

# ***Study Proposal:***

Randomized trial comparing the incidence of EVD related CNS infection with the use of peri-operative -vs- prolonged antibiotic prophylaxis

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EVD Related Antibiotic use for prevention of  
Infectious complications

-DRAIN  Trial-

# EVD Related Infections

- External ventricular drains (EVD) have been used for many years as a method of diverting cerebral spinal fluid out of the cranium.
- External drainage is utilized in brain trauma and a number of other CNS conditions.
- EVD related infections occur ~8%\*(2 - 24%)
- After placement of these drains, it has been customary in many centers to initiate antibiotics to prevent drain related infections.

# EVD Related Infections

- Two types of ABX prophylaxis has emerged:
  - Peri-operative
  - Prolonged-usually for the duration the catheter is in place
- Evidence supporting
  - Only retrospective data
  - Some data suggest resistance development without reduce in incidence\*\*.

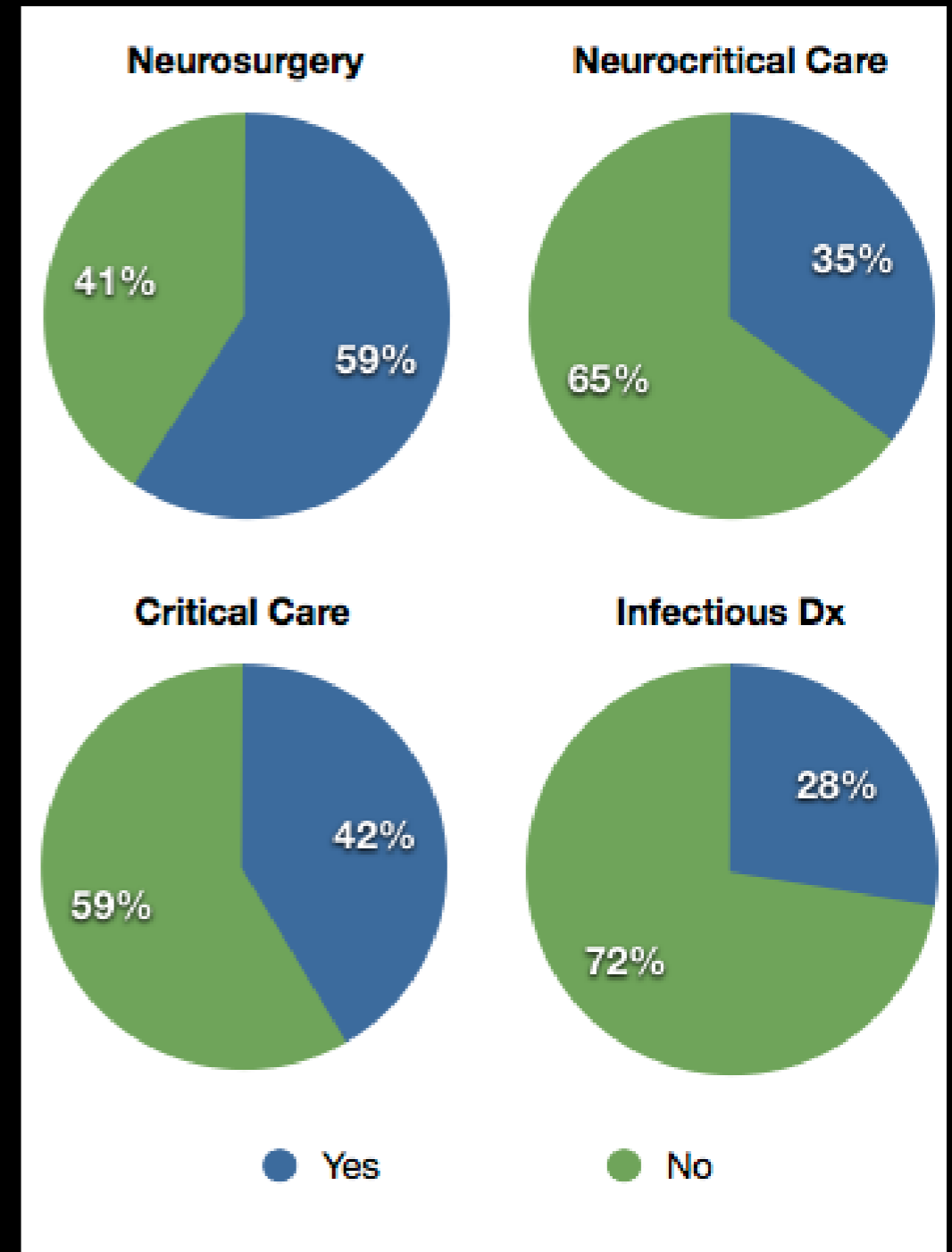
\*\*Curr Neurol Neurosci Rep, 6(6), 525-30.

# Survey (Poster #104)

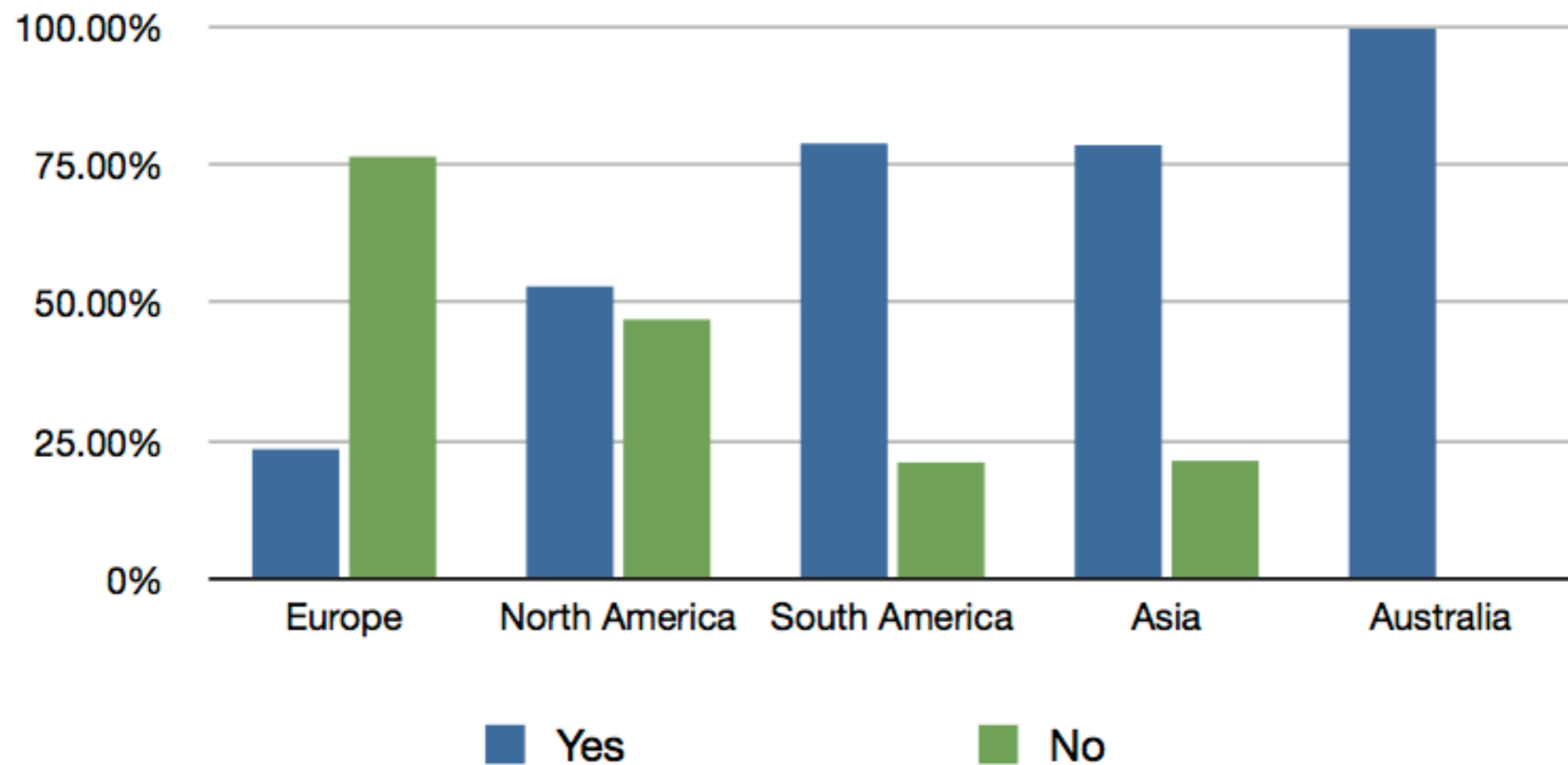
- LSU Health Sciences EVD Survey
  - NS, NCC, CCM, ID
- N. America, S. America, Europe, Asia, Australia
- Basic question: Is there an unintended best practices/consensus?

# Survey

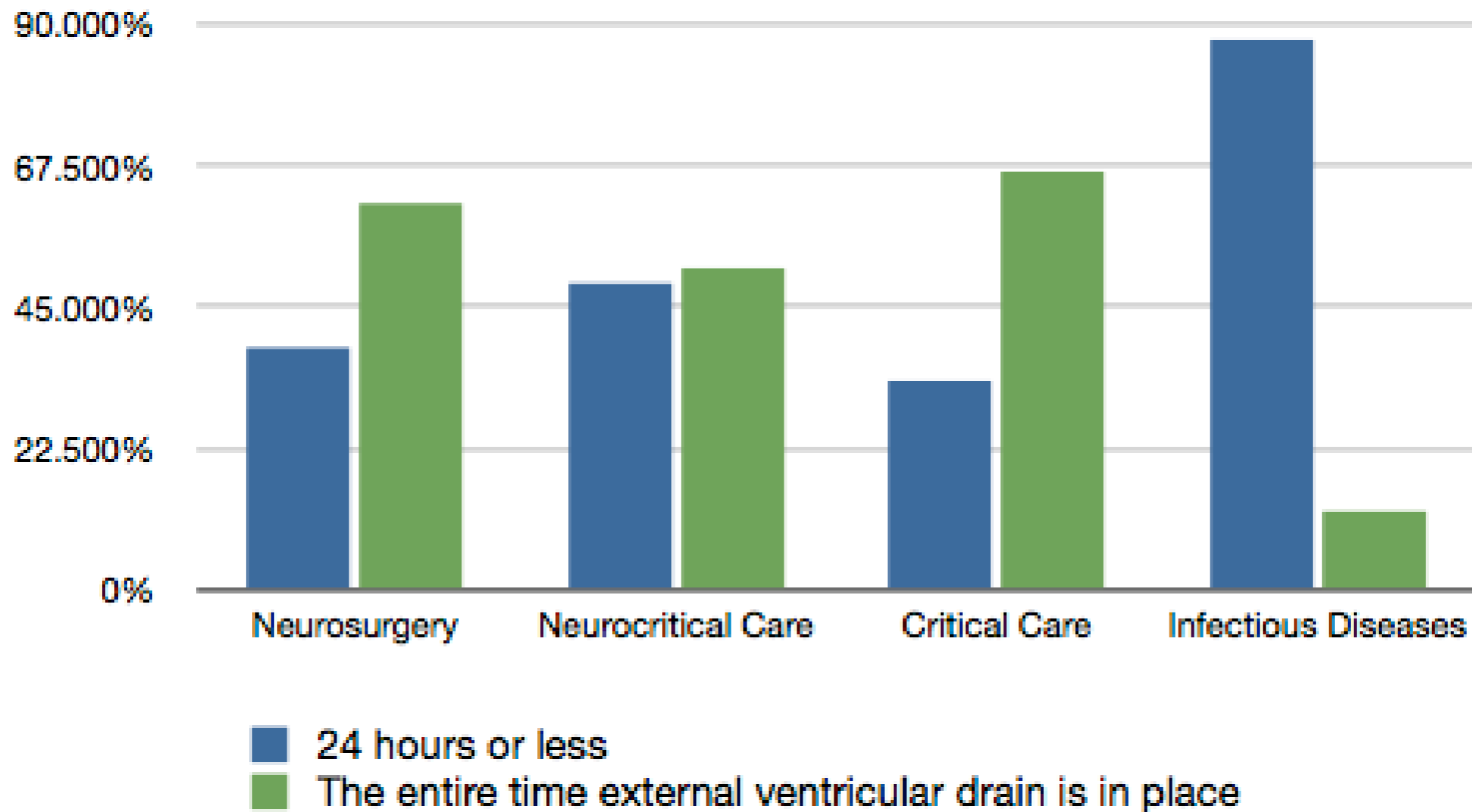
**Question:** Do you use or recommend ABX prophylaxis with EVD placement?



# Locale of participants that responded to the question of whether ABX prophylaxis should be used?



# Of those that recommend ABX prophylaxis, how do they recommend or use them?



Question 14: Is a prospective randomized controlled trial comparing antibiotic practices for EVD'd and ICP monitors warranted?

	Neurosurgery	Neurocritical Care	Critical Care	Infectious Diseases	
Yes	77.20%	80.50%	70.70%	89.80%	77.80%
No	22.80%	19.50%	29.30%	10.20%	22.20%

# Hypothesis

*Prolonged antibiotics as a strategy to prevent ventricular or meningeal infectious complications after EDV placement offer no advantage to peri-operative prophylactic antibiotics.*

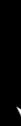
## ***Eligibility:***

- 1) EVD placement for a non-infectious process.
- 2) No antibiotics in the previous 48 hours.
- 3) Not immunosuppressed by underlying disease states, steroids or chemotherapy.
- 4) > 18 years of age  
(separate Peds trial planned DRAIN-P)

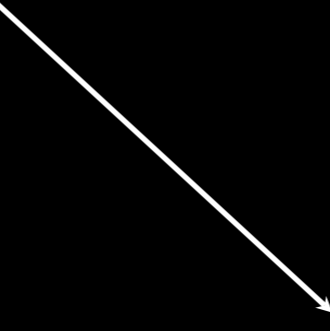
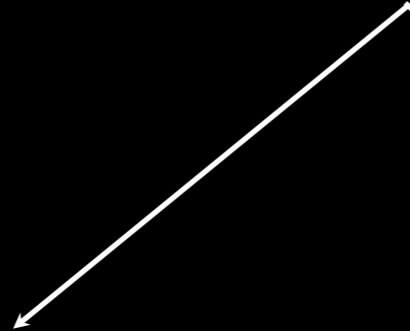
## ***Exclusion:***

- 1) Received ABX in previous 48 hours
- 2) Evidence of infection upon insertion of drain
- 3) HIV, on-going chemotherapy, exposed to glucocorticosteroids within the past two weeks

EVD Placement

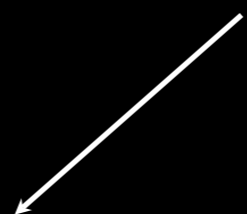
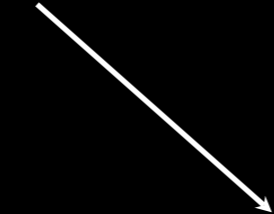


Randomization



Peri-operative

Prolonged



Incidence of infection

ABX susceptibility patterns

LOS (ICU and hospital)

Drain duration

Drain related complications

C. diff (+ or -)

# Power analysis

## *Infection defined as:*

- 1) positive cultures with a supporting gram stain or,
  - 2) pleocytosis with low glucose, high protein and strong clinical suspicion.
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## *Non-inferiority study with a 95% CI;*

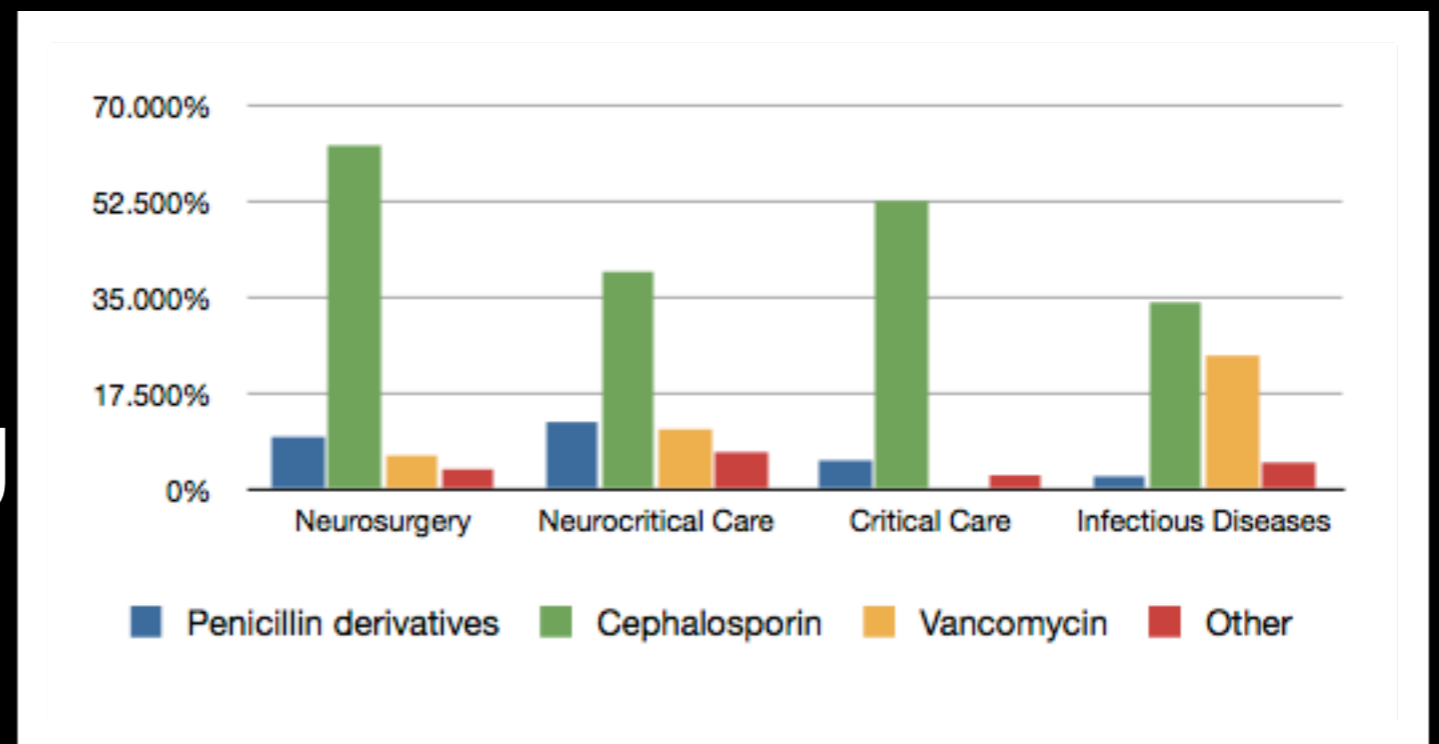
Based on an 8% incidence,

5% increase infection rate considered as inferiority.

Sample size **1138**.

# The “DRAIN Trial”

- Blinded?
- Difficult because there is no consensus on ABX to use for prophylaxis-survey showed cephalosporins most common
- Allergy issues
- Levels
- Lab monitoring



# The “Drain Trial”

- LSUHSC-S Coordinating Center
  - Section of Critical Care Research
  - Web based randomization and data entry
- Goal
  - ~30 centers
  - two years
  - 17-18 patients enrolled a year/center
  - Interim analysis at 125 enrollees

Questions?