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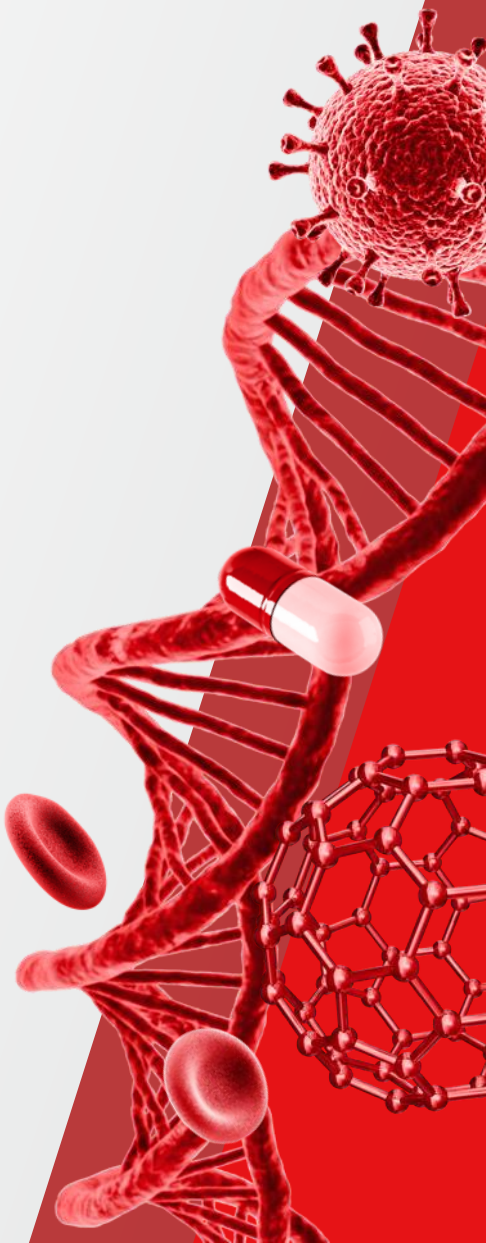
How to Expertly Use Procalcitonin to Safely Reduce Antibiotic Use and Improve Outcomes



Mike Broyles, PharmD

Director of Medical Affairs, Biomarkers

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Objectives

- Differentiate the pathophysiology and kinetics of procalcitonin (PCT) in comparison to current biomarkers of infection
- Establish the role of procalcitonin in Antimicrobial Stewardship (AMS or ABS or ASP's)
- Apply PCT principles of use in case studies
- Translate published clinical and health economic data on expected outcomes with proper use

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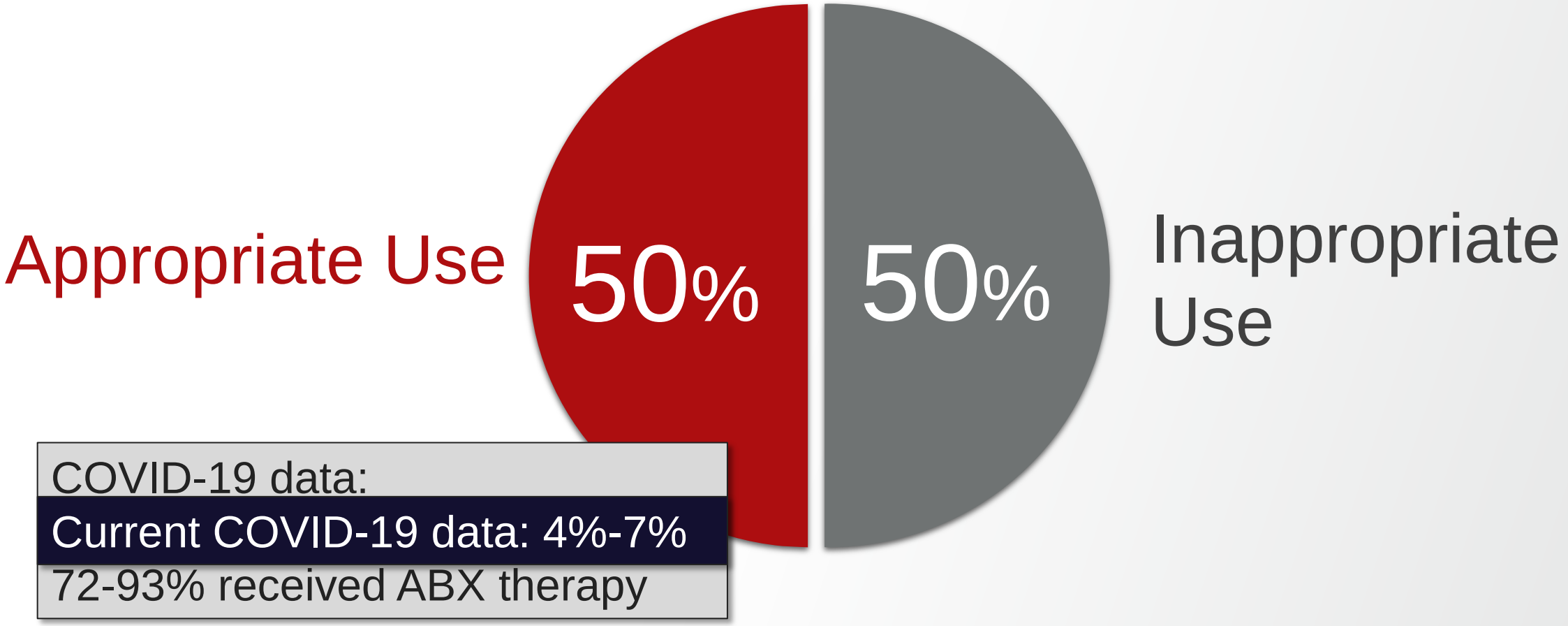
Antimicrobial Use and "Misuse"

Acute Care Setting

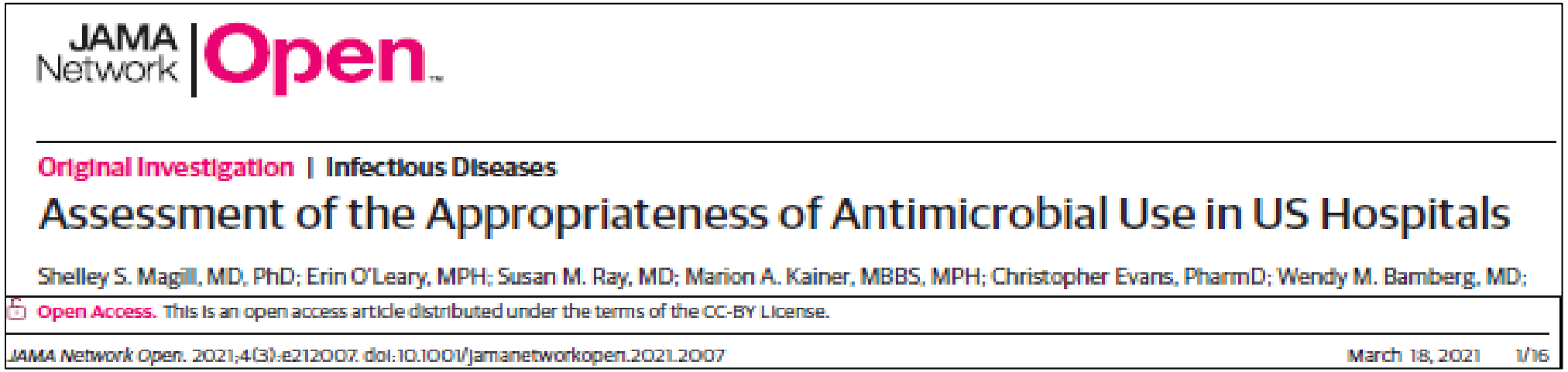


COVID-19 data:

Current COVID-19 data: 4%-7%

72-93% received ABX therapy

Fridkin S, et al. Morbidity and Mortality Weekly Report. United States Center for Disease Control and Prevention. 2014;63(09):194-200.



JAMA Network | Open

Original Investigation | Infectious Diseases

Assessment of the Appropriateness of Antimicrobial Use in US Hospitals

Shelley S. Magill, MD, PhD; Erin O'Leary, MPH; Susan M. Ray, MD; Marion A. Kainer, MBBS, MPH; Christopher Evans, PharmD; Wendy M. Bamberg, MD;

JAMA Network Open. 2021;4(3):e212007. doi:10.1001/jamanetworkopen.2021.2007 March 18, 2021 1/16

Evaluated four common prescribing habits in hospitalized patients for CAP & UTI in 192 hospitals

- Overall: 55.9% inappropriate
- CAP: 79.5% inappropriate
- UTI present on admission, 76.8% inappropriate
- Patients prescribed fluoroquinolones, 46.5% not recommended
- Patients prescribed IV vancomycin, 27.3% not recommended

HOME | INFECTION PREV

Too many antibiotics

Sep 2nd, 2020

Photo by Volodymyr Hryshchenko

AUGUST 4, 2020

Many COVI antibiotics,

by Amy Norton, Healthday Re

Treating COVID-19 may increase antibiotic resistance

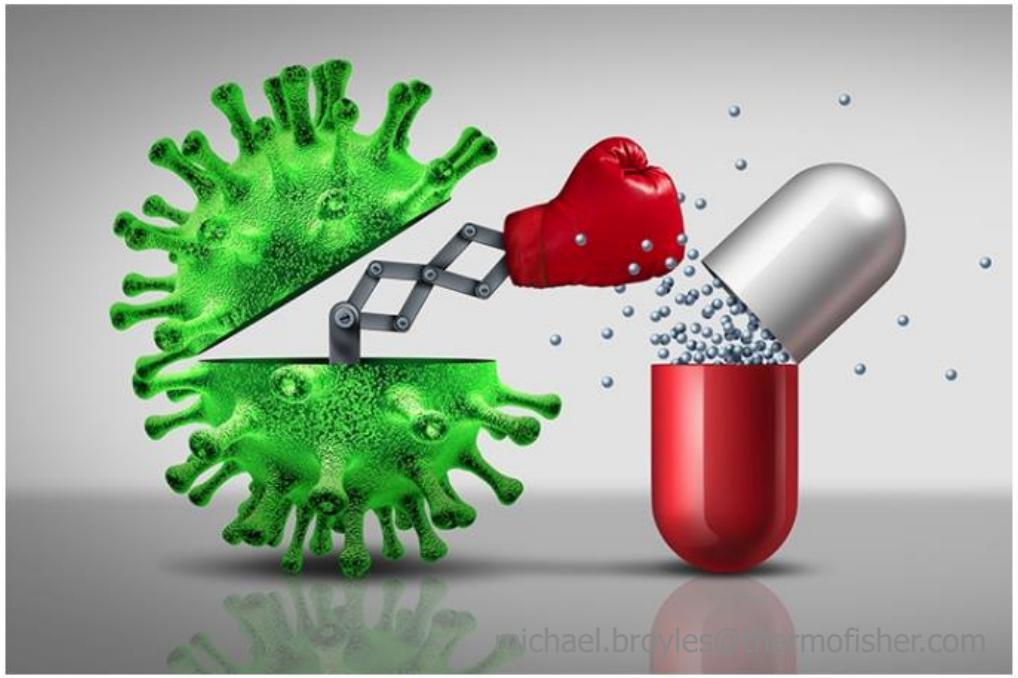
may result
an involve
ects may be

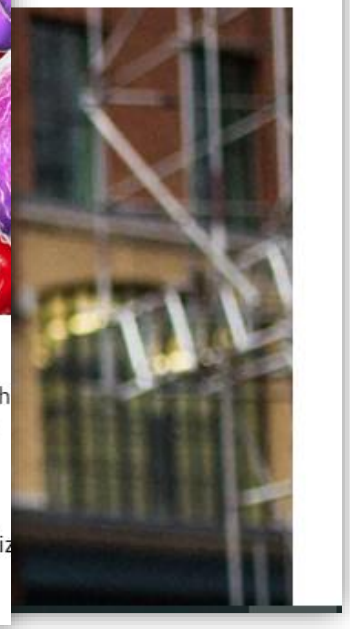
Infectious Disease > COVID-19

COVID-19 Antibiotic Overuse Puts Stewardship Efforts at Risk

— Researchers worry that copious prescriptions will worsen resistance problem

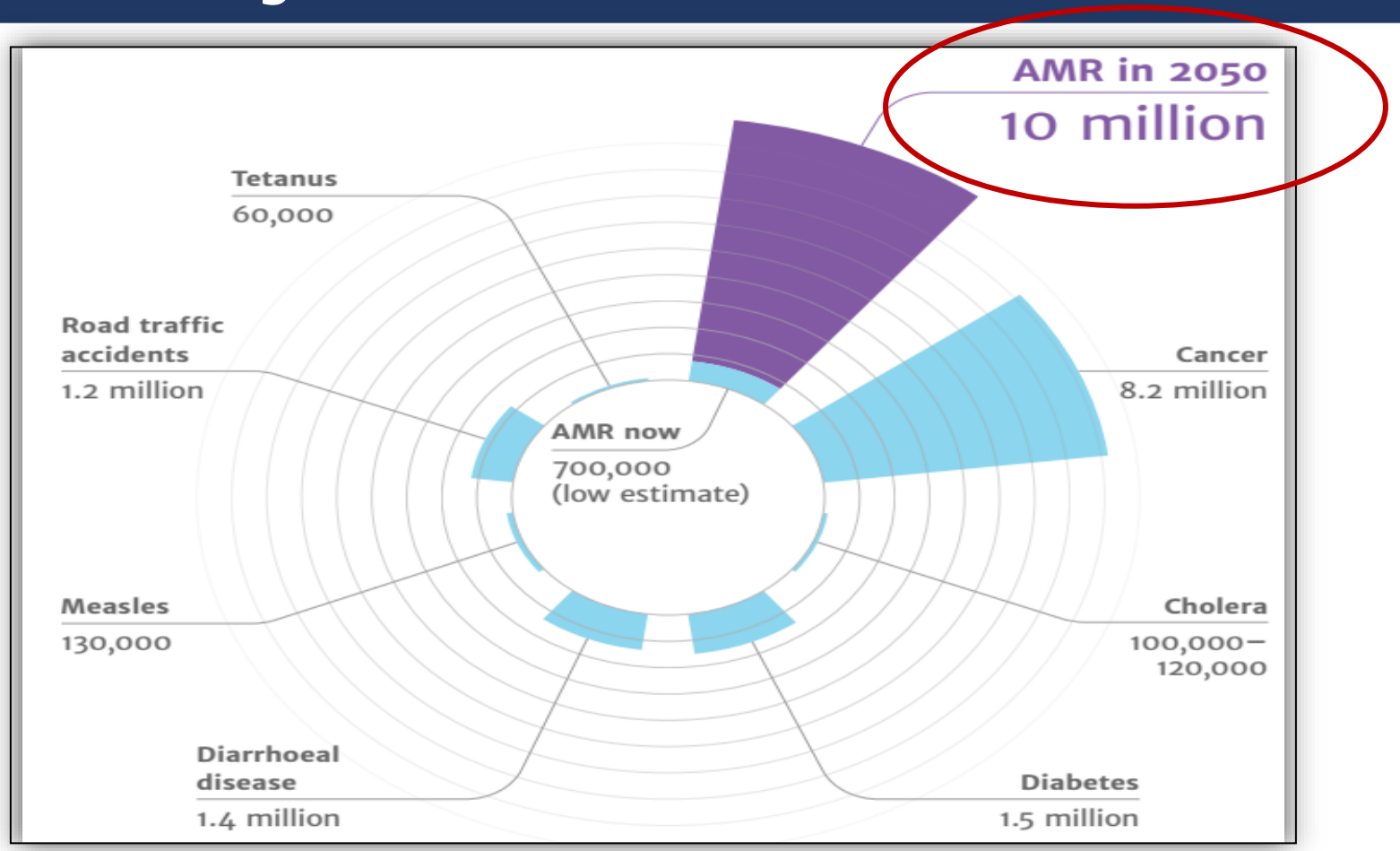
by Ryan Basen, Enterprise & Investigative Writer, MedPage Today May 12, 2020





AMR will become the leading cause of death worldwide

"Left unchecked, the current trend in rising drug resistance is a crisis of global scale"



ESTIMATED YEARLY DEATHS BY 2050

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Tackling drug-resistant infections globally: final report and recommendations. May 2016. (https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf) Accessed 9/25/2017

C. difficile disease or CDAD

- Hospitalizations for CDAD doubled from 2000 to 2010 in the U.S.; now estimated at just under 500,000 annually
- Antibiotics increase risk of CDAD by 7 to 10 times while receiving ABX and up to 1 month later and duration increases the risk
- One in six will get infected with *C. difficile* and will get it again in the subsequent 2 to 8 weeks
- 80% of deaths occur in patients aged 65 and greater
- Within 1 month of diagnosis, 1 in 11 people over age 65 died from CDAD

https://www.cdc.gov/hai/organisms/cdiff/cdiff_infect.html
https://www.cdc.gov/cdiff/clinicians/faq.html

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C. difficile disease or CDAD

Your actions will make a difference!

- 183 hospital study: 30% reduction in use of broad-spectrum ABX will result in a 26% reduction in CDI
- ABX treatment reduction by 1.7 day is expected to lead to an 18% relative reduction in CDI

https://www.cdc.gov/hai/organisms/cdiff/cdiff_infect.html
https://www.cdc.gov/cdiff/clinicians/faq.html
MMWR, CDC S Fridkin, 2012
M van der Maas, ISPOR Congress, 2015

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Poll Question 1: PCT Basics

a. The amount of PCT made and released into the blood stream is in direct proportion to the number of bacteria at the infection site: true or false
b. PCT is stored in cells and released immediately after the TLR is activated by bacteria and related toxins: true or false
c. The initial value for PCT is a good indicator of bacterial burden at time the sample was taken, if the value is elevated then there is no need to repeat the sample the next day: true or false

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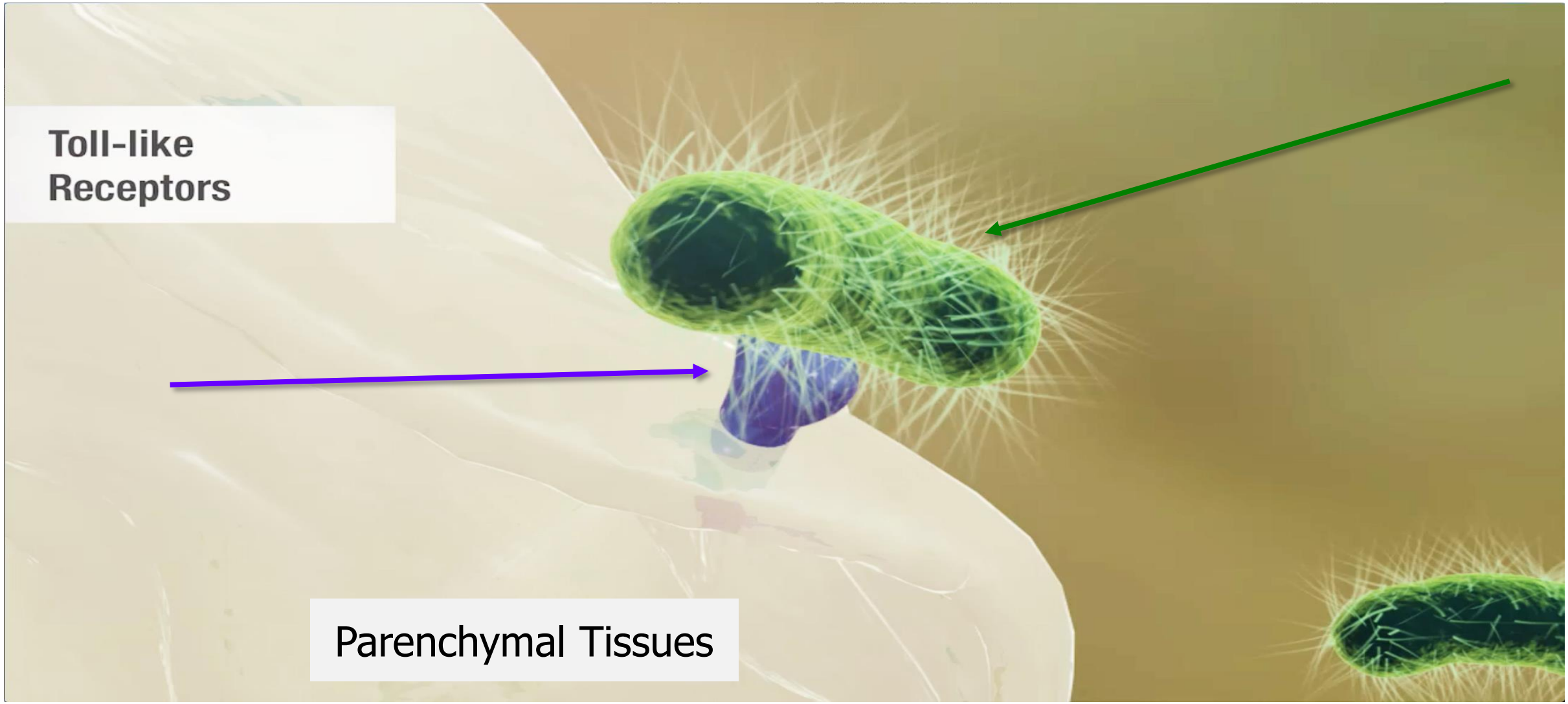
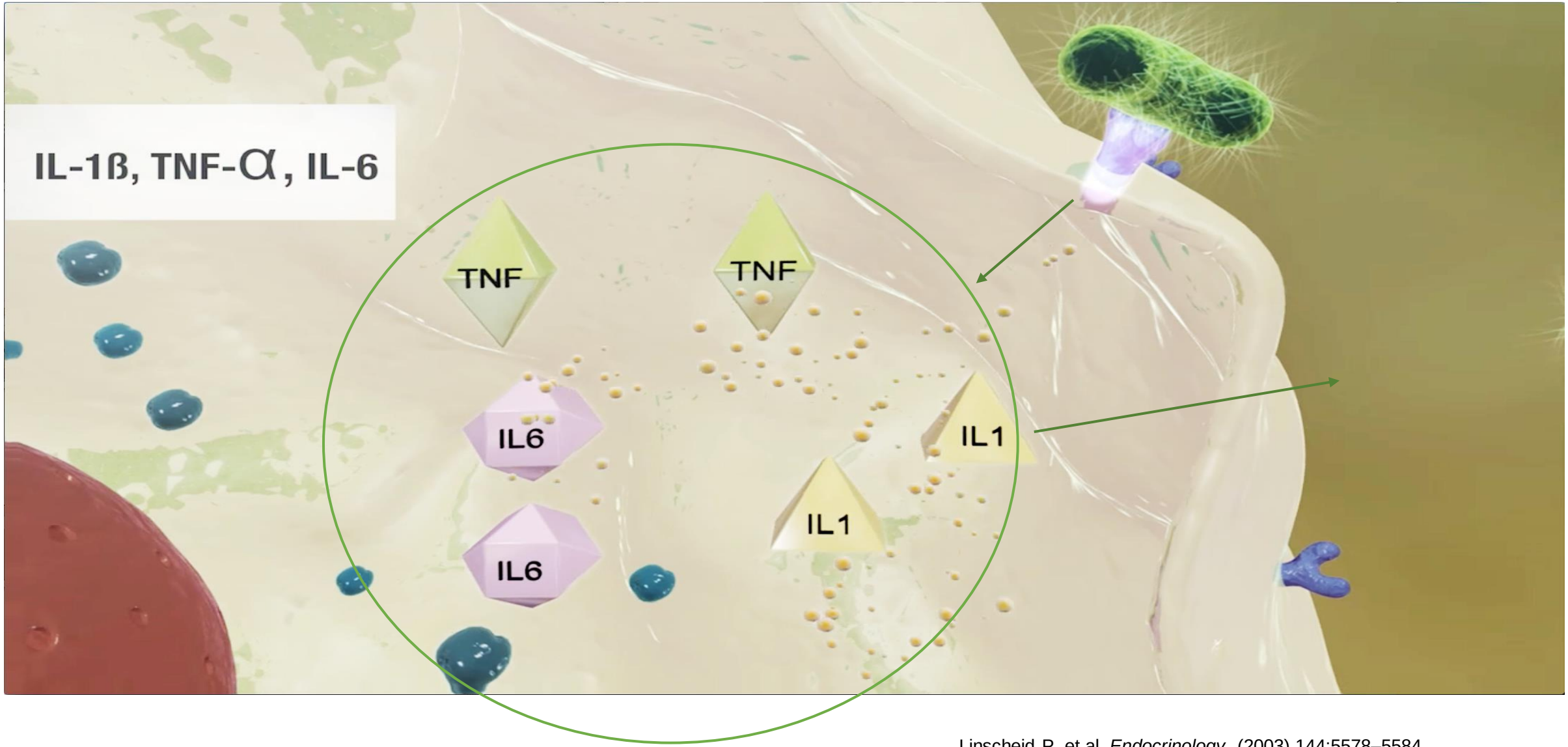
Toll-Like Receptor and Microbial Toxins



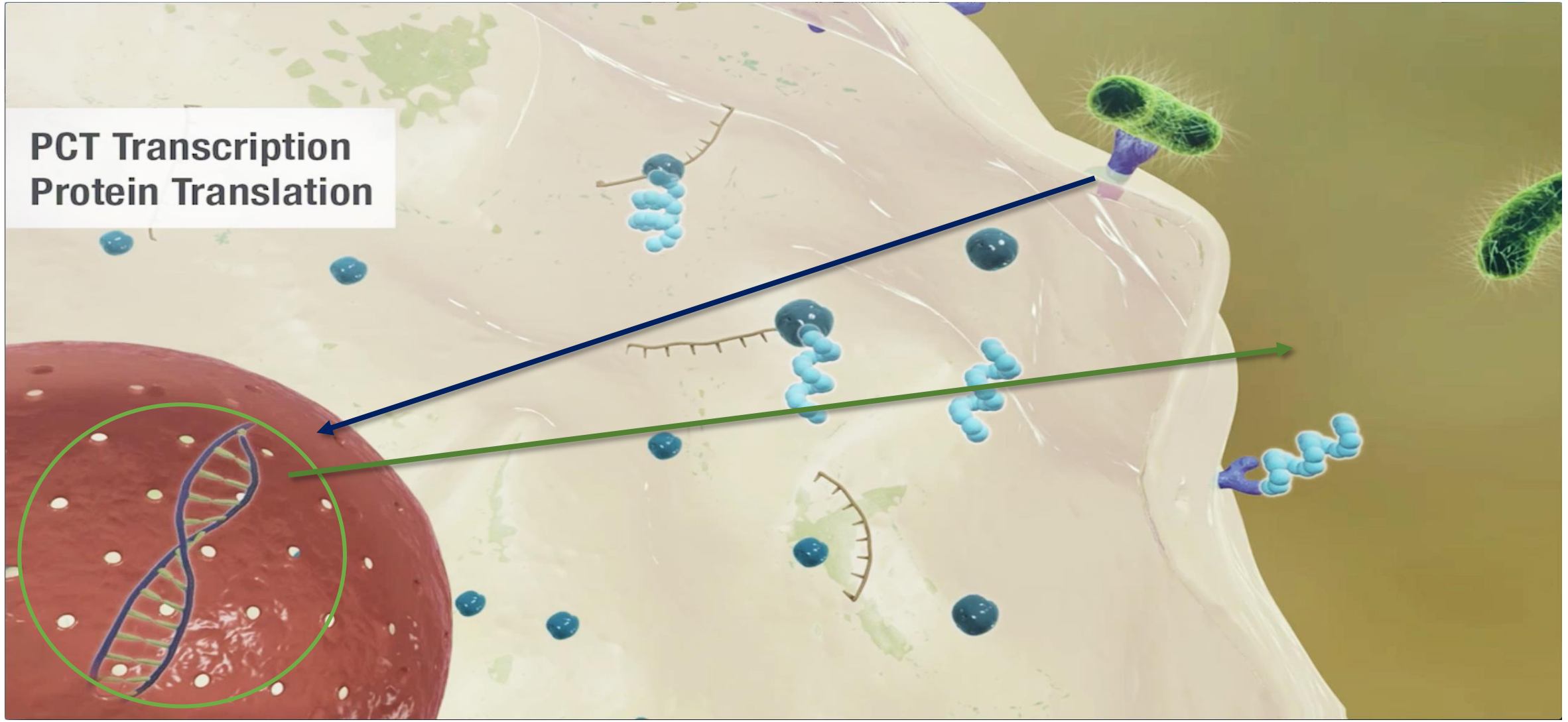
Ryu YH, et al. *Int Immunopharmacol*. (2009) 9:127–133

The key: the toll like receptor



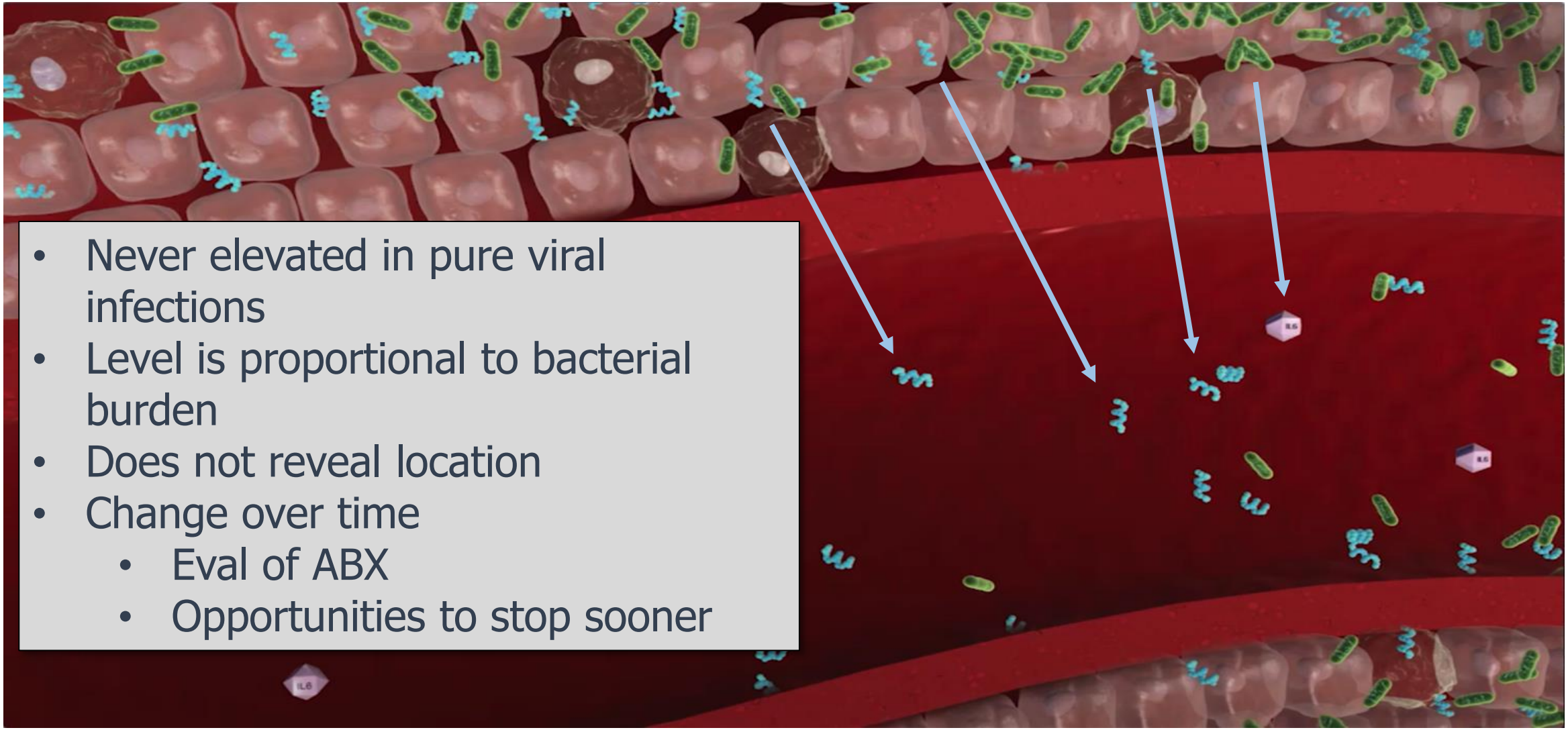
Linscheid P, et al.,*Endocrinology* (2003) 144:5578–5584.

PCT secretion after PCT transcription



Linscheid P, et al.,*Endocrinology* (2003) 144:5578–5584.

PCT release and severity of infection

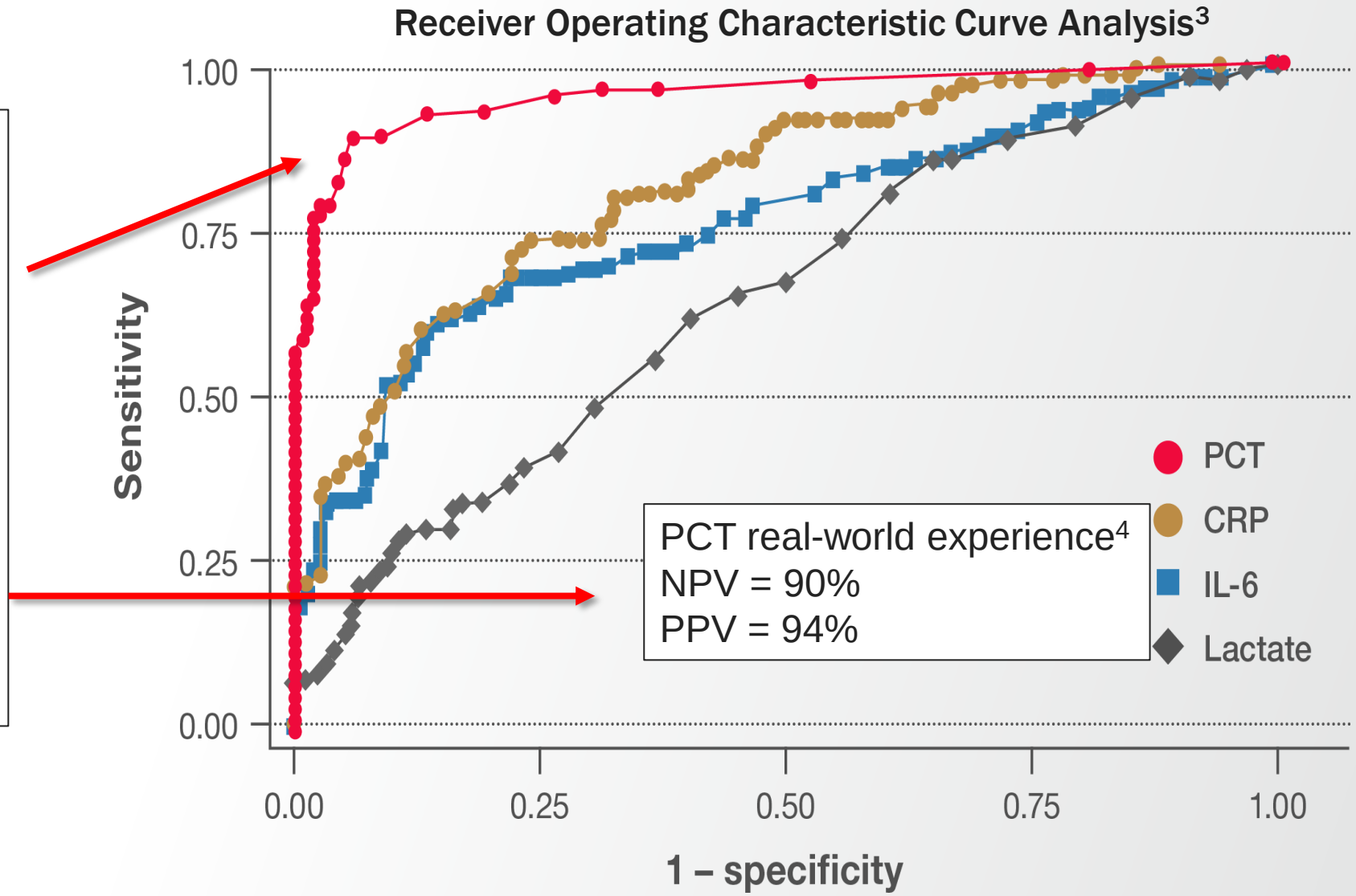


- Never elevated in pure viral infections
- Level is proportional to bacterial burden
- Does not reveal location
- Change over time
  - Eval of ABX
  - Opportunities to stop sooner

Brunkhort FM et al., *Intens. Care Med* (1998) 24: 888-892

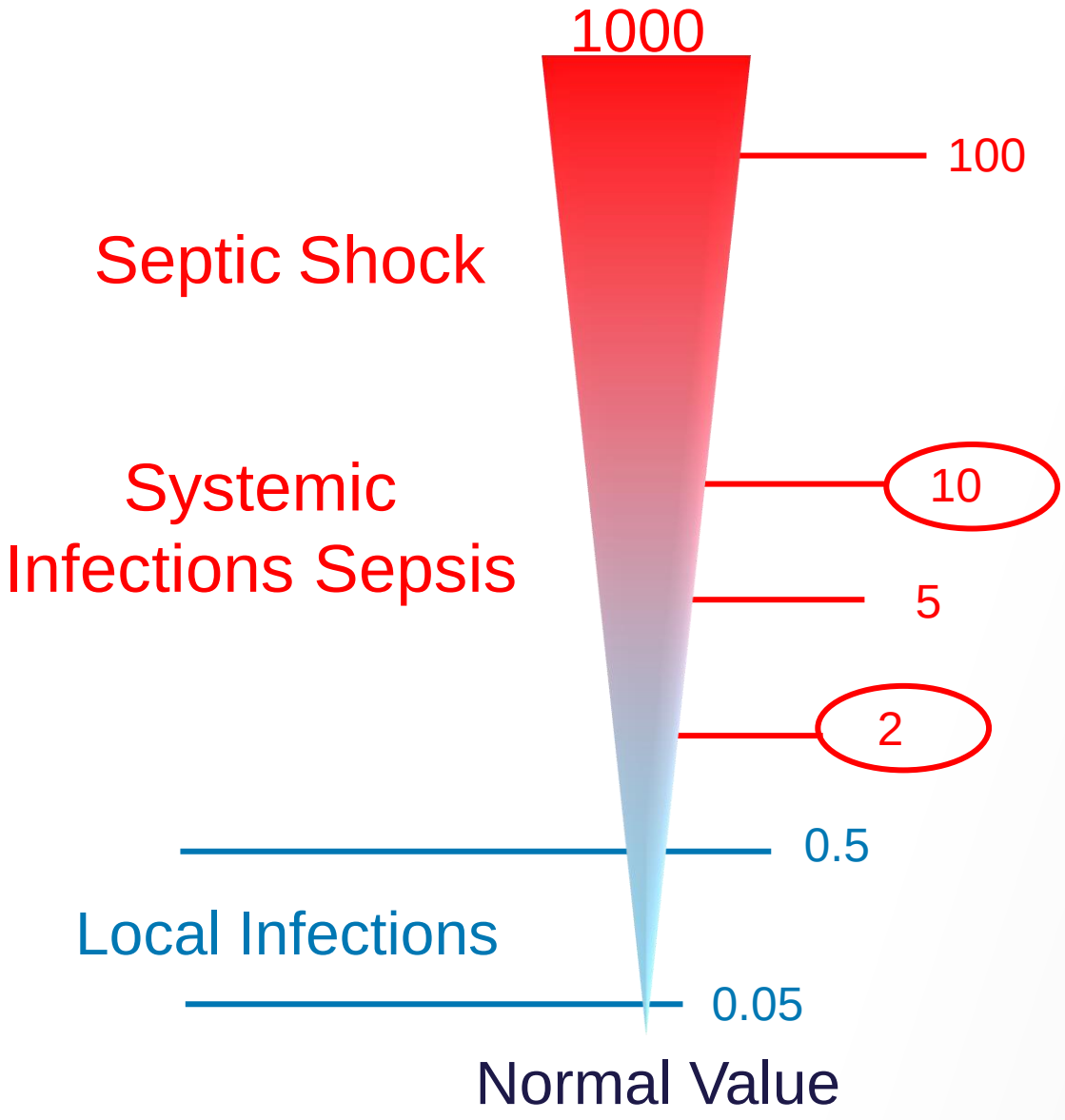
Specificity and sensitivity of PCT make it a better biomarker than CRP, IL-6, and lactate

- PCT is a more sensitive and specific marker of sepsis vs serum CRP, IL-6, and lactate levels[1]
- The diagnostic accuracy of PCT was higher than that of CRP among patients hospitalized for suspected bacterial infections[2]



1. Müller B, et al. *Crit Care Med*. 2000;28(4):977-983. 2. Simon L, et al. *Clin Infect Dis*. 2004;39(2):206-217 3. Lee H. *Korean J Intern Med*. 2013;28(3):285-291.

PCT Interpretation



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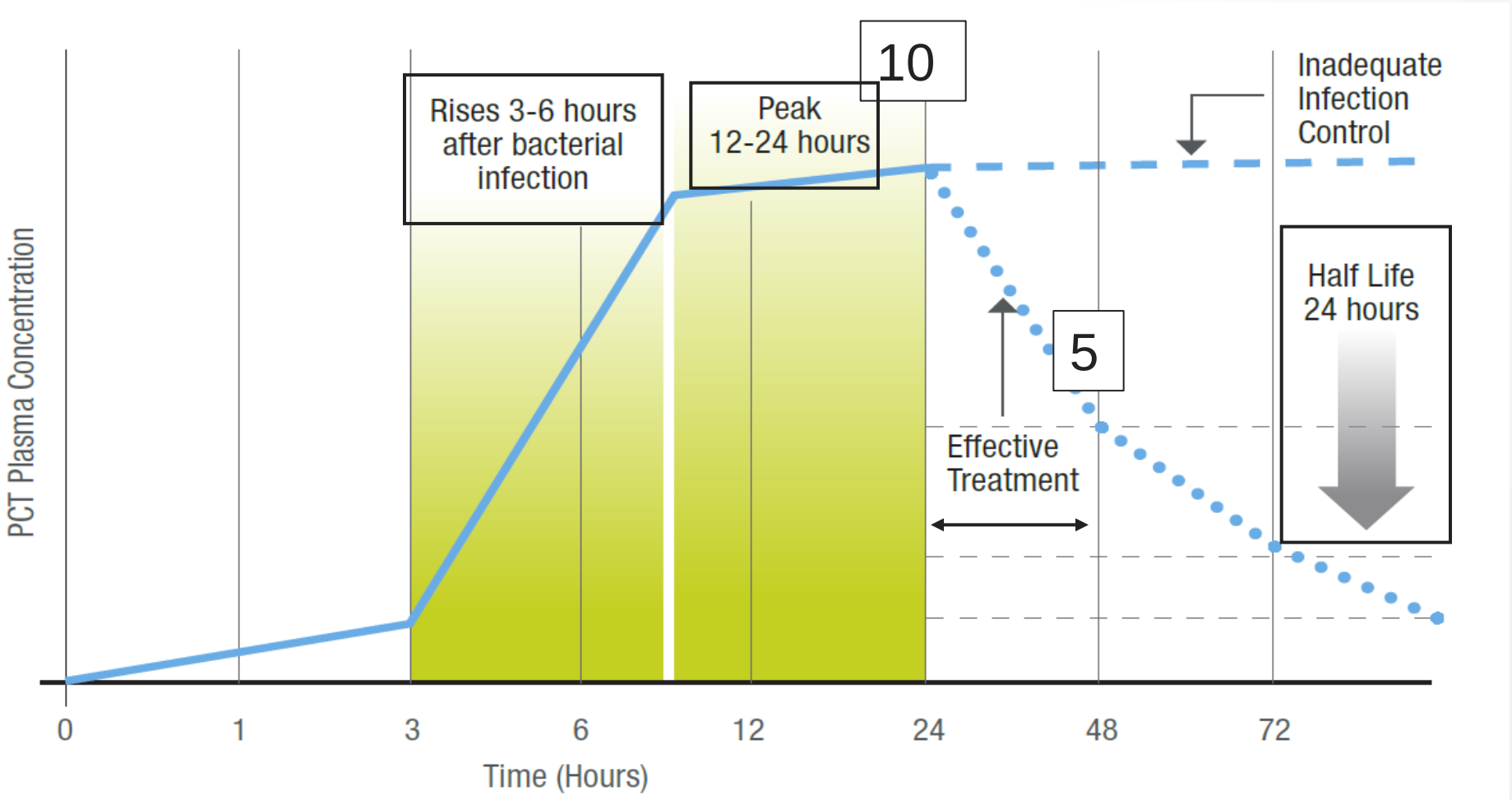
PCT concentrations and sepsis risk

- Less than 0.5ng/ml - low risk for progression to sepsis and septic shock
- Between 0.5 and 2ng/ml – sepsis should be considered
- Greater than 2ng/ml – high risk for progression to sepsis and septic shock
- Correlates with bacterial burden or bacterial load

Harbarth S et al. AJRCC Med. 2001;164:396-402.
Meisner M et al. Crit Care. 1999, 3:45-50.
Krüger S et al. Eur Respir J. 2008;31: 349–55.

Understanding PCT Kinetics



- Rises 3-6 hours after bacterial infection
- Peak occurs 12-24 hours
- Half life of PCT is 24 hours
- Can take 24 hours of appropriate antibiotic therapy to see reduction in serum PCT
- PCT production and serum concentrations will decrease by up to 50% per day with appropriate antibiotic treatment
- If antibiotic therapy is inadequate, PCT levels will remain high

B·R·A·H·M·S PCT is a sensitive and specific biomarker in response to bacterial infection

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Brunkhorst FM et al: Kinetics of Procalcitonin in Iatrogenic Sepsis. Intensive Care Med 1998;24(8):888-889.

B·R·A·H·M·S PCT Guided Therapy* Package Insert

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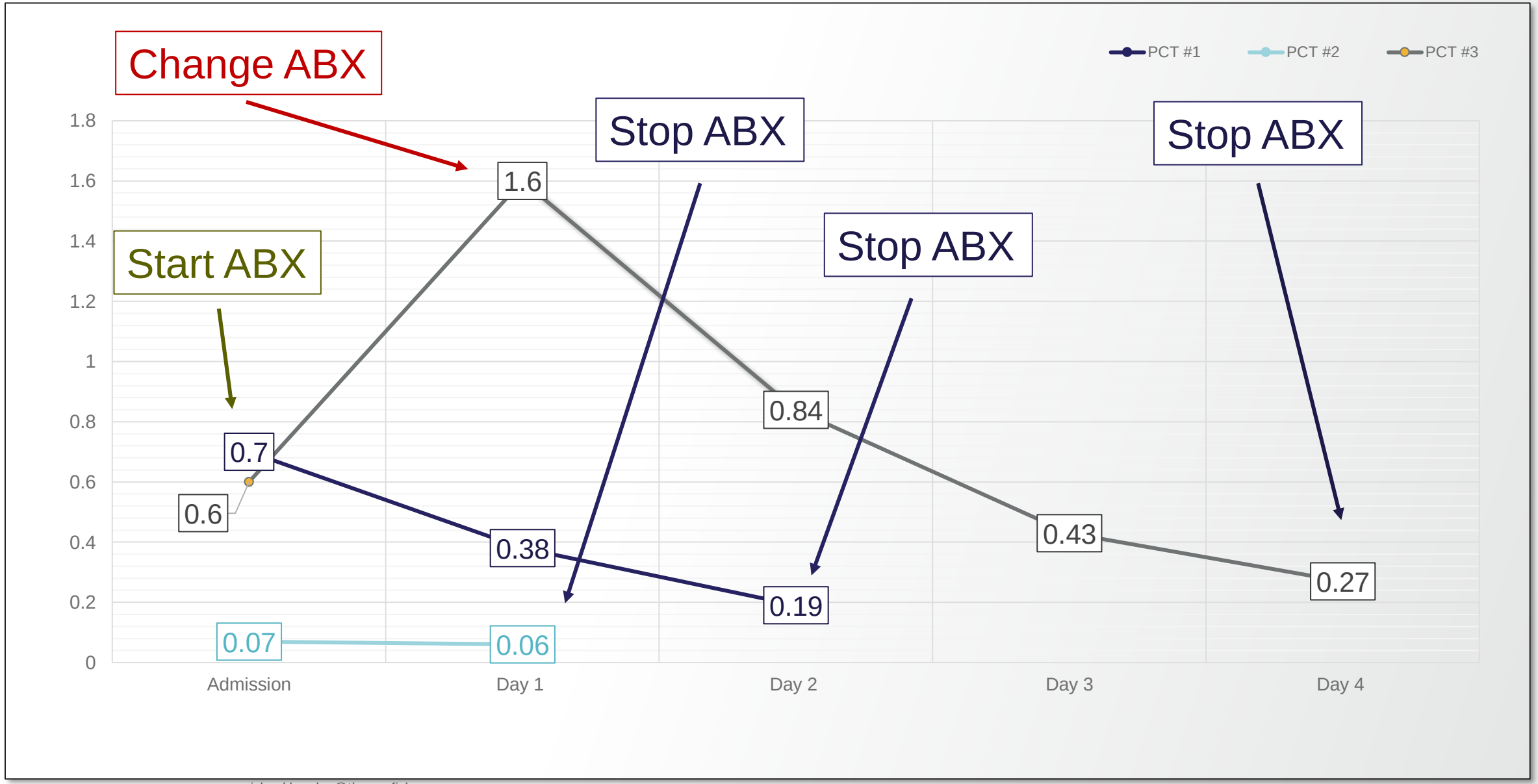
Antibiotic Initiation for LRTI		
PCT value	Antibiotic Use Recommendation	Discussion
< 0.1 ng/ml	Strongly discouraged	Repeat in 6 to 24 hours if needed < 0.1 ng/ml consider non-bacterial source
0.10 - 0.25 ng/ml	Discouraged	
0.26 – 0.5 ng/ml	Encouraged	Consider repeating every 24 hours to evaluate the opportunity for early cessation
> 0.5 ng/ml	Strongly encouraged	

Antibiotic Discontinuation for Sepsis and LRTI		
PCT Value	Antibiotic Use Recommendation	Discussion
LRTI ≤ 0.25 ng/ml or 80% drop	Cessation strongly encouraged with clinical improvement	
Sepsis ≤ 0.5 ng/ml Or drop by > 80%		

Community Acquired Pneumonia (and Sepsis) Case Kinetics



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Role of PCT in Pneumonia

- With IDSA CAP guidelines recommending against use of PCT for antibiotic initiation, are there any scenarios where it might be valuable in CAP?

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Poll question: Critical Thinking

a. If 50% of CAP is a viral infection, does it seem good to treat everyone with five days of antibiotics? Yes or no
b. If a bacterial infection is confirmed, does it seem like five days would be the perfect duration of treatment for all patients? Yes or no
c. If you grow an organism from sputum or a bronchoscopy, should you always treat that organism identified in the specimen? Yes or no

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FDA Indications for B·R·A·H·M·S PCT February 2017

- To aid in decision making on antibiotic discontinuation for patients with *suspected or confirmed sepsis*
- To aid in decision making on antibiotic therapy for inpatients or patients in the emergency department with suspected or confirmed lower respiratory tract infections (LRTI) - defined as community-acquired pneumonia (CAP), acute bronchitis, and acute exacerbation of chronic obstructive pulmonary disease (AECOPD)

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The microbiome and the Respiratory Tract

- The lungs are not sterile as once thought
  - Continually exposed to organisms from the oropharynx
- Large numbers of microorganisms coexist in the lung similar to the oropharyngeal microbiota and dominated by members of [1]
  - Gram positive cocci, IE Clostridia + bacilli
  - Anaerobic & aerobic gram-negative rods
  - Anaerobic & aerobic gram-negative rods distributed in the oral, vagina, and gut
- "Host inflammation arises from disruption of a preexisting homeostasis of biodiversity[2]
- "Balanced, diverse microbiome contributes to better overall health[3]
  - Antimicrobials cause disruption of the microbiome
    - Less diversity
    - Diminished immunity > less health

[1] R Faner et al, The microbiome in respiratory medicine: current challenges and future perspectives, Eur Respir J 2017; 49:1602086, doi.org/10.1183/1393003.02086-2016,
[2] R Dickson et al, The microbiome and the respiratory tract, Annu Rev Physiol, 2016, Feb 10, 78:481-504. doi:10.1146/abbyrev-physiol-021115-105238
[3] Y Belkaid and T Hand, Role of the microbiota in immunity and inflammation, Cell, 2014, March 27, 157(1): 121-141, dio:10.1016/j.cell.2014.03.011

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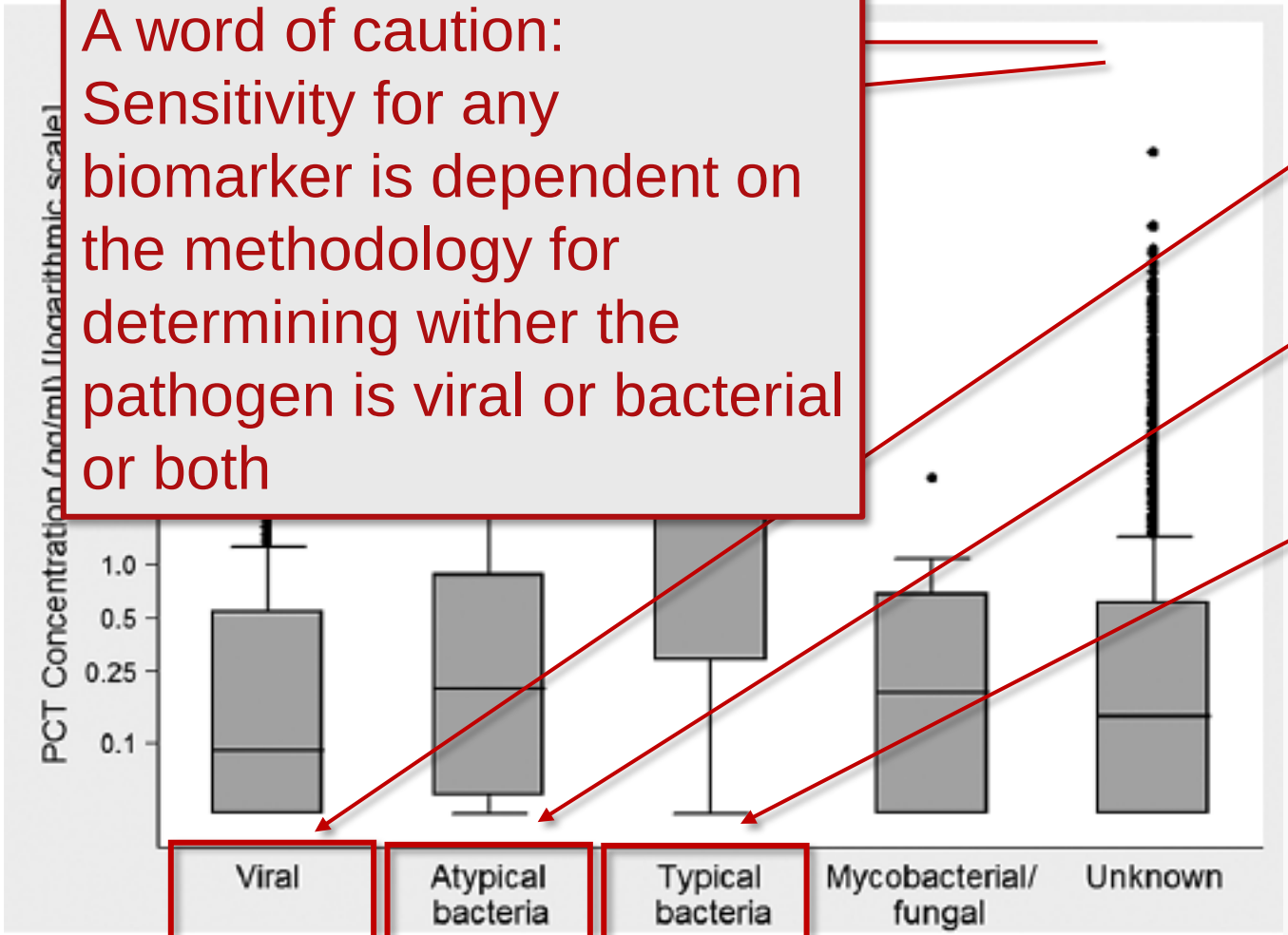
Procalcitonin differentiates viral, atypical, and typical bacterial causes of CAP

A word of caution:
Sensitivity for any biomarker is dependent on the methodology for determining wither the pathogen is viral or bacterial or both



	Viral	Atypical bacteria	Typical bacteria	Mycobacterial/ fungal	Unknown
n patients	409	67	169	15	1,075
PCT median (ng/ml)	0.09	0.20	2.5	0.19	0.14
PCT IQR (ng/ml)	<0.05, 0.54	<0.05, 0.87	0.29, 12.2	<0.05, 0.68	<0.05, 0.61

- PCT is always low in pure viral pneumonia
- Atypical bacteria do not generally produce as much PCT – organism dependent
- In extracellular (typical) bacteria PCT is elevated and proportion to bacterial burden
- Start ABX on initial diagnosis, but use PCT to evaluate ABX effectiveness, the need to continue and possibly early cessation

Evaluated 1735 patients with organism identified in 37%
Self, W.H. et al., Clin Infect Dis 2017; Jul: 183-190

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Bacterial testing sensitivity

- ATS/IDSA guidelines for CAP
- Initiate empirical antibiotic therapy for radiologically confirmed pneumonia
- “A study of 1735 patients admitted with CAP who had comprehensive pathogen detection procedures, including PCT testing as part of the CDC Prevention EPIC (Etiology of Pneumonia in CAP) study”
- No pathogen in 67% of the cases
- Viral in 24%
- Bacterial in 14%
- According to this study
- The negative predictive value was 82.4% (95% CI, 72.2% to 86.9%)

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Pneumonia in the Post-antibiotic Era

- Pinpointing the source of infection in community-acquired pneumonia (CAP) can be a daunting task that more often than not results in failure. Although *Streptococcus pneumoniae* are the most frequently isolated bacterial pathogens, they are no longer the most common cause of CAP. In fact, despite extensive testing, no pathogen is detected in 60% of patients with CAP.[1] Even when a pathogen is isolated, it's usually a rhinovirus, influenza virus, or human metapneumovirus. This shift to viral causes of pneumonia is probably due in part to the pneumococcal conjugate vaccination of children

The environment has changed allowing opportunities to avoid antibiotics in pure viral infections

https://www.medscape.com/viewarticle/914104?nlid=130230_805&src=WNL_mdplsfeat_190618_mscpedit_infd&uac=161631CJ&spon=3&impID=1998946&faf=1

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How is it possible that fewer antibiotics can have better outcomes….. After all more is better “just to be sure”?

- Not giving more than you need
- Not giving less than needed
- Giving only what is needed based on that patient’s presentation
- A set duration of antibiotics rarely is the correct duration for each patient….

  How could it be correct with variations like…..?
  - Bacterial burden at onset and during illness
  - Host immune response
  - Source of infection
  - Pharmacokinetic and pharmacodynamics of antibiotics

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B-R-A-H-M-S PCT Guided Therapy* and CAP

Antibiotic Discontinuation for Sepsis and LRTI		
PCT Value	Antibiotic Use Recommendation	Discussion
LRTI ≤ 0.25 ng/ml or 80% drop	Cessation strongly encouraged with clinical improvement	Not recommended for endocarditis, osteomyelitis, skin & skin structure infections, and those on chemotherapy
Sepsis ≤ 0.5 ng/ml Or drop by > 80%		

- Consider starting ABX with the diagnosis of CAP and discontinuing with 2nd normal value or 80% reduction from the maximal value.
- If you look at well done studies on PCT guidance in CAP, failure to use PCT results is poorer outcomes and more cost

Schuetz et al. Role of Procalcitionin in Managing Adult Patients with Respiratory Tract Infections, CHEST 2021; 141(4):1063-1073
Schuetz P, Christ-Crain M, Thomann R, Falconnier C, Wolbers M, Widmer I, et al. Effect of procalcitonin-based guidelines vs standard guidelines on antibiotic use in lower respiratory tract infections: the ProHOSP randomized controlled trial. JAMA. 2009 Sep 9;302(10):1059-66.
Bouadma L, Luyt CE, Tubach F, Cracco C, Alvarez A, Schwebel C, et al. Use of procalcitonin to reduce patients' exposure to antibiotics in intensive care units (PRORATA trial): A multicentre randomised controlled trial. Lancet Infect Dis. 2010 Feb 6;375(9713):463-74.

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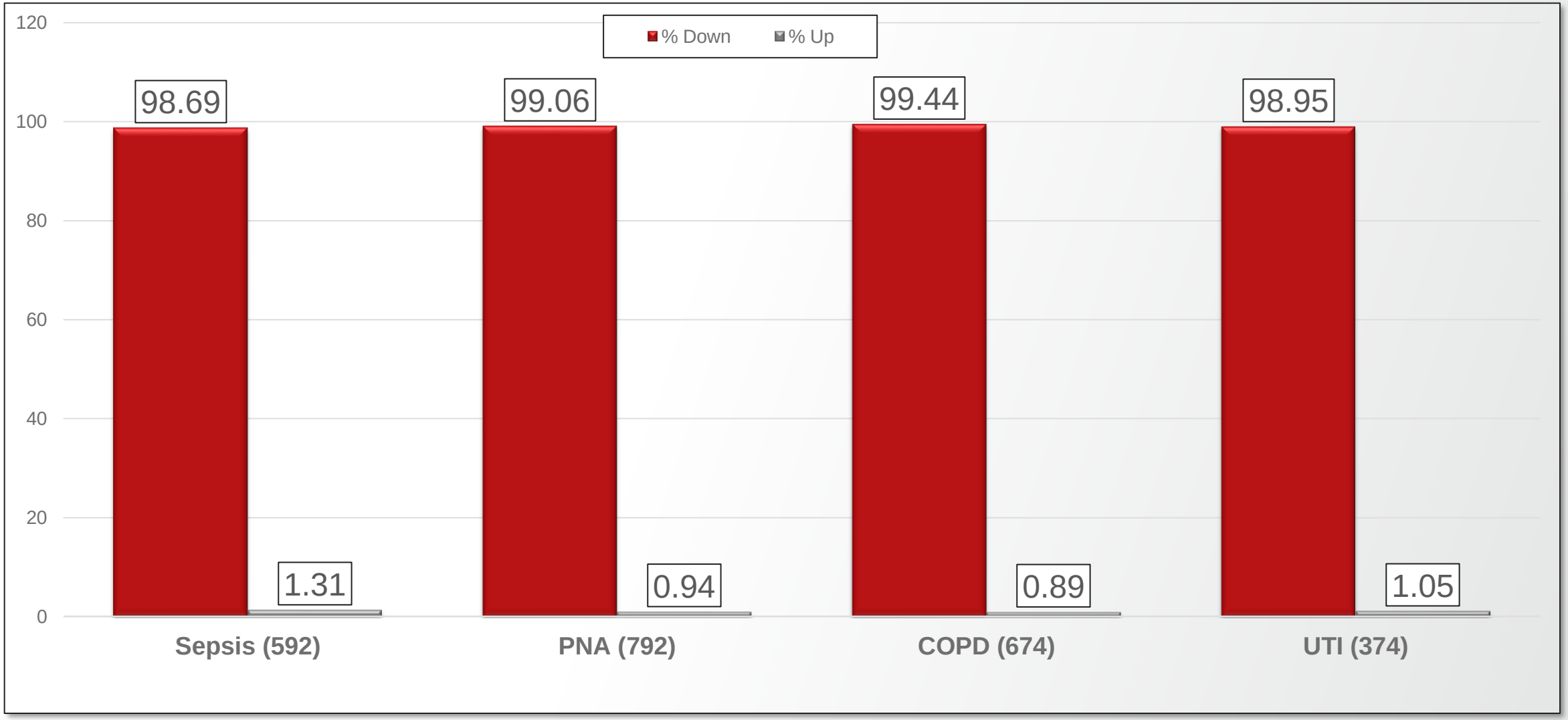
Real-world data: St Bernard's Five Rivers PCT remains normal after two negative values (%)



Treatment of Community-Acquired Pneumonia During the Coronavirus Disease 2019 (COVID-19) Pandemic

Joshua P. Metlay, MD, PhD, and Grant W. Waterer, MB, BS, PhD

"1. Empirical coverage for bacterial pathogens is recommended in patients with CAP without confirmed COVID-19 but is not required in all patients with confirmed COVID-19–related pneumonia"

"4. Procalcitonin could be helpful in limiting overuse of antibiotics in patients with COVID-19–related Pneumonia"

"Before the COVID-19 pandemic, the inflammatory biomarker procalcitonin was shown to safely reduce antibiotic use in patients with CAP"

This article was published at Annals.org on 7 May 2020

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Value of PCT Sepsis

- Required to start ABX per Surviving Sepsis/CMS guidelines on initial presentation
- FDA approved to stop antibiotics in “sepsis”
- Viral vs. bacterial
- Initial severity assessment
- ABX working?
- Early cessation

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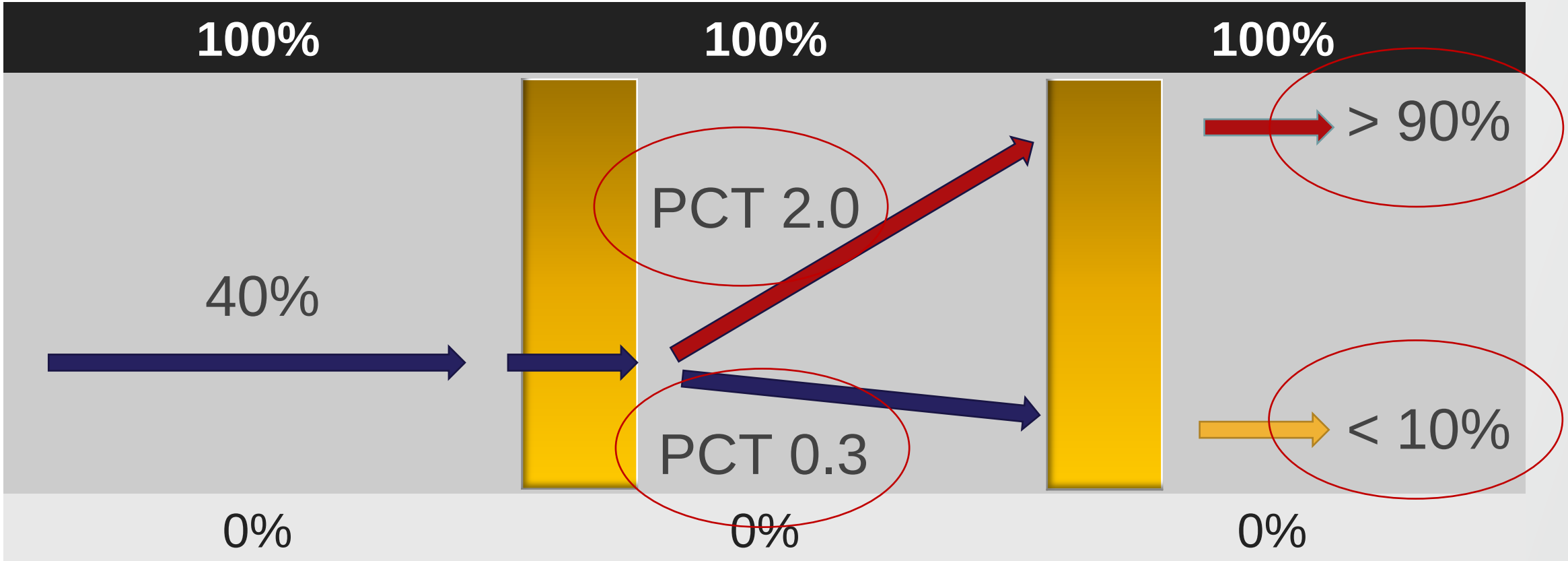
Probability of a Sepsis Diagnosis: No PCT/PCT



Pretest situation: only clinical assessment is available

Assessment of individual features and addition of PCT

Post-test situation: Individually adjusted risk assessment

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Meisner M, Procalcitonin-Biochemistry and Clinical Diagnosis, UniMed 2010

BE

CC/Hx

67 Y/O female

CC: Mild mental confusion, c/o pain in neck, shoulders, upper and lower back, and other diffuse arthralgia's

Medical History:

Recurrent Urinary Tract Infections

Hypertension

Migraine headaches

Depression NOS

Generalized Anxiety D/O

Fibromyalgia

Restless leg syndrome

OsteoporosiS

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BE

Urinalysis

- Sq Epi 4-6
- Nitrite positive
- Leuk 1+
- WBC: 10
- Bacteria +2
- pH 6
- SG 1.025
- Dark yellow
- Clarity: cloudy

Other Lab

- WBC: 9.6 x 1000
- Neutrophils 62
- PCT: 0.05ng/ml

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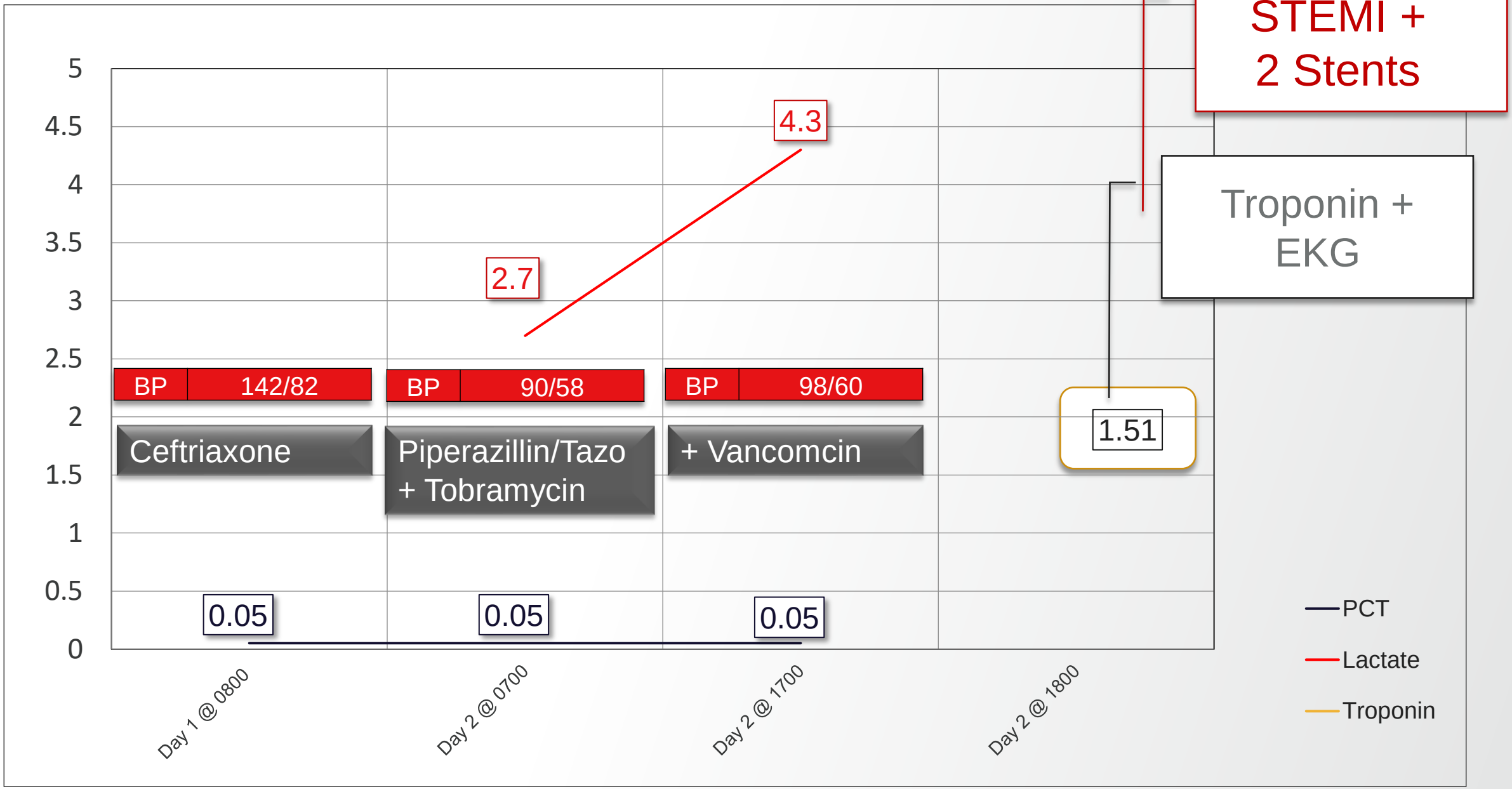
BE: UTI and Lactate Specificity



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FW a 72 male with a history of AECOPD and heart failure w/ Increasing SOB						
Presentation	# 1	# 2	# 3	# 4	# 5	# 6
Temp	98	98.9	99.2	98.6	98.9	99.2
RR	22	23	24	22	24	22
Pulse Ox	92	92	91	92	89	92
WBC (x1000)	13.9	12.1	15.9	14.2	12.8	8.9
Bands (%)	5	6	7	8	4	12
Lactate (mmol/L)	2	1.9	2.7	2.4	3.2	3.9
NTproBNP	WNL	1+	2+	0.5	3+	2+
PCT (ng/ml) Day 0	0.06	0.7	0.05	0.82	0.07	2.9
PCT (ng/ml) Day 1	0.05	0.53	0.05	0.55	0.05	2
Diagnosis						
Antibiotics ?						
Comments						

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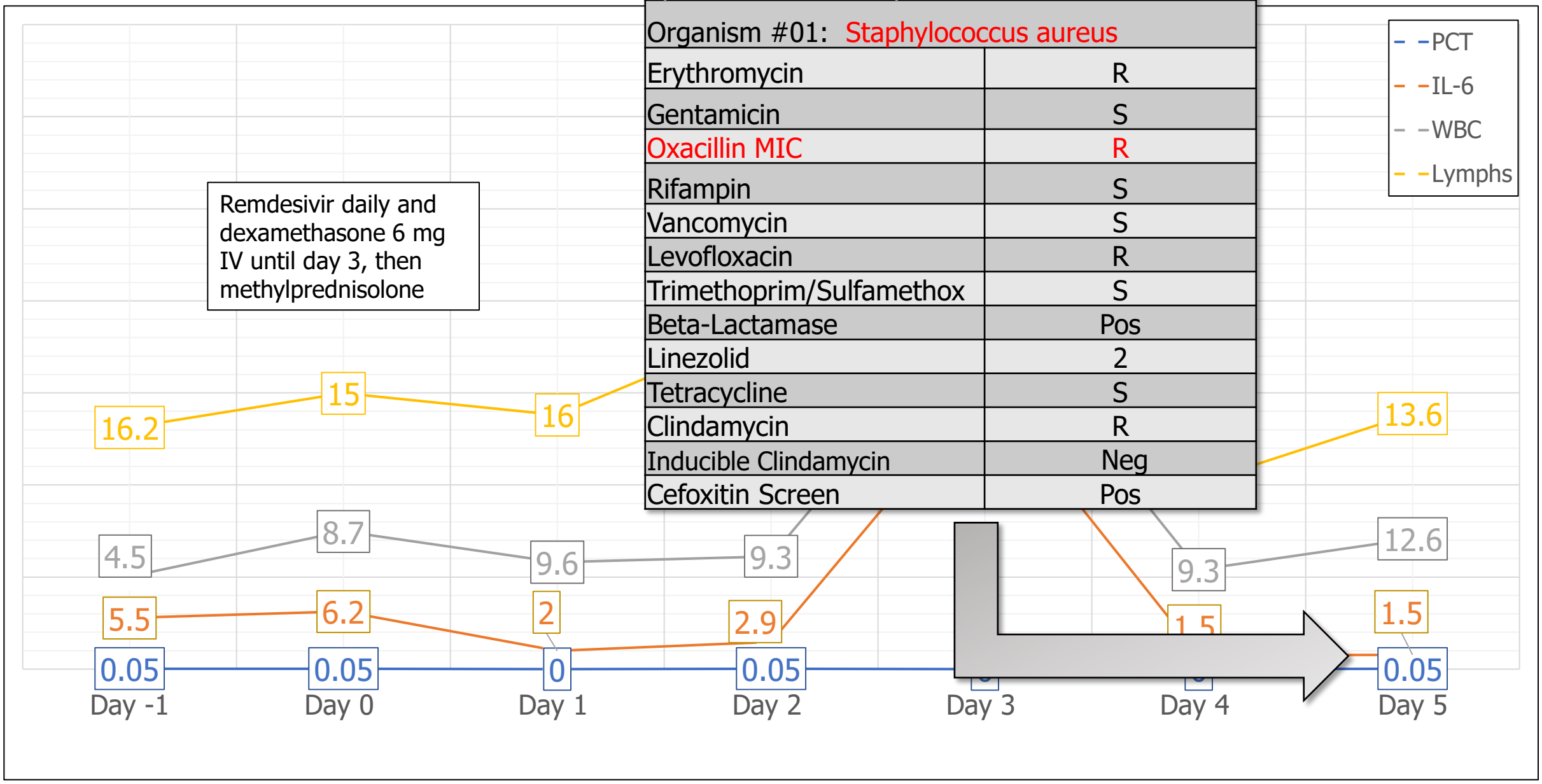
TB/2 – COVID-19

Specimen Source: Sputum	
Organism #01: Staphylococcus aureus	
Erythromycin	R
Gentamicin	S
Oxacillin MIC	R
Rifampin	S
Vancomycin	S
Levofloxacin	R
Trimethoprim/Sulfamethox	S
Beta-Lactamase	Pos
Linezolid	2
Tetracycline	S
Clindamycin	R
Inducible Clindamycin	Neg
Cefoxitin Screen	Pos



Real World Data

- The following real-world data was presented on November 10th, 2016 for the FDA and to CID Open Forum
- Added to a mature stewardship program of 18 years

http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/MicrobiologyDevicesPanel/ucm515517.htm

Open Forum Infectious Diseases

MAJOR ARTICLE

Impact of Procalcitonin-Guided Antibiotic Management on Antibiotic Exposure and Outcomes: Real-world Evidence

Michael R. Broyles[1]

[1]Department of Clinical Pharmacy and Laboratory Services, Five Rivers Medical Center, Pocahontas, Arkansas

Background. Delayed pathogen identification and nonspecific clinical findings make definitive decisions regarding antibiotics challenging. The stimuli of bacterial toxins and inflammation make procalcitonin (PCT) unique in its ability to differentiate bacterial infection from other causes of inflammation, and thus it is useful for antibiotic management. The objective of our study was to evaluate the impact of a PCT algorithm (PCT-A) on current practice.

Methods. A single-center, retrospective cohort study was conducted to evaluate the impact of adding PCT-A to stewardship practices. Data from 4 years prior to and after PCT-A implementation were compared in critical and acute care patients of all ages receiving parenteral antibiotics for a DRG coded for infection. A baseline PCT was obtained on admission in patients with suspected bacterial infection. Serial PCT measurements were repeated daily to evaluate effectiveness of therapy. Outcomes of interest were antibiotic exposure, hospital mortality, 30-day readmission, *Clostridium difficile* infection (CDI), and adverse drug events during hospitalization.

Results. A total of 985 patients (pre-PCT-A group) were compared with 1167 patients (post-PCT-A group). Antimicrobial stewardship alone (pre-PCT-A) resulted in a median days of therapy (DOT) of 17 (interquartile range [IQR], 8.5–22.5) vs 9.0 (IQR, 6.5–12) in the post-PCT-A group ($P < .0001$). Secondary outcomes were also significantly reduced in the post-PCT-A group.

Five Rivers Medical Center Study Outcomes (N = 2152)	Pre-PCT n=985	Post-PCT n=1167	Between-Group Difference	% Reduction	P value
Primary Outcome					
Days of Therapy DOT, median (IQR)	17.0 (8.5-22.5)	9.0 (6.5-12.0)	-8.0	47%	<0.001
Secondary Outcomes					
Hospital All-Cause Mortality, n (%) Hospital Mortality from Infection, n (%)	75 (7.6) 68 (6.9)	35 (2.9) 33 (2.8)	4.7% 4.1%	62% 59%	<0.001 <0.001
30-day All-Cause Readmission*, n (%) 30-day Readmission for Infection*, n (%)	204 (22.4) 177 (19.5)	119 (11.1) 111 (9.8)	11.3% 9.5%	50% 49%	<0.001 <0.001
Hospital C. difficile Infection, n (%)	25 (2.5)	10 (0.9)	1.6%	64%	0.002
ADEs from Antimicrobials**, n (%)	160 (16.2)	94 (8.1)	8.1%	50%	<0.001

*30-day hospital readmission rate calculated by eligible readmissions (e.g. # readmissions/(# patients in cohort – # in-hospital deaths));

**Adverse Drug Events (ADEs) during hospitalization from Antimicrobials defined as: infusion related injury or irritation, nausea, vomiting, diarrhea, Q-T interval prolongation, or arthralgia.

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Research Article

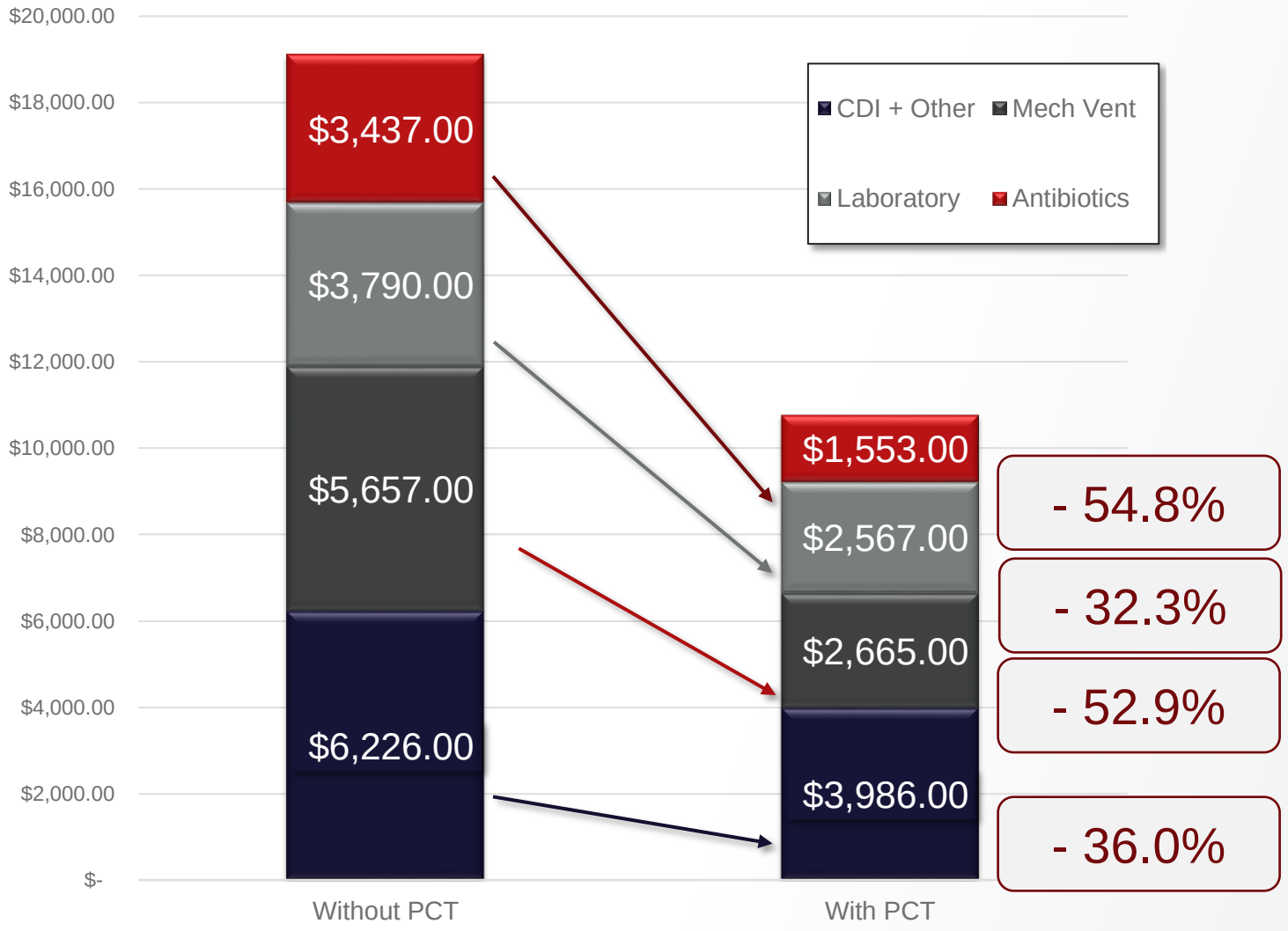
Cost-Effectiveness Analysis of a Procalcitonin-Guided Decision Algorithm for Antibiotic Stewardship Using Real-World U.S. Hospital Data

Anne M. Voermans,[1] Janne C. Mewes,[1] Michael R. Broyles,[2] and Lotte M. G. Steuten[3,*]

Abstract

Medical decision-making is revolutionizing with the introduction of artificial intelligence and machine learning. Yet, traditional algorithms using biomarkers to optimize drug treatment continue to be important and necessary. In this context, early diagnosis and rational antimicrobial therapy of sepsis and lower respiratory tract infections (LRTI) are vital to prevent morbidity and mortality. In this study we report an original cost-effectiveness analysis (CEA) of using a procalcitonin (PCT)-based decision algorithm to guide antibiotic prescription for hospitalized sepsis and LRTI patients versus standard care. We conducted a CEA using a decision-tree model before and after the implementation of PCT-

Financial results: Sepsis

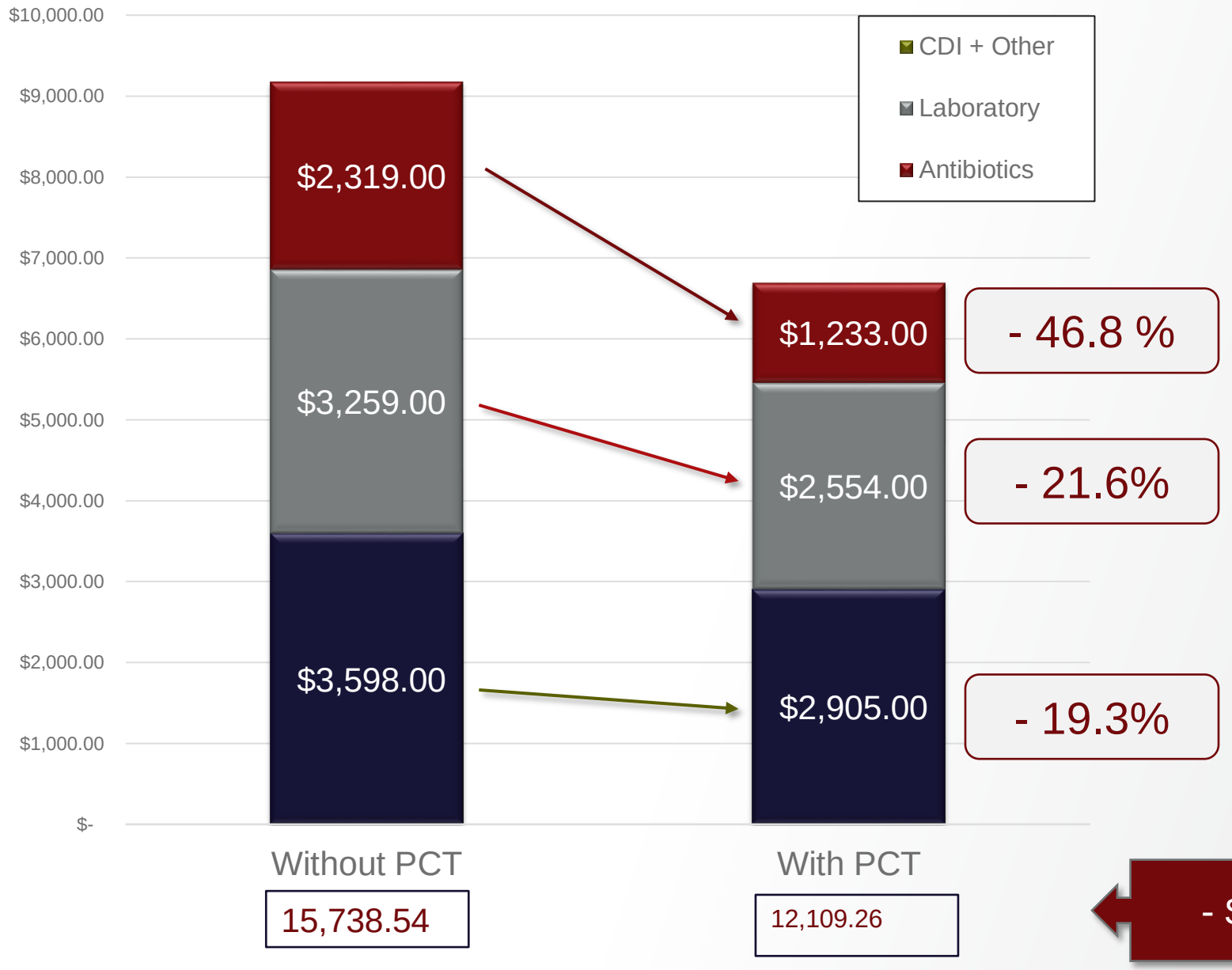


52,055.30

26,433.88

- $25,621.42 / patient (- 49.2%)

Financial Results: LRTI



- $3,629.28 / patient (- 23.1%)

The cost impact of PCT=guided antibiotic stewardship versus usual care for hospitalised patients with suspected sepsis for lower respiratory tact infections in the US; A health economic model analysis

J Mewes, M Pulia, M Mansour, M Broyles, HB Nguyen, L Steuten
PLoS One 14(4):e0214222, April 23, 2019, . https://doi.org/10.1371/journal.pone.0214222

Compare effectiveness and costs of a PCT-algorithm versus standard care to guide antibiotic prescriptions in patients hospitalized with a diagnosis of suspected sepsis or lower respiratory tract infection (LRTI) in the US

Use of a previously published economic model for evaluations

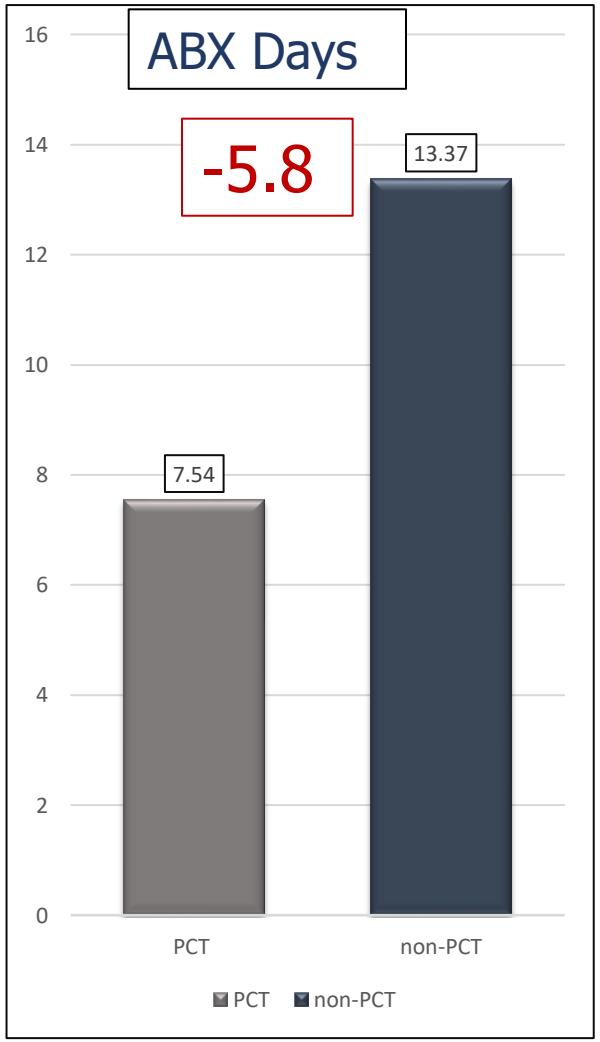
US studies (n=13)

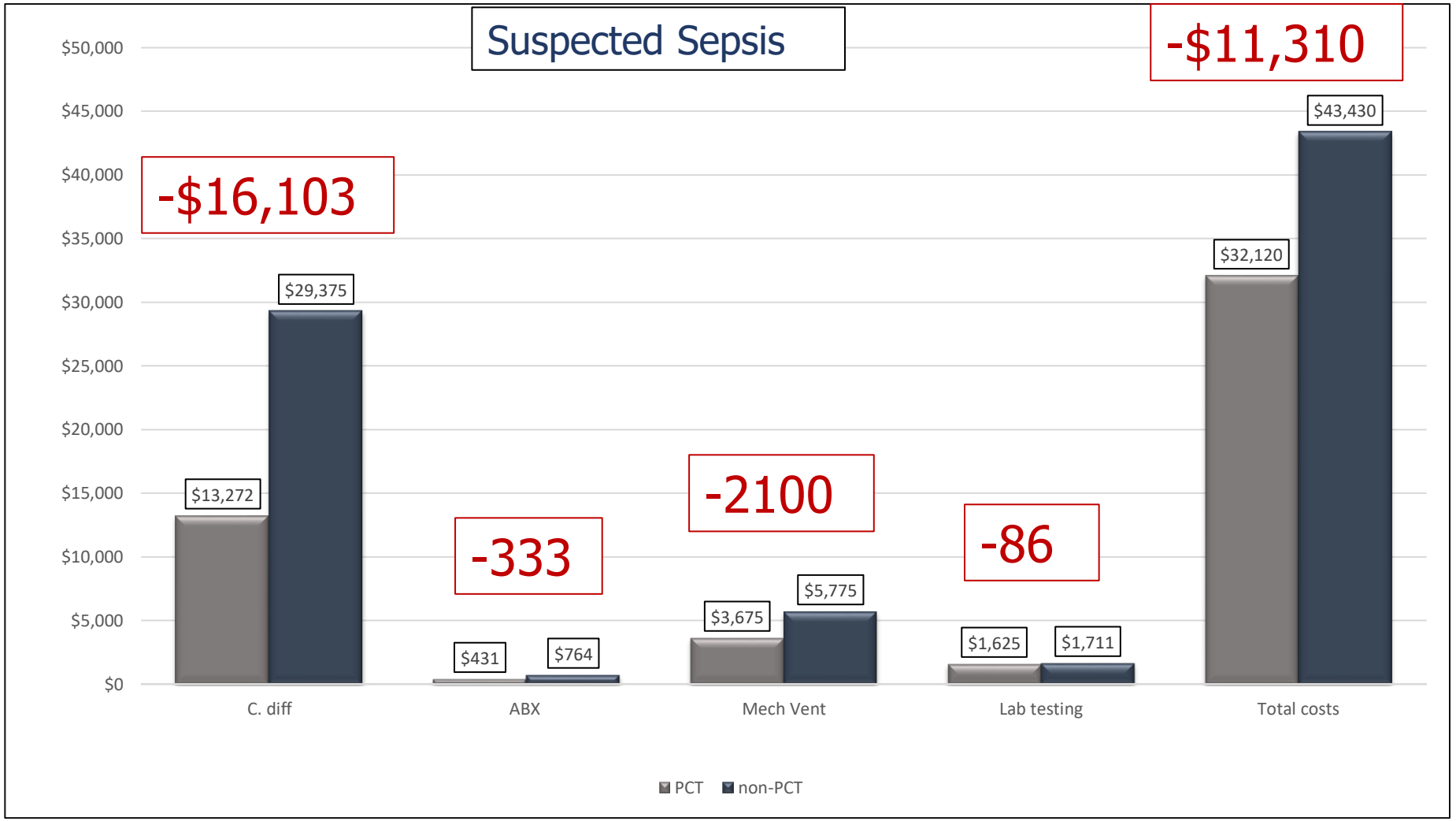
- RCT n=2
- Retrospective study: n=8
- Economic analysis: n=3

Non US studies, systematic reviews, and meta-analyses: n=47

- RCT: n=17
- Meta-analysis: n=13
- Observational study: n=5
- Review: n=6
- Controlled study: n=1

The cost impact of PCT-guided antibiotic stewardship versus usual care for hospitalised patients with suspected sepsis for lower respiratory tact infections in the US; A health economic model analysis





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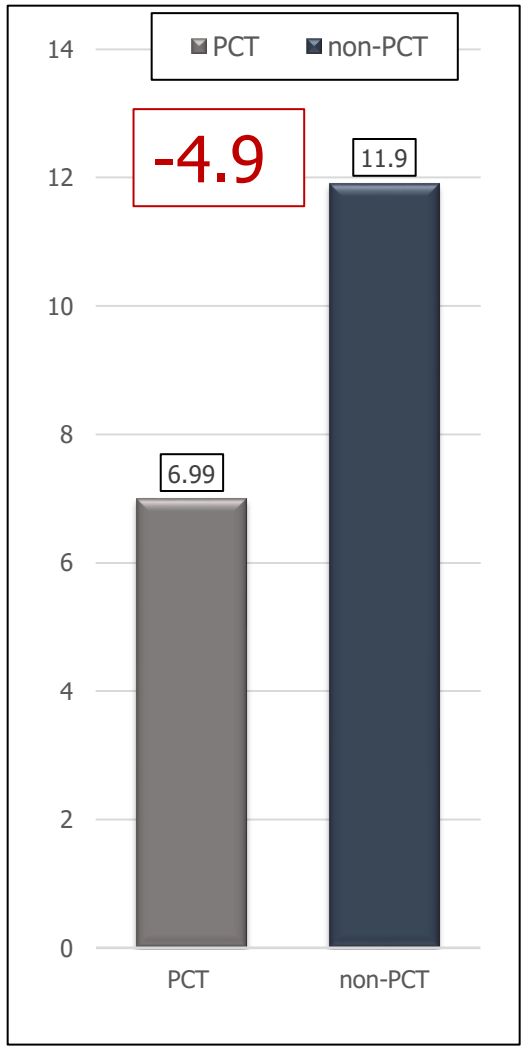

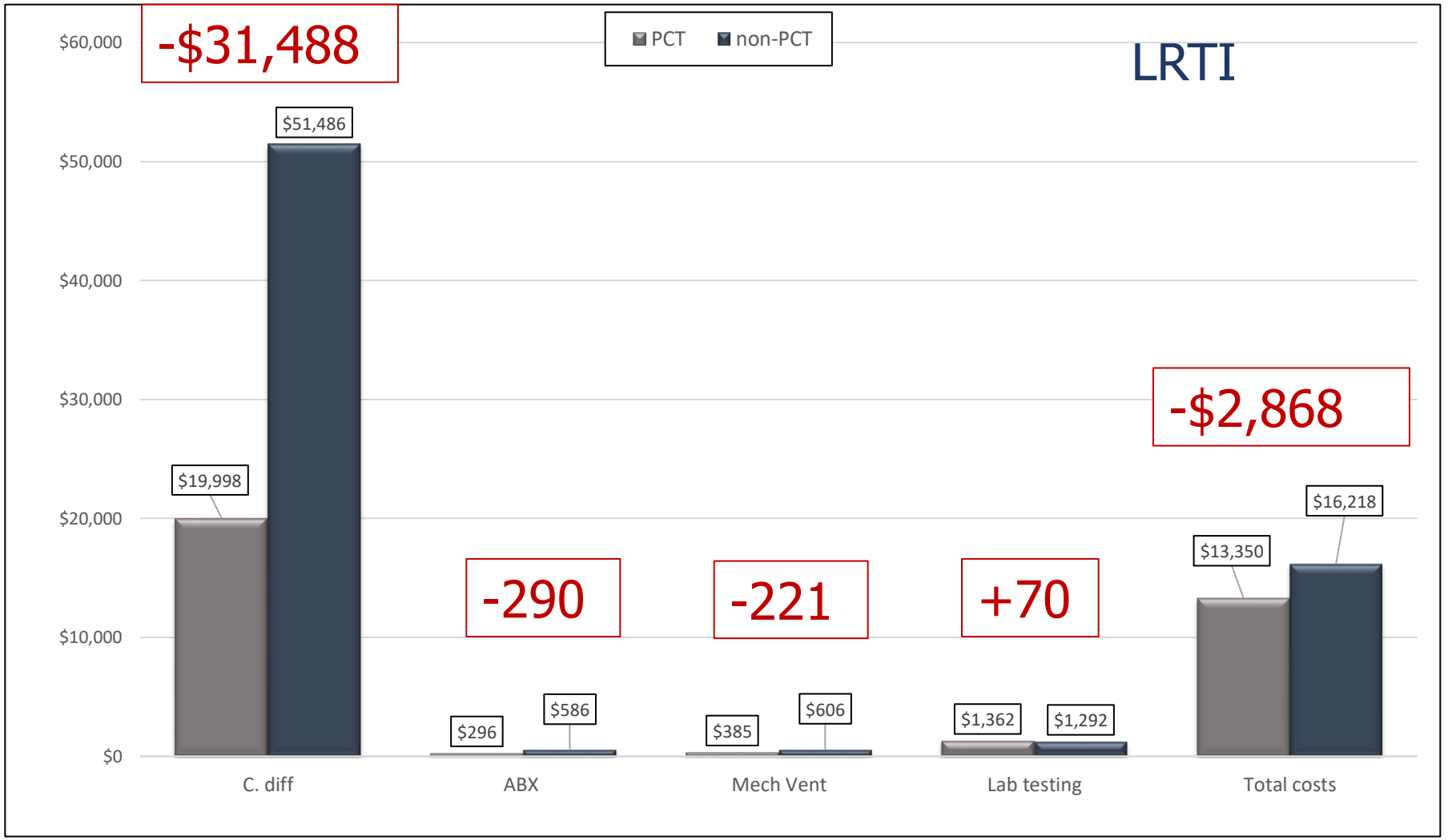

J Mewes, M Pulia, M Mansour, M Broyles, HB Nguyen, L Steuten, PLoS One 14(4):e0214222, April 23, 2019, . https://doi.org/10.1371/journal.pone.0214222

The ideal biomarker or laboratory marker for bacterial infections would…

- Have the ability to differentiate bacterial from viral infection
- Have good positive and negative predictive value
- Stratify patients as to severity of infection
- Have a defined cutoff value for diagnosis
- Risk-stratify patients for appropriate disposition
- Change or support therapeutic decision making
- Determine when to start and stop antibiotic therapy
- Monitor progress of disease and response to therapy
- Improve emergency department and hospital resource utilization

Blomkalns AL. https://pdfs.semanticscholar.org/1f67/eb51f3f9d88c83af59b0fbaf01a4ef237eeb.pdf. 2007;7:1-11. Accessed April 16, 2018.

Special Questions often Asked

- Acute renal failure
- Dialysis – hemodialysis and peritoneal
- Immune diseases
- Skin and skin structure infections
- Colonization
- Fungal infections
- Correlation with positive and negative blood cultures
- Cytokine storm
- Surgery general
- Endocarditis
- Osteomyelitis
- Immunocompromised
- Pregnancy
- Thyroid conditions
- Burns
- Pancreatitis
- Meningitis
- Transplant surgery
- Trauma
- Post CPR

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Questions?

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