ALL HANDS ON DECK

Crisis Management and the Fungal Meningitis Outbreak
Objectives

- Research, Remedies and Resilience for patients with Fungal Meningitis
Nursing Administration

Denise Harrison, MSN, RN, NE-BC
In the fall of 2012... 17,500 vials of fungal contaminated steroids were shipped to clinics and hospitals in 22 states.

Steroids were produced at a New England supplier known as “The New England Compounding Center”.

Steroids that should have been produced under the utmost of sterile conditions.... Instead were tainted with a fungal growth.

None of the steroids were administered within SJMHS
• A National Disaster had emerged.

• A Failure in Drug Safety in the United States occurred.
Our Story Begins

• SJMH - Ann Arbor saw our first wave of patients beginning on October 4, 2012.

• Patients were presenting to the ED with Signs and Symptoms of Meningitis.

• Spinal taps confirmed the presence of **Fungal Meningitis**. This type of Fungal Meningitis had not been seen before.
Our story continues

- Patients diagnosed with Fungal Meningitis were admitted for **aggressive medical** and **antifungal treatment**.

- Many medical authorities both internal and external were contacted and consulted so that “**Care Protocols**” could be developed for these patients.
Our story continues

• Approximately three weeks later, when SJMH thought the worst was over…

• A second wave soon developed and more patients presented in severe pain and were diagnosed with **spinal abscesses, arachnoiditis and other related infections** requiring surgery and debridement.
• Our SJMH capacity soon became overwhelmed with the volume of patients that needed care.

• An Incident Command Center was opened and remained opened 7 days/week for 12 weeks.
Hospital Capacity Exceeded

• Every flex bed and bedded space was occupied. Our Fungal Meningitis volume soon rose to the equivalent of greater than 2 full - 30 bed units.

• In early November (now 1 month into the outbreak) a decision was made to open a unit once closed – 10 East. **Unit was opened in 48 hours.**

• Needed to maximize use of our own **Internal First Choice Agency.**
Hospital Capacity Exceeded

• Staffing office utilized a “war zone approach” to staff our overwhelmed units 24/7.

• Collaborated with multiple Trinity MO’s, Schools and Universities deploying nurses and nursing students to Ann Arbor.

• We received a Tremendous Response from Trinity nurses in Michigan and Ohio.
Facts and Figures

- St. Joseph Mercy Hospital –Ann Arbor (SJMH) has treated more cases than any other hospital in the country.
  - Treated 75% of the reported cases in Michigan.
  - Treated 25% of the reported cases in the United States.

- SJMH identified and called affected patients (over 600) to notify them of their risk and offer to schedule diagnostic MRI’s.

- By January, of the fungal meningitis outbreak, SJMH-Ann Arbor had reported 187 cases to the MDPH.
A Team Response

- Leadership
- Emergency Department
- Nursing: ICU, PCU, Med-Surg
- Infectious Disease Physicians
- Anesthesiology
- Radiology
- Surgery
- Pharmacy
- Microbiology
- Pastoral Care
- Social Work & Case Management
- Facilities
- Food services and Environment Services,
- Communications
- TIS
Medical Care
Clinical Overview of the Fungal Meningitis Outbreak

October 30, 2013

Anurag Malani, M.D.
Medical Director, Infection Prevention and Antimicrobial Stewardship Programs
St. Joseph Mercy Health System
Adjunct Assistant Professor, University of Michigan
Background

- Sept 18, Index case - Aspergillus meningitis
- Sept 26, New England Compounding Center (NECC) recalled 3 lots of methylprednisolone acetate
  - # 05212012@68
  - # 06292012@26
  - # 08102012@51
- 17,500 vials recalled - 76 facilities & 23 states
- Sept 27, Investigation by TN DOH, CDC, and NC DOH identified 8 additional pts with culture negative meningitis

Background

- By Oct 3, 6 cases of culture negative meningitis had been identified at SJMH
- Oct 4, CDC Health Advisory warning of meningitis and stroke associated with MPA
- Public health outreach by MDCH, SJMH, and independent pain facility
Clinical Presentations

- October (wks 1 – 3): mostly meningitis
- Incubation period: 1 – 4 wks after last injection (range 7 – 58 D)
- Symptoms: headache, meningeal sx, back pain, neck pain, + fever
- Laboratory: CSF WBC: < 10 WBC to 15K; at times neutrophil predominant, often low glucose, elevated protein
Clinical Presentations

- Oct, 12 – May, 13: Spinal and paraspinal infections (including those with meningitis)
- Incubation period: Median of 56 days after last injection (Range 21 – 229 D)
- Symptoms: Back/neck pain (at injection site), headache, limb weakness/numbness
- Some patients with minimal symptoms
- MRI screening from Nov, 12 – April, 13
Clinical Presentation: Arachnoiditis

- Pain at the injection site
- Perineal and buttock pain/numbness
- Cauda equina syndrome: urinary retention, incontinence, leg weakness/numbness
- MRI: intradural clumping of nerve roots, operative intervention: + pus
Spinal and Paraspinal Infections
MRI Screening for Spinal & Paraspinal Infections

544 Patients were exposed to ≥1 contaminated steroid injection between August 9, 2012, and October 2, 2012

326 Had been tested for meningitis by lumbar puncture or for spinal or paraspinal infection by imaging prior to November 8, 2012

218 Without meningitis or symptoms of spinal or paraspinal infection identified for screening cohort

26 Magnetic resonance imaging (MRI) scheduled or requested but not completed
12 Received care outside hospital system
8 Contraindication to MRI

172 Had ≥1 MRI

36 Had evidence of infection
24 Received surgical and antifungal therapy
11 Received antifungal therapy alone
1 Ongoing clinical and radiological follow-up

18 Equivocal results
18 Ongoing clinical and radiological follow-up

118 No evidence of infection

Monthly Admissions for Fungal Infections Related to Contaminated MPA

No. of Monthly Admissions

- Meningitis
- Spinal or paraspinal
- Joint
- Meningitis + spinal or paraspinal

Clinical Summary

195 Cases
65 confirmed for fungus

54 Meningitis

128 Spinal / Paraspinal

13 Peripheral Joints

42 Spinal / Paraspinal
Exserohilum rostratum

- Dematiaceious or black mold
- Melanin in its cell wall
- Found in the environment, plant debris, soil, and water
- Human infection uncommon
- Rarely, caused invasive infection in immunocompromised hosts
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Therapeutic Drug Monitoring of Voriconazole

Voriconazole Levels

Level


7.3 Vori. 400 mg BID
5.6 Vori. 350 mg BID
Vori. 400 mg BID
Vori. 550 mg BID
Voriconazole-Induced Photosensitivity
Voriconazole-Induced Alopecia
Liposomal Amphotericin B

- Drug infusion rxns
- Renal toxicity
- Electrolyte abnormalities – significant hypokalemia, hypomagnesemia
- Significant weight gain/edema with aggressive IV hydration, at times resulted in heart failure
Costs of Anti-Fungal Therapy

- Anti-fungal budget from Oct, 12 – July, 13
  - Inpatient: $1.74 Million
    - Voriconazole: $500/day
    - Liposomal amphotericin: $400/day
  - Outpatient: $1.62 Million
    - Monthly voriconazole costs: $3000 – 7000
Case 1: Meningitis + Arachnoiditis

Chief complaint: 72 y/o F with 1 wk of headache, neck stiffness, chills, and fatigue on 10/5/12

Epidural steroid injection: L3-L4 on 9/20

Lumbar puncture:

<table>
<thead>
<tr>
<th>WBC: 549 cells/µl</th>
<th>Glucose: 45 mg/100mL</th>
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<tr>
<td>PCR: negative for fungal DNA</td>
<td>Protein: 53 mg/100mL</td>
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Medical treatment:
- Inpatient: voriconazole + L-AMB for 5 D

Discharge: 10/16 (26 D after ESI)
- Symptoms: Improved
- Outpatient treatment: oral voriconazole
Case 1: Meningitis + Arachnoiditis

- **Chief complaint:** back pain, lower extremity weakness 10/26/12 (36 D after ESI)
- **Imaging:**
  - MRI: Enhancement projecting intradural at L3 level
- **Operative treatment:**
  - Evacuation of epidural abscess, L3 laminectomy
  - **Intraoperative findings:**
    - Phlegmon-like material adherent to clumping nerve roots
    - Small amount of pus, necrotic debris
Case 1: MRI 36 Days after Injection

Enhancement in dorsal thecal sac
Case 1: MRI 36 Days after Injection

Enhancement and clumping of nerve roots.
Case 1: Operative Findings

Phlegmon covering thecal sac
Case 1: Operative Pathology of Intradural Abscess

- **Stain:** H+E
- **Findings:** purulent inflammation

- **Stain:** GMS
- **Findings:** fungal hyphae
Case 1: Meningitis + Arachnoiditis Hospitalization 2

- **Medical treatment:**
  - **Inpatient:** voriconazole + L-AMB for 5 wks
- **Discharge:** 11/30/12
  - **Symptoms:** improved
  - **Outpatient treatment:** oral voriconazole
- **Imaging:** 3/18/13 (About 5 Mo. after surgery)
  - **MRI:** Post-surgical change at laminectomy site, no abnormal epidural or intrathecal enhancement
Case 1: Meningitis + Arachnoiditis

- Development of rib pain after 3 Mo. of voriconazole
- Imaging:
  - CT scan: periosteal reaction along B/L R 5-7, L 6-7 ribs
  - Bone Scan: intense tracer uptake B/L R 5-7, L 6-7 ribs
- Laboratory:
  - Fluoride level .39 mg/L (normal < .10 mg/L)
- Medical treatment:
  - Voriconazole dose reduced, trough decreased
  - Periostitis pain resolved
  - Repeat LP normal in April, 2013 (4 WBC)
  - Transitioned to itraconazole in May, 2013, symptom free
Case 1: MRI 2 Months after Surgery

No abnormal intrathecal or epidural enhancement
Case 1: Periostitis of the Ribs

Periosteal reaction along ribs
Lessons Learned

- Largest healthcare associated outbreak
- Broad spectrum of clinical disease and pathology
- Meningitis evolving disease
  - CVA or arachnoiditis - greater severity of illness
- Spinal/paraspinal infections: at site of injection
  - No evidence of noncontiguous spread
  - Surgical intervention an important role
  - Low threshold for MRI imaging, even in those with minimal change in symptoms – “asymptomatic”
- Optimal duration of therapy unclear
  - Varies upon disease presentation
Nursing Care: Pain Management

- All were chronic pain patients
- Acute pain as well as Chronic pain
- Pain often a symptom of worsening disease
- Could be symptom free but with grossly abnormal MRI: abscess, phlegmon, arachnoiditis
- Surgical pain: spinal debridement
- Medications up or down titrated based upon severity and character of pain
- Antifungals can interfere with efficacy of opioids
Liposomal Amphotericin B

- “Awful Ampho or Ampho Terrible”
- Strict and complicated administration guidelines
- Management of adverse side effects: rigors, fever, chills, myalgias, nausea
- Pre-hydration and pre-medications
- Managing fluid balance: approx 1600 ml of IV fluid with each dose
- Use of PICC lines: strongly encouraged
- Managing electrolytes: serial lab draws/replacement
Nursing Care: Antifungal Medications

Voriconazole

- Administration
- Side effects: hallucinations and opioid interference
- Electrolyte imbalance
- Trough levels
- Dosage adjusted for hepatic impairment
- Transition to oral
- Outpatient expense: approx $7000.00 per month with unknown duration of therapy
Nursing Diagnosis

- Risk of infection: sepsis screen
- Activity intolerance
- Knowledge deficits: patient & caregivers
- Grieving, fear, stress overload
- Altered mental status
- Risk for electrolyte imbalance
- Deficit/excess fluid volume
- Risk for impaired renal/hepatic function
- Caregiver strain
- Risk for PTSD
- Compromised family function
- Disturbed sleep pattern
- Ineffective coping
- Acute/Chronic pain
Psychosocial Aspects

- Complicated and Individualized
- Very long length of stay
- Whatever stressors in place prior to hospitalization continued in the hospital
- Attorneys and News crews
- Depression
- Emotions: fear, sadness, anger, frustration
- Fear of the unknown: patients, family and caregivers
- Family stress
- 23 hour passes for holidays: pharmacy
- Pet visitation
- Patient support group
- Pastoral Care involvement
- Out-patient fungal clinic
Education

Lisa Friedman MS, RN, NE-BC
Preparing and Sharing

- Open up bed capacity – bring on new staff
- Provide consistent, high quality care
- Share information and resources
- Duration unknown
Rapid and Safe Approach to Patient Surge: Lessons Learned

• Use of our First-Choice system resource pool
• Support from our regional MOs to staff their own sites
• Reaching out to other Trinity Health MOs
• Multi-State response; Licensure implications
• Monitoring the Unit mix of SJ staff and “Guest RNs” at all times
• Reaching out to Schools and Universities for Student support (as Aides, transporters, etc.)
• Use of External agency staff
• Cohort patients on units
Trinity Health Comes Together

- St. Mary's - Livonia, MI
- Port Huron, MI
- St. Mary's - Grand Rapids, MI
- Oakland - Pontiac, MI
- Mt Carmel - Columbus, OH
Preparing a Courageous Team

• Getting a License:
  – States of Michigan and Ohio

• Schools of Nursing recruited for students
  – over 80 responded, filled roles as PCTs, and transporters

• Checking Competency:
  – HealthStream

• Orientation:
  – Standard Established, Safety, Individual Needs, JIT

• Controlling Assignments
• Using the Buddy system
• Performance Evaluations
• Physicians and Volunteers recruited as well
Deploying a Courageous Team

- **The Basics:**
  - Lodging, tours, safety codes, access codes, badges, time keeping
- **Powerchart:**
  - Nursing protocols and documentation
- **Equipment:**
  - IV pumps, defibrillators, glucometers, lifting devices, etc..
- **Meds:**
  - Pyxis, fungal meningitis meds
- **Communication:**
  - PCDs, Emergin, How to contact physicians
- **Safety:**
  - High risk equipment, restraints, falls, language interpretation
- **Resources and references**
Emotional Support

Lynne DeGrande, MSW
Challenges for Staff

- Uncharted territory
- Organization-wide impact
- Sense of urgency
- Patient volume/acuity
- Fast pace
- Ongoing demand
- Finite resources
- Personal connections
- Holiday time
- Exposure to intense patient/family suffering
- Tedium & exhaustion
Care For The Caregivers

- Acknowledgement of efforts being made
- Daily briefings by critical leaders
- Increased leadership presence on work units
- Outreach by EAP and Pastoral Care
- Handouts on maintaining resiliency, coping during crisis, dealing with burnout,
- Comfort aids: food, massages, healing arts,
Patient-Family Experience

- Sudden Onset
- Unknown etiology/duration
- Significant suffering
- Long, slow road
- Confinement
- Fear and angst
Patient-family Outreach

- Physician notification to injected patients
- Physician calls re: MRI results
- Family inclusion efforts
- Fungal outbreak clinic opened
- Day passes for patients
- Patient-family support group
- Diversion/relaxation activities
Teachables

- Achieving resilience during critical challenges is both a journey and a goal
- Reaching for resilience can be a shared experience between patient, family & staff
- Sharing the mutual challenge and holding onto hope bind us together
- “Being present” was the key
A Patient’s View Point

JR Mazure
A Patient Perspective

- How it began
- Being hospitalized
- Being hospitalized again, again…
- How life has changed
- What helped me
- What the future holds
- Advice for caregivers
questions
REMARKABLE MEDICINE.
REMARKABLE CARE.