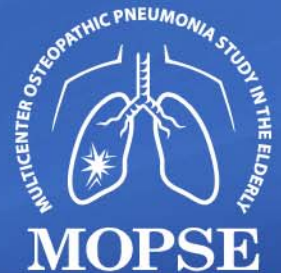
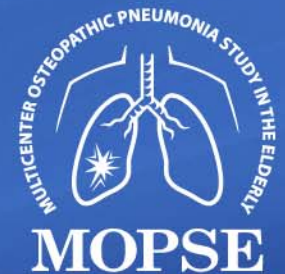


Multicenter Osteopathic Pneumonia Study in the Elderly (MOPSE)

The Primary Outcomes



BACKGROUND



MOPSE

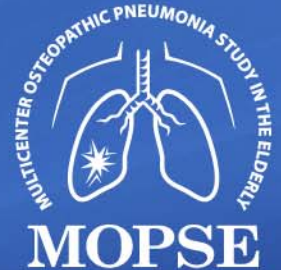
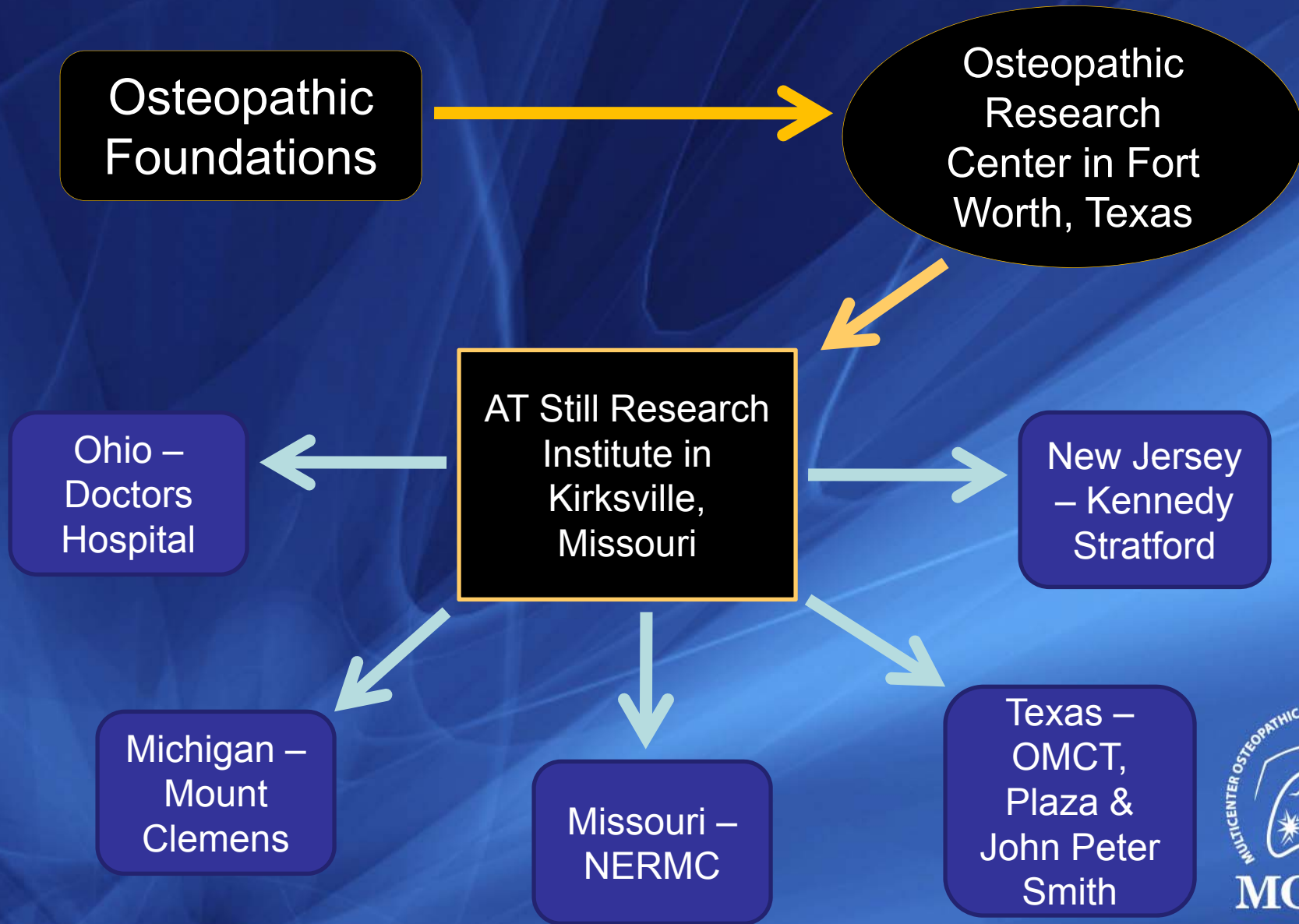
(Multicenter Osteopathic Pneumonia Study in the Elderly)

- A registered study at www.clinicaltrials.gov
- Conducted between March 2004 and April 2007
- Protocol Paper: www.jaoa.edu
 - Noll DN, Degenhardt BF, Fossum C, and Hensel K. *Clinical and Research Protocol for Osteopathic Manipulative Treatment of Elderly Patients with Pneumonia* JAOA September 2008; 108: 508-516
- Main Outcomes Paper: www.om-pc.com
 - Noll DR, Degenhardt BF, Morley FM, Blais FX, Hortos FA, Hensel K, Johnson CJ, Pasta DJ, and Stoll ST. *Efficacy of osteopathic manipulation as an adjunctive treatment for hospitalized patients with pneumonia: a randomized controlled trial.* Osteopathic Medicine and Primary Care 2010, 4:2

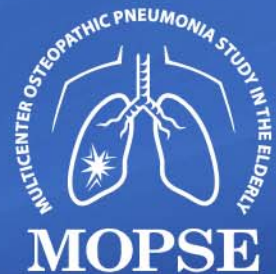
Funded by a Consortium of Osteopathic Foundations

- Brentwood Foundation (Ohio)
- Colorado Springs Osteopathic Foundation (Colorado)
- Foundation for Osteopathic Health Services (Maryland)
- Muskegon General Osteopathic Foundation (Michigan)
- Northwest Oklahoma Osteopathic Foundation (Oklahoma)
- Osteopathic Founders Foundation (Oklahoma)
- Osteopathic Institute of the South (Georgia)
- Osteopathic Heritage Foundation (Ohio)
- Quad City Osteopathic Foundation (Iowa)

Multicenter study structure

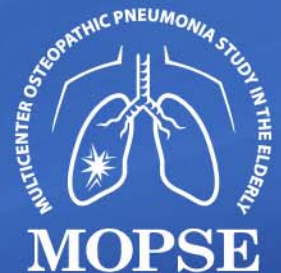


Study Methods



Primary Hypothesis

- Osteopathic Manipulative Treatment will:
 - Reduce length of stay (LOS)
 - Reduce time to clinical stability
 - Improve the symptomatic and functional recovery score



Length of stay (LOS)

- A traditional measure
- Taken from the time and date the order was written for;
 - Admission
 - Discharge
 - Or the closest approximation found in the chart
- At midnight, a new day starts

Time to Clinical Stability

- Measured DAILY – The # of days it takes for all SEVEN clinical measures to be “stable”
 - Lowest Systolic BP ≥ 90 mmHg
 - Highest Heart Rate ≤ 100 beats / minute
 - Highest Respiratory Rate ≤ 24 breaths / minute
 - Highest Temperature 38 degrees Centigrade
 - Lowest Oxygen Saturation $\geq 90\%$
 - Ability to eat by mouth or feeding tube
 - Mental status grossly back to baseline

Halm JP, et al. *Time to clinical stability in patients hospitalized with community-acquired pneumonia: implications for practice guidelines.* JAMA 1998, 279;1452-1457.

Symptomatic and Functional Recovery Score (SFRS)

- Calculated from a pneumonia-specific validated questionnaire
 - Cough, Dyspnea, Sputum production, Pleuritic chest pain, and Fatigue
- Higher SFRS, the worse the symptoms
- Measured on
 - Admission (Day 1), Day 14, Day 30 and Day 60

Metlay JP et al. *Measuring symptomatic and functional recovery in patient with community-acquired pneumonia.* J Gen Intern Med 1997, 12:423-430

MOPSE Key Aspects (Slide I)

1. Randomized Controlled Clinical Trial
 - Efficacy study, not a mechanistic study
2. Seamless Design
 - Not to interfere with usual care
3. Blinded Study
 - For the decision makers
4. Three arm study design
 - OMT group
 - Light touch “sham” group
 - Conventional care only group

MOPSE Key Aspects (Slide II)

5. OMT is an adjunctive treatment modality
 - Does not replace conventional care
6. Balances uniformity with individualization
 - 15 minutes standard, 5 minutes specific
7. Best effect design over pragmatic design
 - Build upon the previous studies
8. 24 hour window
 - From admission to first treatment

Inclusion Criteria

- Age \geq 50 years
- NEW pulmonary infiltrate on x-ray
- Two of the following
 - New, increased cough
 - Fever \geq 38 degrees Centigrade
 - Pleuritic chest pain
 - New findings on physical exam
 - Respiratory rate \geq 25 bpm
 - Mental status change
 - WBC \geq 12,000 cells/mm³

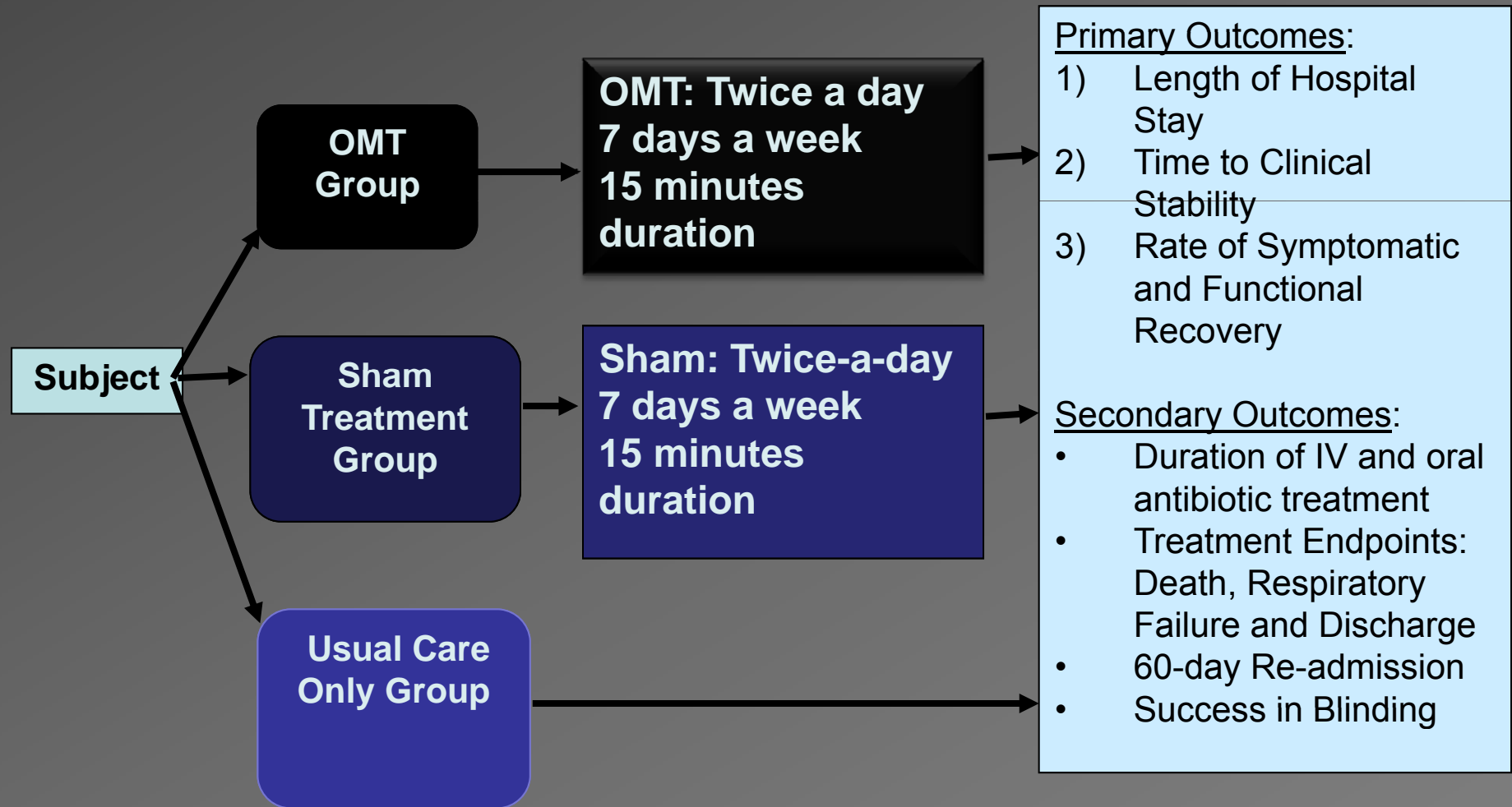
Exclusion Criteria

- Nosocomial Pneumonia
- Lung Abscess
- Advancing Pulmonary Fibrosis
- Bronchiectasis
- Pulmonary Tuberculosis
- Lung Cancer
- Metastatic Cancer
- Acute Rib or Vertebral Fracture
- Previous Participation

Eight Standardized Techniques

1. Thoracolumbar soft tissue
2. Rib raising
3. Doming of the diaphragm myofascial release
4. Cervical soft tissue
5. Suboccipital decompression
6. Thoracic inlet myofascial release
7. Thoracic lymphatic pump
8. Pedal lymphatic pump

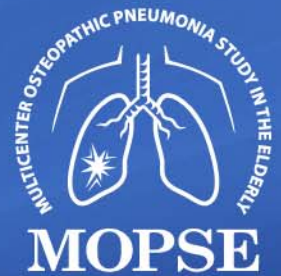
MOPSE Study Design Summary



Two Kinds of Statistical Analysis

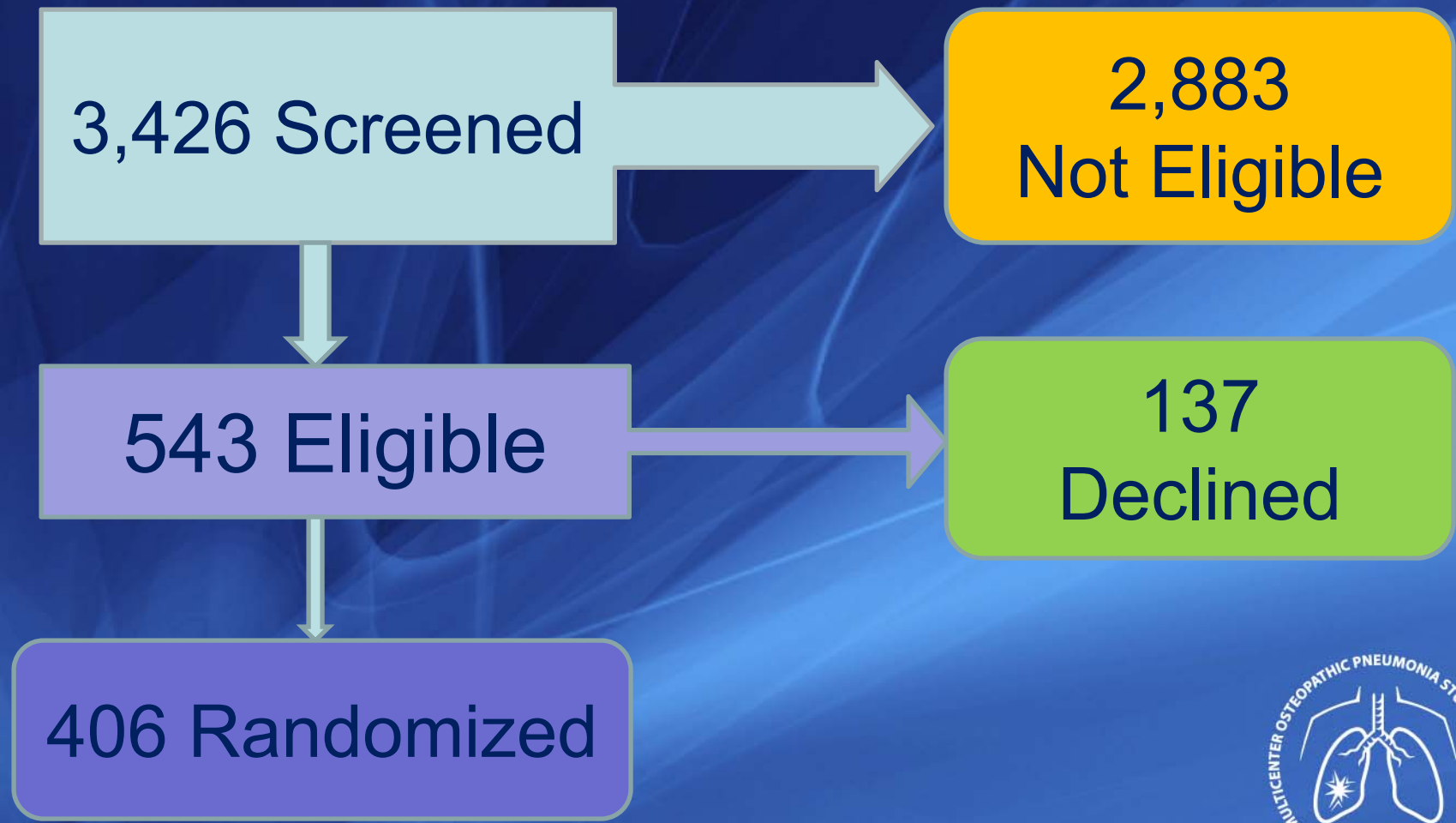
- Intention to treat analysis
 - Everyone who randomized into the study
 - Excludes for change in diagnosis
 - Excludes for first treatment beyond 30 hours
- Per protocol analysis
 - Everyone who got the protocol as designed
 - Excludes for first treatment beyond 24 hours
 - Excludes for treatment contrary to protocol
 - Excludes subjects who dropped out of the study
 - Excludes for missing a treatment session

RESULTS



Subject Recruitment

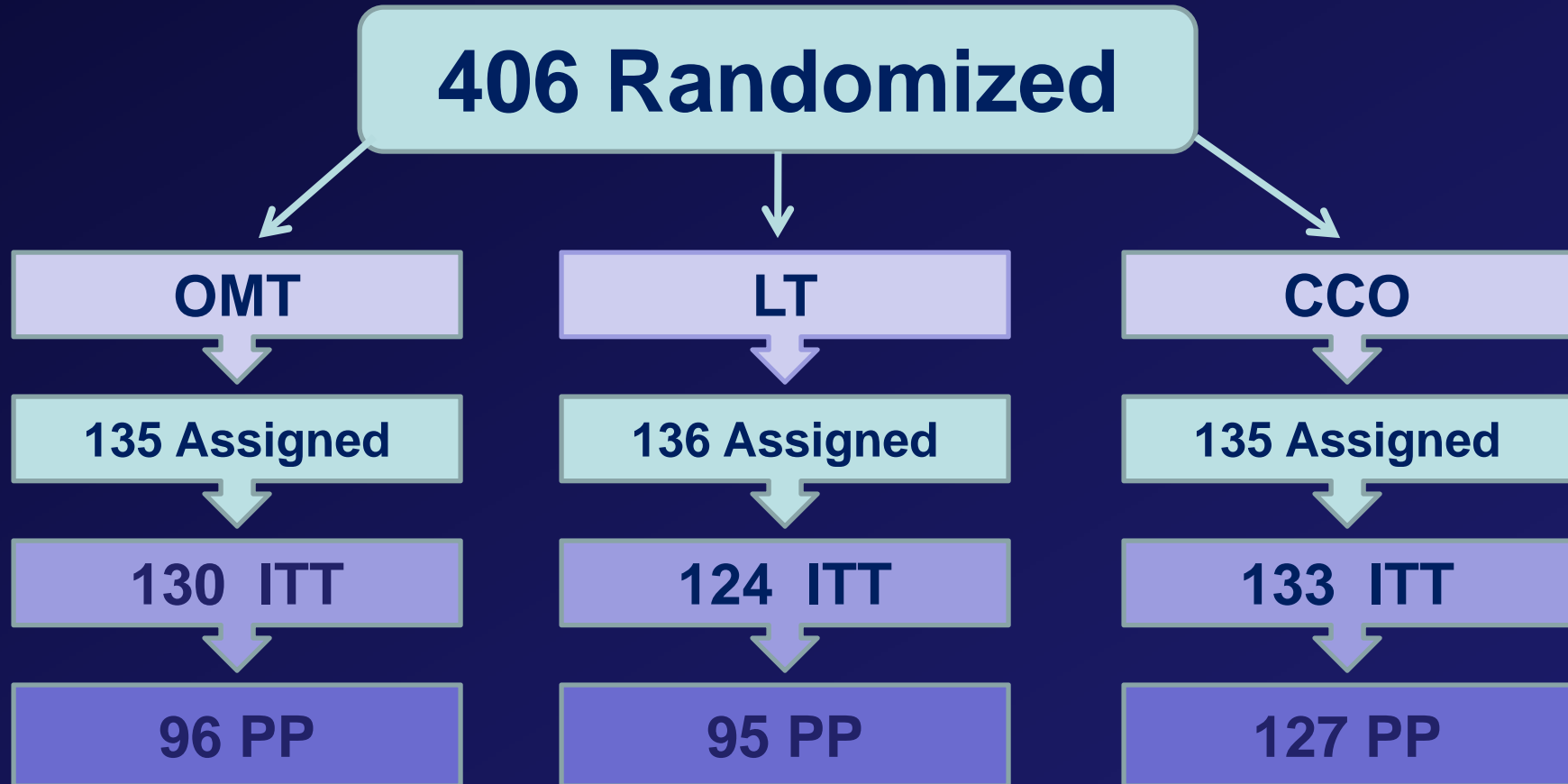
(from seven community hospitals)



Demographics

- Antibiotic Selection
 - 84% agreement with practice guidelines
- Demographics
 - No differences, except
 - Aspiration risk (LT > CCO) by ITT analysis
 - Current Alcohol Use (OMT < LT, CCO) by PP analysis
- Pneumonia Severity Index
 - no between group differences

Randomization and Numbers



ITT = Intention to treat statistical analysis

PP = Per protocol statistical analysis

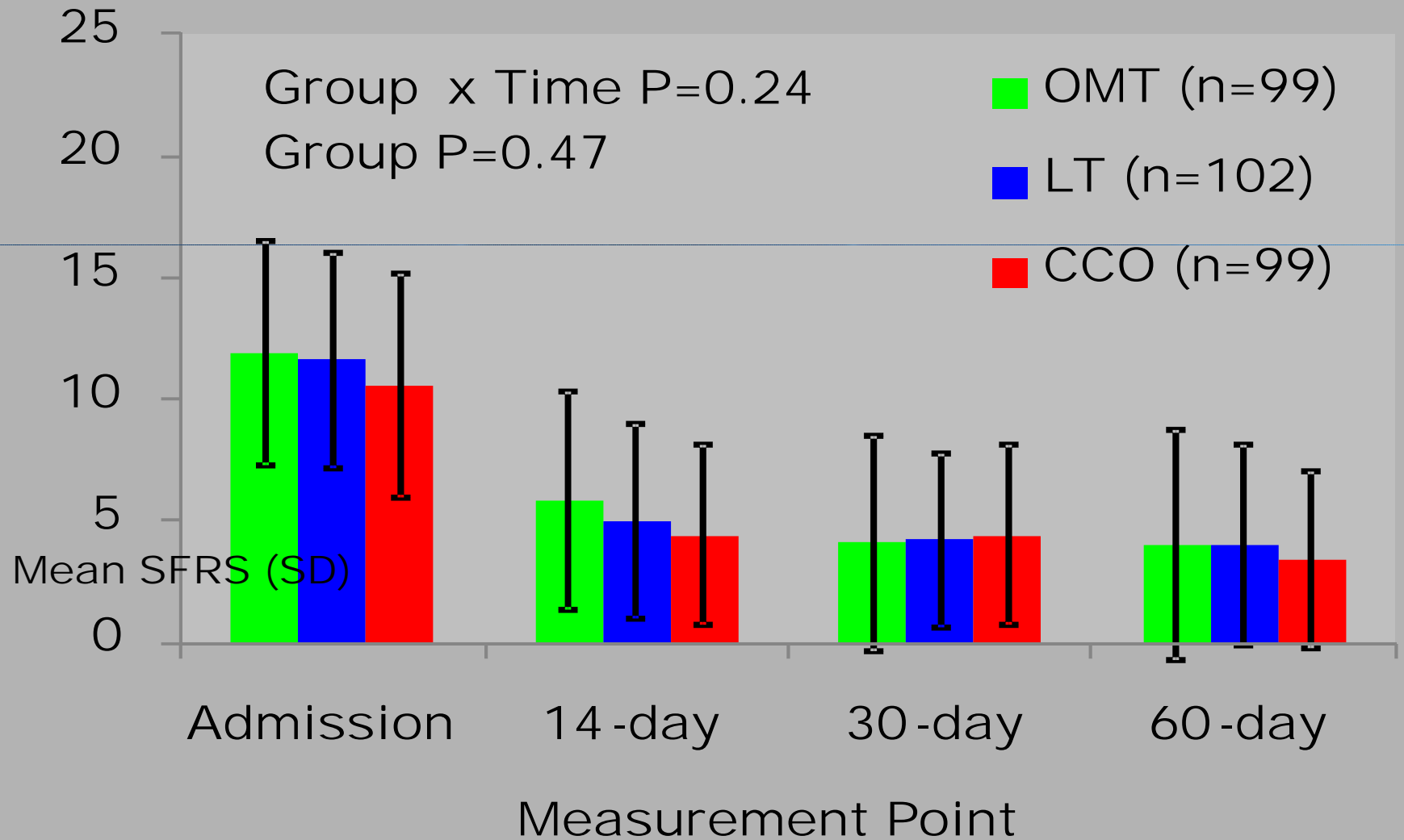
Mean LOS

OMT	LT	CCO	
Intention to treat analysis			
n = 130	n = 124	n = 133	
4.5 days (SD 2.7)	4.9 days (SD 2.7)	4.5 days (SD 2.6)	p = 0.53
Per protocol analysis			
n = 96	n = 95	n = 127	
4.0 days (SD 2.0)	4.4 days (SD 2.4)	4.5 days (SD 2.6)	p = 0.01 (OMT<CCO)

Time to Clinical Stability

OMT	LT	CCO	
Intention to treat analysis			
n = 121	n = 118	n = 130	
2.5 days (SD 1.6)	2.5 days (SD 1.4)	2.6 days (SD 1.6)	p = 0.97
Per protocol analysis			
n = 90	n = 90	n = 124	
2.3 days (SD 1.4)	2.5 days (SD 1.5)	2.6 days (SD 1.6)	p = 0.47

Symptomatic and Functional Recovery Score (no statistical difference)



Treatment End Point Data: Intent to treat analysis

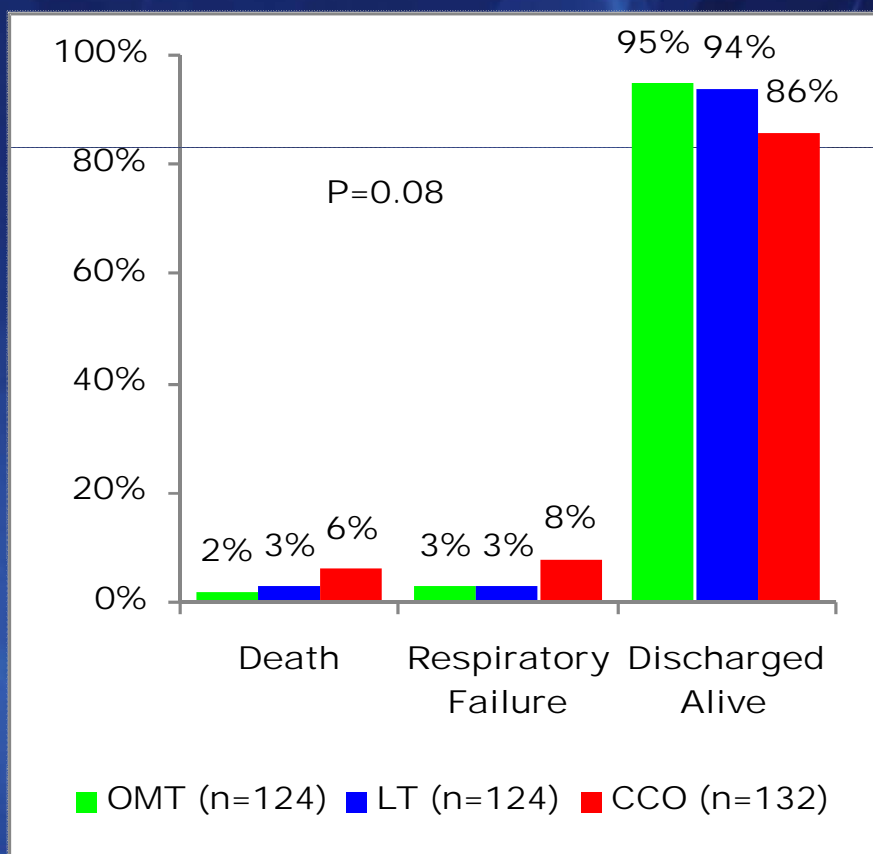
	OMT	LT	CCO	
	n = 124	n = 124	n = 132	
Death	2%	3%	6%	
Respiratory Failure	3%	3%	8%	
Discharged Alive	95%	94%	86%	p = 0.08

Treatment End Point Data: By per protocol analysis

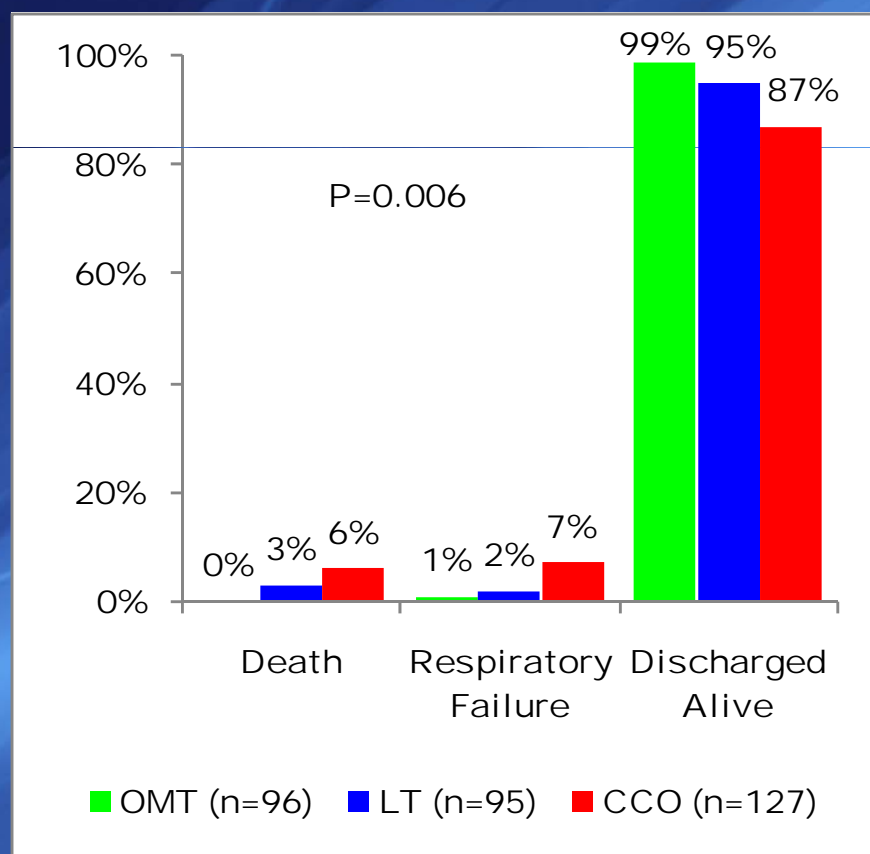
	OMT	LT	CCO	
	n = 96	n = 95	n = 132	
Death	0%	3%	6%	
Respiratory Failure	1%	2%	7%	
Discharged Alive	99%	95%	87%	p = 0.006

Treatment Endpoint

Intention-to-Treat Analysis



Per-Protocol Analysis



60-Day Readmission Rate

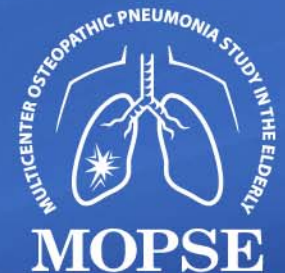
OMT	LT	CCO	
By intention to treat analysis			
n = 93	n = 96	n = 96	
17 %	20 %	21 %	p = 0.64
OMT	LT	CCO	
By per protocol analysis			
N = 80	N = 79	N = 92	
11 %	20 %	21 %	p = 0.16

Blinding: Percent Correctly Identifying their Group

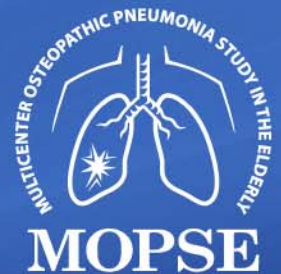
Intention to treat analysis

OMT	LT	CCO
53 %	44 %	49 %

Per protocol analysis produced similar numbers



Conclusions and Discussion

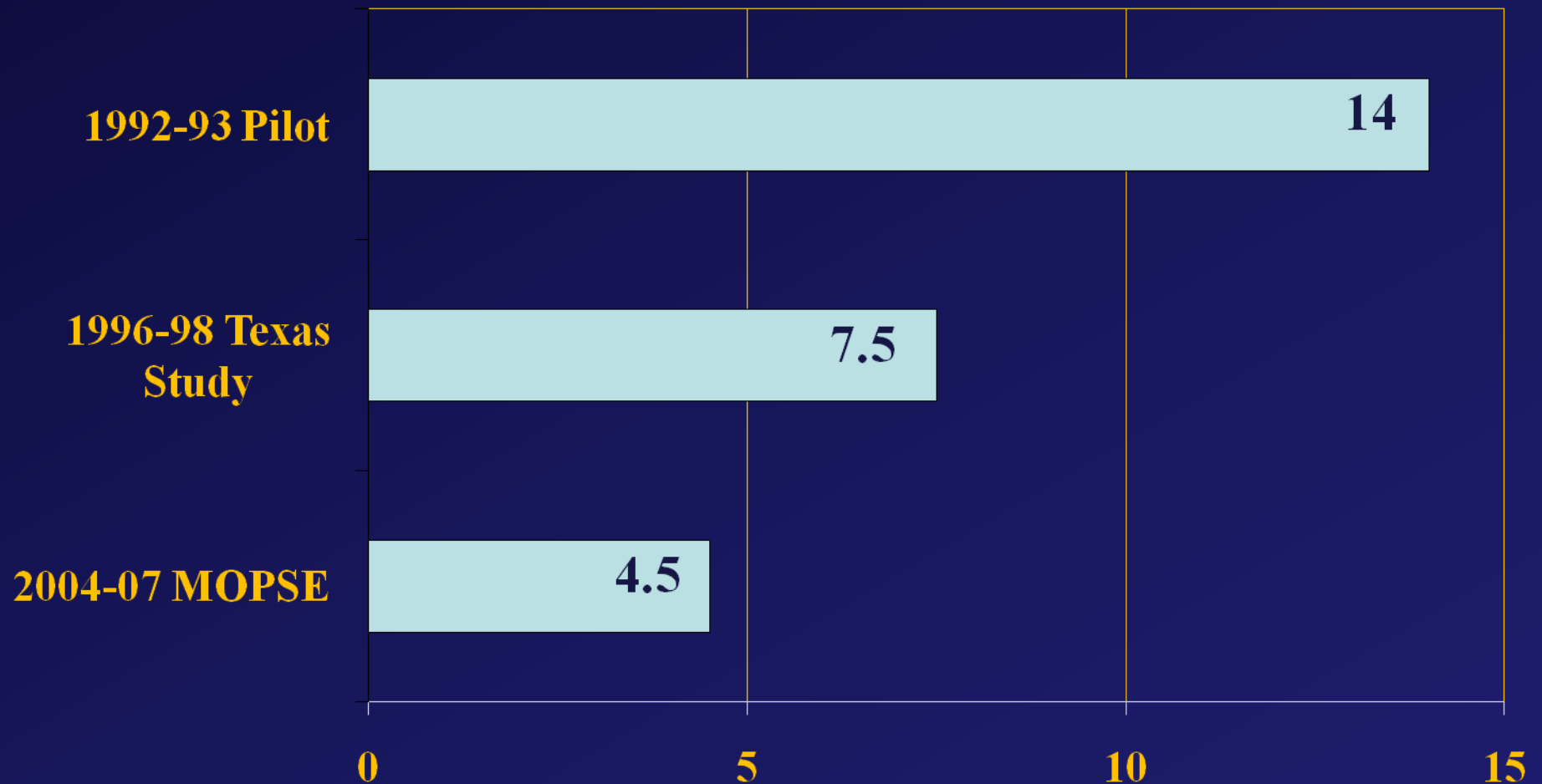


Conclusions

- By ITT analysis
 - outcomes not improved
- By PP analysis
 - OMT decreased LOS, duration IV antibiotics, and Mortality
 - Relative to the CCO group
- LT groups
 - outcomes tended to fall between the OMT and CCO outcomes

Changing Mean Length of Stay for Pneumonia in the Elderly

■ Average Length of Hospital Stay in Days



Points for Discussion

- Does the shortened hospital LOS make OMT obsolete?
 - Where might OMT find a therapeutic role?
- How significant are the positive outcomes?
 - ITT analysis verses PP analysis
- Is LT more like OMT or CCO?
 - How should the three group outcomes be interpreted?

Stay tuned for the panel discussion



MOPSE Research Team

MOPSE