor. Apparent lack of personal hygiene</td>
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<td>Mac Degen. Lives in assisted Living facility since husband's death</td>
<td>None identified</td>
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<tr>
<td>424202497</td>
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<td>29</td>
<td>29</td>
<td>1</td>
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<td>Hawkins</td>
<td>Johnson</td>
<td>2.5% Neosyn., 1% Mydriacyl, 1% Cyclogel, Ocufox</td>
<td>Ocuflox</td>
<td>Ocufox</td>
<td>Wrapped</td>
<td>Neg</td>
<td>CEBIL</td>
<td>Postop. Gernal abrasion; optometrist d/c'd drops, applied omentum &amp; shield. Pt. is diabetic, manic depressive, unkempt, body odor. Apparent lack of personal hygiene</td>
<td>None identified</td>
<td>Mac Degen. Lives in assisted Living facility since husband's death</td>
<td>None identified</td>
</tr>
<tr>
<td>426463624</td>
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<td>35</td>
<td>35</td>
<td>1</td>
<td>Richards</td>
<td>Hawkins</td>
<td>Johnson</td>
<td>2.5% Neosyn., 1% Mydriacyl, 1% Cyclogel, Ocufox</td>
<td>Ocuflox</td>
<td>Ocufox</td>
<td>RISS</td>
<td>Lactobacillus (resistant to Ocuflox) Lab: “may be contaminated”</td>
<td>Staph epidermidis (resistant to Ocufox)</td>
<td>Staph epidermidis (resistant to Ocufox)</td>
<td>Pre-op 20/70; now 20/CF Referred to RS, continues to improve</td>
<td>None identified</td>
<td>None identified</td>
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<tr>
<td>426789790</td>
<td>6/10/03</td>
<td>22</td>
<td>22</td>
<td>1</td>
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<td>Hawkins</td>
<td>Johnson</td>
<td>2.5% Neosyn., 1% Mydriacyl, 1% Cyclogel, Ocufox</td>
<td>Ocuflox</td>
<td>Ocufox</td>
<td>Wrapped</td>
<td>Staph coh neg</td>
<td>CEBIL</td>
<td>Postop. Gernal abrasion; optometrist d/c'd drops, applied omentum &amp; shield. Pt. is diabetic, manic depressive, unkempt, body odor. Apparent lack of personal hygiene</td>
<td>None identified</td>
<td>None identified</td>
<td>None identified</td>
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<tr>
<td>426789790</td>
<td>6/24/03</td>
<td>17</td>
<td>17</td>
<td>1</td>
<td>Richards</td>
<td>Richards</td>
<td>Stanford</td>
<td>2.5% Neosyn., 1% Mydriacyl, 1% Cyclogel, Ocufox</td>
<td>Ocuflox</td>
<td>Ocuflox &amp; Acular</td>
<td>RISS</td>
<td>None identified</td>
<td>CEBIL</td>
<td>Postop. Gernal abrasion; optometrist d/c'd drops, applied omentum &amp; shield. Pt. is diabetic, manic depressive, unkempt, body odor. Apparent lack of personal hygiene</td>
<td>None identified</td>
<td>None identified</td>
<td>None identified</td>
</tr>
</tbody>
</table>

Other Considerations:

- Dr. #3 uses reusable retrobulbar needle for blocks in preop.
- Staph. Coh 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 rather than bacterial endophthalmitis.
- Instrument processing is methodical. Phaco tubing is machine-irrigated between each case. No ultrasonic machine is used.
ABC Surgery Center

Date

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

SUPPLIES/EQUIPMENT
- Reusable tubing
- Autoclaves
Infections


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.

Trends

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. The following is an attempt to summarize 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.

Hospitalizations:

None. One patient resides in a nursing home.

Recent Illnesses (on/around DOS):

- Post-op corneal abrasion – 1

Skin Integrity:

- No compromises listed – 7
- One patient was diabetic, manic depressive, had poor personal hygiene

Type of Procedure:

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

Outcome:

- Six reported good outcomes.
- One continues to improve.
- One was undetermined.

Miscellaneous:
• The infections were identified 1 – 3 days post-operatively.
• Some 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. Hands are not washed or rescrubbed between patients.
• 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 machine prior to manual cleaning.

Protocols

Pre-op:

Preparation was methodical. There is 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 assistant 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 they wait greater 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 very competent. When all of the staff is trained, the number of people actually scrubbed and sterile could be reduced, if the assistant sets the case up in each room.

**Eye Prep:**

There are lots of ways to prep the eyes. In my experience, alcohol is not used in any other centers as part of the prep. *The prep can be simplified, and various prep methods can be discussed if the leadership wants to examine this issue.*

**Instrument Handling:**

Instruments should be handled as little as possible. It is best to only sterilize the 5 – 7 instruments that are always utilized, keeping others sterile for use as needed.

**Instrument Handling Post-Operatively:**

All instruments were manually cleaned and flushed under pressure prior to sterilization.

**Sterilization:**

- Counter-top autoclaves are used to sterilize and flash 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 commonly used in eye centers with no problems. At one point, the tubing was cultured with negative results.

**PACU:**

Care was standardized, except that with two of the patients, post-op eye drops were instilled and an eye patch was applied in PACU by an office assistant.

**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. The data was returned, and with the help of several outside sources, the
anonymous information was reviewed and comments were returned for compilation.

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. Some of the items that were mentioned for your consideration were:

- 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 full scrub, but scrub again after breaks or bathroom visits. Re-apply the foam. Re-inservice the staff and physicians on application and use of the foam.

- Prep: One source suggested 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.

- BSS: Adding Vancomycin to the bottle was mentioned as being a very common practice. This MD also stated that he injects intracameral Vancomycin at the end of the case, if there are no allergies. Jim Gills, MD was cited as the source for the use of Vancomycin. Dr. Gill’s website is [http://www.stlukeseye.com/default.asp](http://www.stlukeseye.com/default.asp). Visit the site for more information on these injections.

- When BSS is used on more than one patient, use a filter. This is another recommendation of Jim Gills, MD.

- 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, and this may also have an effect on decreasing the infection rate.

Awareness of the problem will often solve the problem itself, and this 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
<table>
<thead>
<tr>
<th>Case</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOS</td>
<td>9/12/11</td>
<td>9/30/11</td>
<td>11/22/11</td>
</tr>
<tr>
<td>MR#</td>
<td>ID# 17952</td>
<td>ID# 11510</td>
<td>ID # 18262</td>
</tr>
<tr>
<td>Surgeon</td>
<td>Dr. 4</td>
<td>Dr. 22</td>
<td>Dr. 28</td>
</tr>
<tr>
<td>Statim</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Anesthetic</td>
<td>1% lido intracameral</td>
<td>Jelly</td>
<td>Jelly</td>
</tr>
<tr>
<td>Tray use of the day</td>
<td>2nd</td>
<td>4th</td>
<td>2nd</td>
</tr>
<tr>
<td>BSS</td>
<td>w/epi+vanco</td>
<td>w/epi</td>
<td>Plain (usually uses epi+vanco)</td>
</tr>
<tr>
<td>PO antibiotic</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>ST/T</td>
<td>RM/RL</td>
<td>KC+RM/RM</td>
<td>RM/VT</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Evisceration</td>
<td>Vision 20/400</td>
<td>Vision</td>
</tr>
<tr>
<td>C/S</td>
<td>MRSA</td>
<td>Coagulation-negative staphylococcus</td>
<td>Cornea Ulcer grew back: Pseudomonas; Serratia Marcescens</td>
</tr>
<tr>
<td>Contributing Factors</td>
<td>MRSA (+) in nares</td>
<td>Stage 4 Bone CA</td>
<td>Pt very active the week after surgery</td>
</tr>
<tr>
<td></td>
<td>1 pt had a skin rash (shingles) and was on Acyclovir. 3rd pt. w/chronic, recurring shingles</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Considerations/Actions**

1. Pts #2 and #3 had topical jelly after the pt was prepped and draped. This jelly is in a reusable tube that is used on other pt’s and may not be sterile.
2. Patient #1, who cultured positive for MRSA in the vitreous fluid also tested positive MRSA in the nares. This was patient #5 and used the tray that was used on pts 1 and 3, who both had active shingles (both on medication).
3. Patient #2 had Stage 4 Bone CA, causing him to be immunocompromised.
4. Patient #3 developed post op corneal ulcer. The vitreous did not grow anything. This bacteria is commonly found in Resp, GI and GU tract infections.
5. Spoke with all ST staff and inserviced on sterile conscience, sterile field, sterile processing.
6. BioMed serviced Statim #3; changed all the seals and they have ordered filters for us to be changed after the first of the year.
7. Spoke with Dr. 22 and he requested that we let him know ahead of time if the cefuroxime is on back order. We did contact him prior to this surgery and he wanted to go ahead without it.
TASS Investigation Summary

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 cystotome 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 vanco that we use is not preservative free and compounded by the nurse. This poses a lot problems. First, the TASS taskforce in Utah recommends not using any medications in the eye that are not preservative free. Second, since the nurse is compounding and mixing the vanco, there is the possibility of error. Third, this vanco 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 vanco 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 vanco 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 (3 years).