### Test Taking Strategies for BPS Exams Conquering the Biostatistics Question

Anthony J. Busti, MD, PharmD, MSc, FNLA, FAHA

HIGH-YIELD MED REVIEWS

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# Introduction



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# Agenda

- A General Overview
- Part 1 Conquering the Biostatistics Question
- Part 2 Interpreting Statistical Results Correctly
- A Special Coupon Code
- Live Q&A

HIGH-YIELD MED REVIEWS

### Conquering the Biostatistics Question

- Essential steps and decision points
  - 1. Consider drawing out study design in question
  - How many groups are being studied?
     a. Are those groups related or independent of each other?
  - 3. What type of data is represented in the outcome of interest (i.e., nominal, ordinal, continuous)?
  - 4. Connect the row and column on summary table
  - The Killer Foil Moment → If "applicable" results/data are available, consider the following:
    - a. How many patients are in each group?
    - b. Does it appear to be parametric or nonparametric?

Participation Required You Must Fill in Some Blanks



### Test-Taking Strategies Memorize the Chart

Type of Data	Two Independent Samples	Related or Paired Samples	3 or more Independent Samples	3 or more Related Samples	Measures of Correlation
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HIGH-YIELD MED REVIEWS

#### Essential steps and decision points

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#### The New England Journal of Medicine



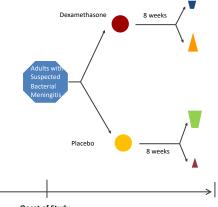
N Engl J Med 2002;347:1549-56.

#### Treatment

Patients were randomly assigned to receive dexamethasone sodium phosphate (Oradexon), at a dose of 10 mg given every six hours intravenously for four days, or placebo that was identical in appearance to the active drug. The study medication was given 15 to 20 minutes before the parenteral administration of antibiotics. After the interim analysis, the protocol was amended to allow administration of the study medication with the antibiotics.

Balanced treatment assignments within each hospital were achieved with the use of a computer-generated list of random numbers in blocks of six. The code was not broken until the last patient to be enrolled had completed eight weeks of follow-up. Treatment

### Dexamethasone - Adult Meningitis Study

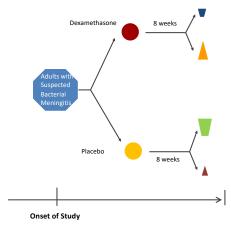


### Conquering the Biostatistics Question

#### Essential steps and decision points

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# Dexamethasone – Adult Meningitis Study



#### The Lancet · Saturday 13 August 1988



Summary 17 187 patients entering 417 hospitals up t 24 hours (median 5 hours) after the onset of suspected acute myocardial infarction were randomised with placed control hours of a 1 hour infarction. 0.2%), and of confirmed cerebral haemorthage (0.1%, or 0.4%), but with lever other strokes (0.6% to 0.9%). These "other" strokes may have included a few undiagnosed cerebral haemorthages, but still three was na increase in cerebral insurancing, but still three was na increase in Aspirin significantly reduced non-final reinfluerion (1.0% to 2.0%) and non-final stroke (0.3% to 0.6%), and was not associated with any significant increase in cerebral haemorthage or in bleeds requiring translasion. An eccess was used alone, but this appeared to be entirely avoided by the addition of aspirin. Those allocated the combination of

#### Treatment

A 2 × 2 factorial study design was used.<sup>14</sup> Half of all patients were allocated randomly to receive streptokinase (1.5 MU of 'Streptase') and half to receive matching placebo (hepatitis-B-antigen-free albumin), infused intravenously over about 1 hour in 50-250 ml physiological saline, starting immediately. Half of all patients were also allocated randomly to receive oral aspirin (exact dose: 162.5 mg in enteric-coated tablets) and half to receive matching placebo (enteric-coated starch tablets), given daily for one month from a calendar pack, starting immediately with the first tablet crushed, sucked, or chewed for a rapid antiplatelet effect. Hence, there were treatment groups: *streptokinase alone, aspirin alone, both, or neither*. The trial treatments was to be intermined only if this was

ISIS-2 Trial. Lancet 1988

#### ISIS-2 Trial. Lancet 1988

# 2 x 2 Factorial Study

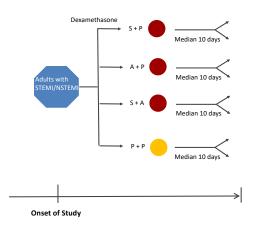
	Aspirin	Placebo
Streptokinase	S + A	S + P
Placebo	P + A	P + P

THE LANCET, AUGUST 13, 1988

	Strept	Streptokinase allocation		Aspirin allocation		Combination therapy			
Clinical event	Streptokinase	Placebo infusion	Absolute	Aspirin	Placebo tablers	Absolute	Streptokinase & Aspirm	Both placebos	Absolute
No randomised No with discharge form	8592 8490	8595 8491	reduction (% Placebo –% SK)	8587 8492	8600 8489	reduction (% Placebo % Asp)	4292 4239	4300 4238	reduction (% Neither -% SK & Asp
Reinfarction Any	238	202	-0.4%	156	284	1.5%	77	123	1.1%

353

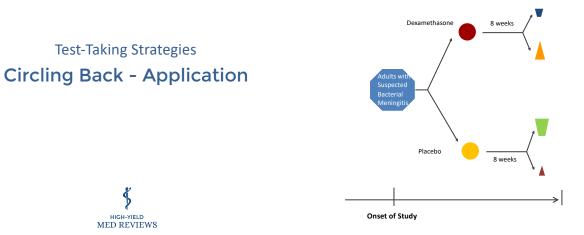
### **ISIS-2** Trial



# Type of Groups

Groups	Groups
SAME patient in ALL arms	DIFFERENT patients in each arm
<ul> <li>Cross-Over Studies</li> <li>Retrospective Study of All Patients Start &amp; End of Study</li> <li>Left eye vs right eye on the same patient</li> <li>Warning:         <ul> <li>Patients Randomized to look almost the same</li> <li>Identical Twins</li> </ul> </li> </ul>	<ul> <li>RCT</li> <li>Cohort Study</li> <li>Case-Controlled Study</li> </ul>

### Dexamethasone – Adult Meningitis Study





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# ISIS-2: 2 x 2 Factorial Study

	Aspirin	Placebo
Streptokinase	S + A	S + P
Placebo	P + A	P + P

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# Nominal Data

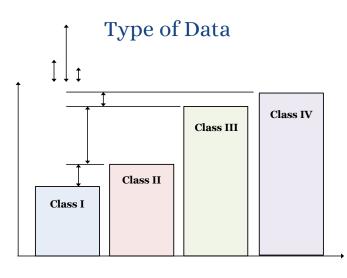
- Key descriptors:
  - Categorical
  - Dichotomous
  - Binomial distribution
  - No sense of "ranking" or "order"
    - Thus the magnitude of difference between the two does not apply
- Assessment of data:
  - The endpoint is treated at the end as:
    - "yes or no"
    - "either did or didn't ....."
    - There CANNOT be an average or a mean value

# Conquering the Biostatistics Question

- Essential steps and decision points
  - 1. Consider drawing out study design in question
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# Ordinal Data

- Key descriptors:
  - Data endpoints have a sense of "order" that also has a sense of "ranking" or "scale"
  - Nonparametric (not normally distributed data)
    Could by continuous data with outliers
- Assessment of data:
  - The "magnitude of differences" between endpoints is NOT the same



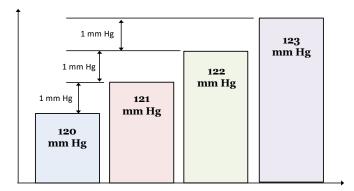
### Type of Data

- Examples of Ordinal Data:
  - Classification of HF (class I IV)
  - Severity of pain:
    - Mild, Moderate, or Severe
  - Well's Score for PE (0 12.5)
    - Low or PE unlikely (< 4 points)</li>
    - Moderate (4-6 points)
    - High probability (> 6 points)
  - What about:
    - NIH Stroke "Scale"
    - Pain Scale: 0 10

### **Continuous Data**

# Type of Data

- Key descriptors:
  - Data endpoints have a sense of "order" that also has a sense of "ranking"
  - Parametrically distributed
    - Assumes no "outliers"
- Assessment of data:
  - The "magnitude of difference" between endpoints is ARE the same



**Continuous Data** 

- Examples of Continuous Data:
  - Temperature
  - Pulse (heart rate)
  - Blood pressure (without a cutoff or designated goal)
  - Labs (Sodium level)

**Test-Taking Strategies Circling Back - Application** 



#### The New England Journal of Medicine

Copyright © 2002 by the Mar chusetts Medical Se VOLUME 347 NOVEMBER 14, 2002 NUMBER 20 DEXAMETHASONE IN ADULTS WITH BACTERIAL MENINGITIS

JAN DE GANS, PH.D., AND DIEDERIK VAN DE BEEK, M.D., FOR THE EUROPEAN DEXAMETHASONE IN ADULTHOOD BACTERIAL MENINGITIS STUDY INVESTIGATORS\*

ABSTRACT Background Mortality and morbidity rates are high among adults with acute bacterial meningitis, espe-

HE mortality rate among adults with acute bacterial meningitis and the frequency of neurologic sequelae among those who sur-vive are high, especially among patients with neumococcal meningitis.<sup>12</sup> Unfavorable neurologic Dneum

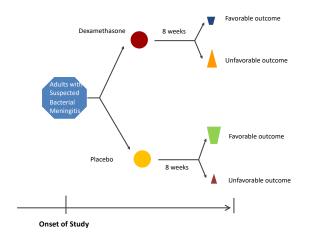
#### Assessment of Outcome

The primary outcome measure was the score on the Glasgow Outcome Scale eight weeks after randomization, as assessed by the patient's physician. A score of 1 indicates death; 2, a vegetative state (the patient is unable to interact with the environment); 3, severe disability (the patient is unable to live independently but can follow commands); 4, moderate disability (the patient is capable of living independently but unable to return to work or school): and 5. mild

or no disability (the patient is able to return to work or school).12 A favorable outcome was defined as a score of 5, and an unfavorable outcome as a score of 1 to 4. The Glasgow Outcome Scale has frequently been used in trials involving stroke and other brain injuries. It is a well-validated scale with good interobserver agreement.<sup>13,14</sup>

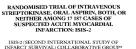
cially those with neurococcal meningitis, espe-cially those with pneurococcal meningitis. In studies of bacterial meningitis in animals, adjuvant treatment

### Dexamethasone - Adult Meningitis Study



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The Lancet · Saturday 13 August 1988

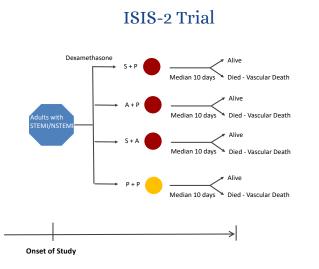


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The present report is of outcome by allocated treatment among all randomised patients, except those 206 (102 active SK vs 104 placebo infusion; 95 active aspirin vs 111 placebo tablets) for whom discharge forms had not yet been obtained by July, 1988. Discharge was at a median of 10 days, and mortality follow-up was for a maximum of 34 and a median of 15 months. The completeness of follow-up is 99% to discharge, 97% to week 5, and 96% to Jan 1, 1988. (About nine-tenths of all deaths in the first 5 weeks occur in hospital, so it is probable that more than 98% of the 5-week deaths among the 17 187 randomised patients are included in the present analysis.)

ISIS-2 Trial. Lancet 1988

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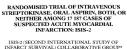
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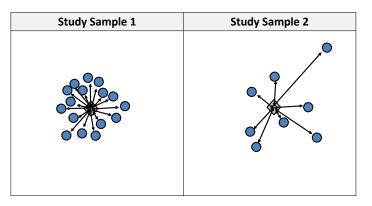
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### Conquering the Biostatistics Question

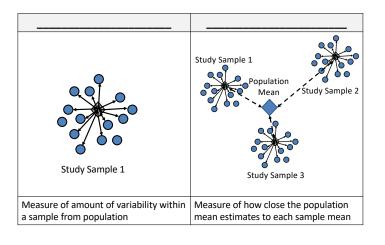
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# Measure of Variability



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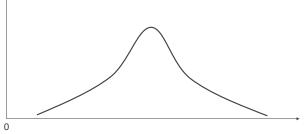
# Chi-squared vs. Fisher's exact

Variable	test	test	
Sample Size	Large	Small	
Desired Accuracy	Approximate	"Exact"	
Considerations	<ul> <li>Becomes more accurate with larger sample sizes</li> </ul>	<ul> <li>More exact regardless of number but harder to calculate by hand using computer.</li> <li>Note: is it really "exact"?</li> <li>Typically used when &gt; 20% of the cells have a frequency of &lt; 5 because an approximation at this level is inadequate.</li> </ul>	

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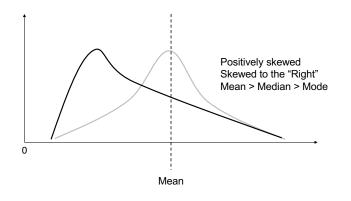
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### Measures of Variability or Data Dispersion

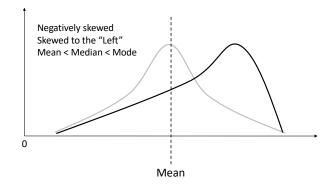


Mean = Median = Mode

### Measures of Variability or Data Dispersion



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Test-Taking Strategies
Circling Back - Application



# Type of Data

# An RCT was done to assess the "average reduction in BP" of a new antihypertensive medication compared to placebo. Is there a sense of order or ranking? Is the magnitude of difference the same?

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- Live Q&A

### Coupon

- Limited time coupon
  - -Coupon = \_\_\_\_
    - 10% OFF ENTIRE ORDER
  - Expires = Sept 30, 2022



### MED REVIEWS

# Live Q&A



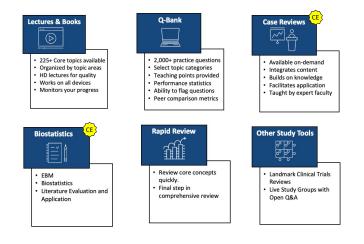


Why Should I Consider High-Yield Med Reviews? ...

### What makes you different?



# High Yield Study Tools

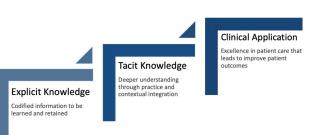


# How does all of that fit together?



# Knowledge Transfer

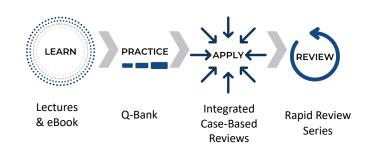
#### The High-Yield Approach



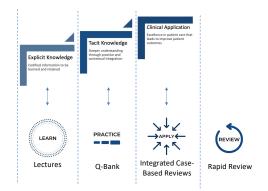
# Knowledge Transfer



# The High-Yield Approach



# The High-Yield Approach



# The High-Yield Approach

