RESEARCH/PROCEEDINGS

Tissue Donor Eligibility Trends and Challenges

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Tissue Donor Eligibility Trends and Challenges

Pharmaconference

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Slide 2:

Lecture Outline

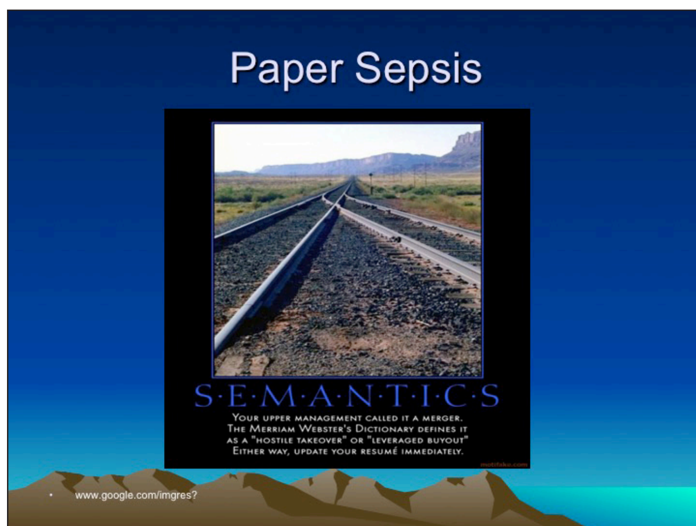
- Cause of Death Issues
- Paper Sepsis
- Delirium vs Dementia
- Flu vs Viremia
- Exotic Diseases (i.e. Ebola)
- Delayed Autopsy Reports
- Follow-up information
- Ancillary test results

Slide 3:

Cause of Death

- Urgency of Certain Tissue Types
- Reluctance of Physicians to Commit To a Clear COD
- Autopsy delays
- Key Issues:
  - Presentation of the Donor
  - Correlation with Clinical, Laboratory, and PMH/PSH findings

Slide 4:



Slide 5:

Current Issues

- FDA Final Guidance for Eyes and Tissues
- AATB Standards
- EBAA Standards
- "Nosocomial Infections" and Medicare Reimbursement

Biggest change was Medicare act of 2009—no more reimbursement for hospital-acquired infections.

Since then, we've seen a huge spike in "sepsis" and "SIRS" in medical records.

MDs are no longer just keeping sepsis in the back of their minds.

They are writing it in the chart, and then, whereas they used to drop it when ruled out by BCXs, etc., they are leaving it on the active problem list in case it develops later….

Teaching hospitals also have residents and students writing daily progress notes on patients and differential diagnoses/working problem list are often wide and items are not dropped when ruled out.

EBAA standards 2012:

- *Contraindications to transplant: Infection*
- *Active viral encephalitis of unknown origin or progressive encephalopathy (e.g., subacute sclerosing panencephalitis, progressive multifocal leukoencephalopathy, etc.)*
- *active bacterial or viral meningitis;*
- *active bacterial or fungal endocarditis*
- *Screening for FDA Defined Relevant Communicable Disease Agents and Diseases*
- *The FDA defines communicable disease agents and diseases considered relevant (Ref. Appendix I). Tissue from persons exhibiting risk factors for, clinical evidence of, or physical evidence of relevant communicable disease and high risk behavior associated with relevant communicable disease must not be used for transplant purposes (Ref. Appendix II).*

FDA 2007: high communicable disease risk factors:

— Persons who are deceased and have a documented medical diagnosis of sepsis that is not explained by other clinical conditions at the time of death. An eye bank should make a determination on how to routinely handle situations of clinical history proximal to death in which sepsis was suspected at the time of admission or part of a differential diagnosis during admission in which the patient may have been shown through clinical data not to be septic prior to death.

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Slide 6:

FDA Screening Measures

Clinical evidence of infection; and

- Two of the systemic inflammatory response criteria **to infection if unexplained:**
  - Temperature of > 100.4° F (38° C);
  - Heart rate > 90 beats/min;
  - Respiratory rate > 20 breaths/min or PaCO2 < 32; or
  - WBC > 12,000 cells/mm^3, < 4,000 cells/mm^3, or > 10% immature (band) forms.
- More severe signs of sepsis include **unexplained** hypoxemia, elevated lactate, oliguria, altered mentation, and hypotension.
- **Positive (pre-mortem) blood cultures** might be associated with the above signs.
- Physical evidence of sepsis, such as **unexplained** generalized rash or fever.

Slide 7:

SO, HOW DO WE BOIL IT ALL DOWN INTO A COHERENT APPROACH?

Slide 8:

Blood Cultures

- The current "gold standard" in diagnosis
- Detection rate increases with number of cultures obtained
  - 73.1% detected with first culture
  - 89.7% with two blood cultures
  - 98.2% and 99.8% with third and fourth cultures

Lee et al, *J Clin Microbiol*, 2007

Slide 9:

How about Contamination?

- Pattern of contamination of Blood Culture results
  - 1/? Cultures positive….
- Common Contaminants
  - Strep viridans
  - Propionobacterium
  - Corenybacterium
  - Coagulase-negative Staph
  - Staph Aureus
  - Bacillus, non-anthracis

Slide 10:

So, What Should We Do?

- Recover donors with "sepsis" in DDX
- Sepsis or SIRS consult after the fact if any two:
  - WBC>12 or <4
  - Bands >10%
  - RR >20
  - Temp >100.5 or >38C
  - HR >100 bpm
  - BP <90 mmHg (systolic i.e. top number
- R/O if sepsis is COD, but death cert may be wrong…
- R/O if clear active sepsis at TOD

Define SIRS here…

Reiterate it is a DX of exclusion, and should not be made when there are clear clinical problems that may manifest as SIRS….

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Slide 11:

The only Clinical Correlation

- 2012 study by Bradly Gustave, MD, MBA et al. evaluated 75 potential donors from the North Carolina Eye Bank with signs of sepsis
- Charts reviewed by infectious disease consultant
- Active sepsis was defined as positive blood cultures with signs of systemic inflammation at the time of death.
- Of the FDA criteria, the only sign found to independently correlate with active sepsis

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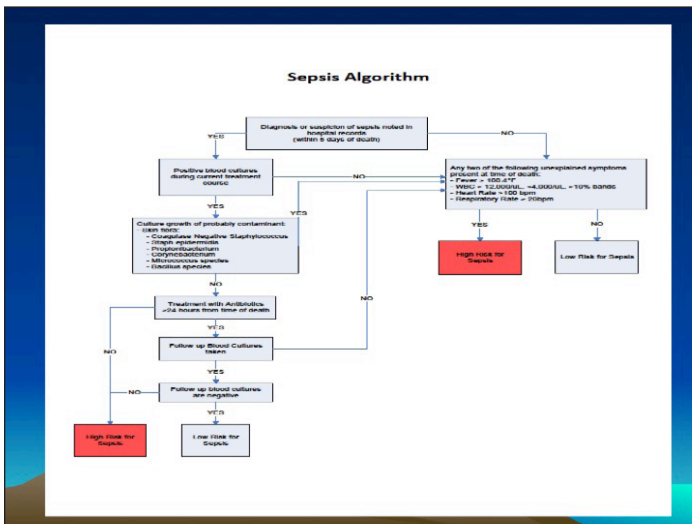

Slide 13:

Criteria for Tissue Suitability

- Two Scenarios:
  - High Clinical Suspicion & +Blood Cultures
  - Clinical Diagnosis of Sepsis
- Follow-up Questions:
  - Antibiotics?
  - How Long?
  - Defervescence?

Usually, 24 hours of ABX and evidence of some kind of defferves-cence is all we need to r/o sepsis at TOD in the truly septic patient.

Patients with severe sepsis should thus receive a broad-spectrum, intravenous regimen that is effective for both gram-negative and gram-positive bacteria, and they should receive it as quickly as possible.

Recovery from severe sepsis or septic shock is unlikely, even with appropriate antimicrobial therapy and diligent ICU care, if the patient has an undrained abscess or obstructed viscus.

Slide 14:

Delirium vs Dementia

- Definitions of Each
- Healthcare Climate and Impact on Misdiagnosis
- Altzheimer's vs Senile Dementia
- 12 month rule

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Slide 15:

Slide 16:

Viremia Rule-Out

- Blood Banking Approach:
  - Follow blood donor recommendations for outbreaks
  - Fever is key
  - Antivirals may be helpful
- Diarrhea
- Cough

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Slide 18:

New Information

- New Test results
- Facebook entries
- Final Autopsy Results after Provisional Release
- Coroner's scene descriptions
- Law Enforcement Reports
- "Hearsay" statements
  - Donor Family Tributes, etc.

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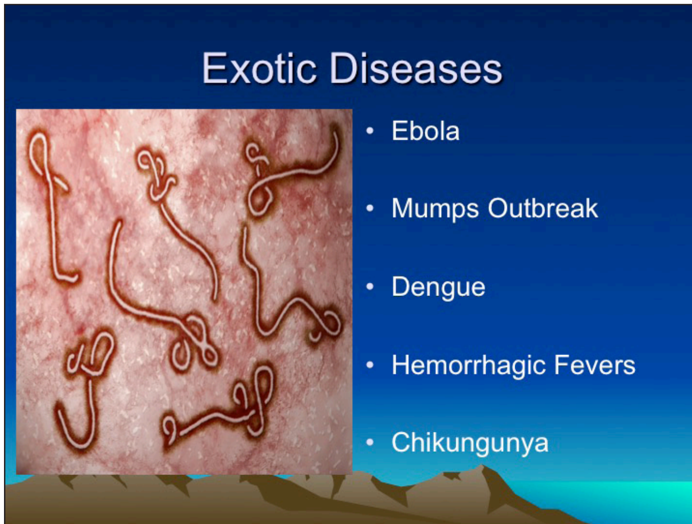
Slide 20:



Slide 21:

Slide 22:

Autopsy Issues

- Timely Release
- Provisional Results
- Medical Director Inverventions
  - Call to ME for “verbal”
  - Chart Review

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