

Antimicrobial Overview

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Carbapenems

“Gorillacillins”

- IMIPENEM/CILASTATIN (PRIMAXIN)
- MEROPENEM (MERREM)
- ~~DORIPENEM~~
- ERTAPENEM (INVANZ)
- MEROPENEM/VABORBACTAM (VABOMERE)
- IMIPENEM/CILASTIN/RELEBACTAM (RECARBRIO)

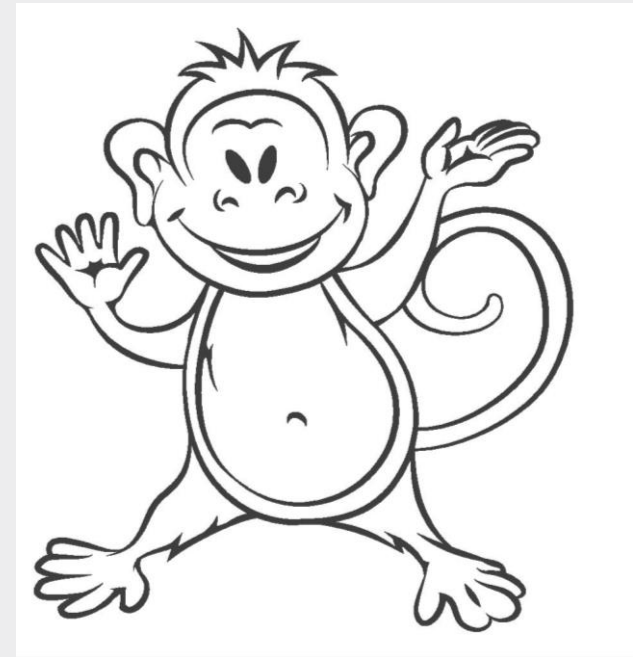


Carbapenems--general principals to apply

- AKA “Gorillacillins”
 - These should be reserved as they are *the nuclear weapons*
- Broadest spectrum of the Beta lactam class
 - Gram positive includes: Strep/Enterococcus*, Staph (MSSA), g+ anaerobes
 - Gram negative coverage includes: all Enterobacteriaceae, Pseudomonas, Acinetobacter, and Extended Spectrum Beta Lactamase (ESBL) g-bacteria (E. coli, Klebsiella)
 - Excellent anaerobic coverage both g (+) and g (-)
- MOR: carbapenemase enzymes exist (KPC, OXA-48, NDM)
 - Famously stable to AmpC β -lactamases and extended-spectrum- β -lactamases
- Low cross reactivity in PCN allergic patients (reported <2%)
- AE: seizures (elderly, h/o seizures (0.2% vs 33%), higher doses and not renally adjusted, bone marrow suppression, infusion related hypotension
- Major DDI (drug-drug interactions): CYP p450 (VPA-decreases levels, increasing risk for seizures)
- **Place in Therapy: DOC (drug of choice) for ESBL**

Ertapenem

- “Monkeycillin” but still a nuclear weapon
- Spectrum of coverage very similar to Mero/imipenem:
 - exception of Pseudomonas and Enterococcus(30-50% resistance reported)
- Excellent anaerobic coverage
- Should be considered over meropenem when is Pseudomonas coverage is not needed
- FDA approved for CAP and complicated DM foot infections
- Q24hr dosing
- May need higher doses in obesity, studies have not recommended dose
- Higher rates of treatment failure in critically ill patients with hypoalbuminemia
- **Place in therapy: ESBLs & AmpC infections**



Meropenem

- Meropenem is formulary
- We do alternative dosing strategy of 500 mg IV Q6H
- Dose escalate in obesity and MDRO's to 1g q6h
- **Place in therapy: ESBLs & AmpC infections**

Imipenem-Cilastin

- Imipenem/cilastin is Nonformulary
- Degraded by dehydropeptidase so must be administered with cilastatin
- Slightly better positive activity of carbapenems (primarily Enterococcus)
- **Place in therapy: Nocardia and Non-tuberculosis Mycobacterium species.**

Meropenem-Vaborbactam (Vabomere)

- FDA approved 2017 for cUTI
- Similar spectrum to cefiderocol but no additional pseudomonas coverage or MBL
- Dosing is 1.25g q6h over 30 min infusion
- Additional Spectrum of Coverage for:
 - MDRO Enterobacterales
 - AmpC
 - ESBLs
 - CRE (eg. KPC)
 - **Place in therapy: CRE infections**

Imipenem-Cilastin-Relebactam (Recarbrio)

- FDA approved 2019 for cUTI & cIAI
- Similar spectrum to Avycaz/cefiderocol but no MBL
- Dosing is 1.25g q6h over 30 min infusion
- Additional Spectrum of Coverage for:
 - MDRO Enterobacterales or *Pseudomonas aeruginosa*
 - AmpC
 - ESBLs
 - CRE (eg. KPC, OXA-48)
 - **Place in therapy: CRE infections & MDRO pseudomonas**

Case

1. V.Y. is a 64-year-old woman (height 5'2", weight 65 kg) who is admitted to a rehabilitation facility. She was hospitalized for 2 weeks after a fall resulted in a C7 fracture and spinal cord injury with dysphagia, neurogenic bowel and bladder, sacral pressure ulcer s/p flap, and spasm of muscle. V.Y. has no known drug allergies. Her Tmax over last 24 hours is 100.6°F, heart rate 78 beats/ minute, blood pressure 130/74 mm Hg, and respiratory rate 16 breaths/minute. She has a solitary kidney, SCr 0.8 mg/dL, and a neurogenic bladder requiring intermittent straight catheterization. Urinalysis showed 50 WBCs, positive for nitrites and leukocyte esterase with many bacteria. V.Y. has history of urinary tract infections caused by ceftriaxone resistant + E. coli. She was last treated for a UTI 5 months ago.
2. Which one of the following would be the best empiric treatment for V.Y.?
 - A. Zosyn.
 - B. Levofloxacin.
 - C. Bactrim.
 - D. Ertapenem

Case

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 - C. Bactrim.
 - D. Ertapenem**



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Introduction

Methodology

General Management
Recommendations

Extended-Spectrum β -
Lactamase-Producing
Enterobacterales (ESBL-E)

Carbapenem-Resistant
Enterobacterales (CRE)

Difficult-to-Treat Resistance

IDSA Guidance on the Treatment of Antimicrobial- Resistant Gram-Negative Infections: Version 1.0

Published by IDSA, 9/8/2020

A Focus on Extended-Spectrum β -lactamase Producing Enterobacterales (ESBL-E), Carbapenem-Resistant Enterobacterales (CRE), and *Pseudomonas aeruginosa* with Difficult-to-Treat Resistance (DTR-*P. aeruginosa*)

Pranita D. Tamma*, Samuel L. Aitken, Robert A. Bonomo, Amy J. Mathers, David van Duin, Cornelius J. Clancy

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Abstract

Introduction

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AmpC β -Lactamase-
Producing Enterobacterales

Carbapenem-Resistant
Acinetobacter baumannii

Stenotrophomonas
maltophilia

IDSA Guidance on the Treatment of Antimicrobial- Resistant Gram-Negative Infections: Version 2.0

Published by IDSA, 11/22/2021

A focus on **AmpC β -lactamase-Producing Enterobacterales, Carbapenem-Resistant *Acinetobacter baumannii*, and *Stenotrophomonas maltophilia* Infections**

AMR Guidance 1.0: ESBL-E, CRE, and *Pseudomonas aeruginosa* with Difficult-to-Treat Resistance

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Cystic Fibrosis: Adult Extended Infusion Beta-Lactam Protocol

- **Purpose:** To achieve clinical success in the treatment of serious infections and prevent the emergence of resistance by optimizing beta lactam dosing in adult (age ≥ 16 yo) CF patients.
- **Definitions**
 - Intermittent Infusion: 30 or 60 minutes
 - Extended Infusion: 3 or 4 hours
- **Examples**
 - [Loading Dose] Zosyn 4.5g, Intravenous, Once for 1 dose. Infuse over 30 minutes.
 - [Maintenance Dose] Zosyn 4.5g, Intravenous, every 6 hours. Infuse over 4 hours.
 - [Loading Dose] Meropenem 1g, Intravenous, Once for 1 dose. Infuse over 30 min.
 - [Maintenance Dose] Meropenem 1g, Intravenous, every 6 hours. Infuse over 3 hours.

Fluoroquinolones

- CIPROFLOXACIN (CIPRO)
- LEVOFLOXACIN (LEVAQUIN)
- MOXIFLOXACIN (AVELOX)
- DELAFLOXACIN (BAXDELA)

Fluoroquinolones – general principles

- Concentration-dependent bactericidal activity
- Drug of choice for CAP & complicated UTIs
- Spectrum of coverage:
 - Gram negative: good coverage, pseudomonas coverage with Cipro & Levaquin
 - Gram positive:
 - Good Strep coverage, Levofloxacin and Moxifloxacin are preferred for Strep but are not be best choice for *S. aureus* (MSSA and MRSA)
- Anaerobes: Moxifloxacin provides coverage. No anaerobic coverage for Cipro or levo (add metronidazole).
- Atypicals: Good coverage but levo and moxi are first line DOC for CAP
- Adverse events:
 - Occasional: GI intolerance, *C. difficile*-associated colitis, hypo/hyperglycemia
 - Rare: Tendon rupture (increased incidence in age >60, concurrent use of corticosteroids, kidney, heart, and lung transplant recipients), QTc prolongation
- Drug interactions:
 - Divalent or trivalent cations(antacids, sucralfate, vitamins, minerals) interfere with absorption (separate 2 hrs)
 - Avoid oral g-tube administration (use IV formulation)
 - Avoid other QTc prolonging drugs (amiodarone, procainamide, propafenone, flecainide, etc), or in pts with hypokalemia/hypomagnesia, bradycardia, or cardiomyopathy

Fluoroquinolones

- **Ciprofloxacin**
 - Best clinical and in vitro data for activity against *P. aeruginosa*
 - Good experience for nosocomial pneumonia, osteomyelitis, chronic prostatitis, and UTIs
 - Other FQ (levo and moxi) preferred for infections due to *S. pneumonia*.
- **Levofloxacin**
 - Good in vitro activity and clinical experience against *S. pneumonia* and atypical agents of pneumonia.
 - FDA approved for PCN-resistant *S. pneumonia* , monotherapy for CAP and nosocomial pneumonia
 - 100% bioavailable
- **Moxifloxacin**
 - Spectrum similar to levofloxacin
 - Includes enhanced activity against *S. pneumonia*
 - Best anaerobic and mycobacteria activity among fluoroquinolones
 - Poor pseudomonal coverage
 - Lower urinary drug concentrations
 - Should not be used for UTIs
- **Delafloxacin (Baxdela)**
 - Good pseudomonal, mycobacteria, and G (+) coverage
 - Claim to fame – only FQ w/ MRSA coverage

FDA Warning on FQ Antibiotic use

1. FDA recommendations state that risks of serious side effects with fluoroquinolones generally outweigh benefits for patients with the following:
 - Acute bacterial sinusitis
 - Acute exacerbation of chronic bronchitis
 - Uncomplicated UTI

Fluoroquinolone Boxed Warning	
July 2008	• increased risk of tendinitis and tendon rupture
February 2011	• increased risk of exacerbating muscle weakness related to Myasthenia gravis
August 2013	• increased potential risk for irreversible peripheral neuropathy
July 2016	• increased CNS effects ((i.e. anxiety, depression, hallucinations, suicidal thoughts, confusion)
July 2018 (new labeling change)	• new mental health side effects updated to include disturbances in attention, disorientation, agitation, nervousness, memory impairment and delirium • serious blood sugar disturbances, particularly risk of coma with hypoglycemia
January 2019	• Increased risk for ruptures or tears in the aorta

Aminoglycosides

- Gentamicin
- Tobramycin
- Amikacin

Aminoglycosides –general principles

- Pharmacy to dose Aminoglycosides at BUMCP – providers enter consult
- MOA: Inhibit 30S ribosomal subunit
- Used for serious gram negative infections (*Enterobacterales*, *Pseudomonas aeruginosa*)
- Concentration dependent bactericidal activity.
 - Efficacy predicted by peak/MIC ratio
 - Dosed once daily to maximize peak levels
 - Do not use QD dosing in patients with unstable renal function, $\text{CrCl} < 30 \text{ ml/min}$, meningitis, or increased V_d (pregnancy, ascites, edema).
- Produce prolonged postantibiotic effects
 - Antibiotic is bacteriostatic for 30-60 min after the concentration decreases below the MIC
- Toxicities commonly include nephrotoxicity and ototoxicity
 - Toxicity is saturable at high drug levels from QD dosing produce less adverse events than smaller doses given more frequently, which would result in prolonged elevated drug concentrations.

Aminoglycosides

- **Gentamicin**
 - Used synergistically against some *Staph*, *Strep*, *Enterococci*, and *Listeria monocytogenes* species
 - Dose at 1 mg/kg IV Q8H (goal peak 3-5 mcg/ml) along with beta-lactam antibiotics for synergy.
 - Tobramycin not active against Enterococci; Gentamicin is active.
- **Tobramycin:**
 - less nephrotoxicity, but more ototoxicity than gentamicin
 - Better susceptibilities to pseudomonas than gentamicin
- **Amikacin** is active against many gram-negative bacteria that are resistant to gentamicin and tobramycin
 - Typically reserved for documented resistant infections to Gentamicin or Tobramycin
 - Also used in Nocardia and NTM infections
 - Levels are sent out with typically ~24 hr turn around.

Case

AZ is a 22-year-old woman of Caucasian origin diagnosed with CF with a history of 2-3 exacerbations per year (previous cultures w/ MRSA & Pan-S pseudomonas) presents to the hospital with acute exacerbation. Which following would be the best course of action?

- A. Consult ID provider for antibiotic selection dosing recommendation
- B. Initiate Zosyn 4.5g x1, 3.375 q8h intravenously + consult pharmacy to dose vancomycin/tobramycin
- C. Initiate Cefepime 2g q8h intravenously + pharmacy to dose vancomycin/tobramycin
- D. Consult pharmacy to dose vancomycin/tobramycin/Zosyn (CF extended infusion β -lactam protocol)

Case

AZ is a 22-year-old woman of Caucasian origin diagnosed with CF with a history of 2-3 exacerbations per year (previous cultures w/ MRSA & Pan-S pseudomonas) presents to the hospital with acute exacerbation. Which following would be the best course of action?

- A. Consult ID provider for antibiotic selection dosing recommendation
- B. Initiate Zosyn 4.5g x1, 3.375 q8h extended infusion intravenously + consult pharmacy to dose vancomycin/tobramycin
- C. Initiate Cefepime 2g q8h intravenously + pharmacy to dose vancomycin/tobramycin
- D. Consult pharmacy to dose vancomycin/tobramycin/Zosyn (CF extended infusion β -lactam protocol)**

Anti-MRSA Agents

- VANCOMYCIN
- LINEZOLID
- DAPTOMYCIN

IV Vancomycin

- Pharmacy to dose vancomycin at BUMCP – providers enter consult
- Spectrum of activity: Strep, Staph (including MSSA/MRSA), and some gram positive anaerobes
 - Higher rates of failure when MRSA MIC is at breakpoint of 2
- Dosed by Pharmacy Consult
 - Goals determined by indication, risk for MRSA (troughs 12-18 mcg/mL, AUC/MIC 400-600)
- Vancomycin ~~Red Man Syndrome~~-Infusion Reaction
 - flushing over chest/face +/-hypotension & pruritis
 - usually avoided by slowing the infusion to 120 minutes (standard is 30-60 min) + Benadryl pre-med
- Can be nephrotoxic in combo with other drugs such as high dose Zosyn, aminoglycosides, diuretics etc.
 - When used alone nephrotoxicity is associated with >4g daily dose & >72 hours of therapy

Linezolid

- Spectrum of activity
 - Primarily gram-positive bacteria including MRSA and VRE
 - Active against penicillin resistance Strep pneumoniae
 - Can be used in some of the drug resistant mycobacteria(non-TB) infections
- FDA approved indications for PNA, SSTI's, and VRE bacteremia
- MOA: Inhibits protein synthesis at the 50s ribosome
 - Bacteriostatic(most bacteria including Staph)
 - Bacteriocidal(Streptococci)
- Controversy over better penetration into lungs than vancomycin
- IV and PO available-100% bioavailable
- Major DDI w/ SSRI can cause serotonin syndrome (incidence $\leq 4\%$)
- No hepatic or renal adjustment required
- AE: severe thrombocytopenia (14d), usually reversible at discontinuation, optic neuritis and peripheral neuropathy (28d)

Daptomycin

- Similar spectrum of activity & need to be reserved for documented resistant infections
- MRSA, VRE or VISA/VRSA
- Daptomycin 10 mg/kg needed for VRE with MIC of 4
- Primary indications: complicated SSSI and non-resolving bacteremia
 - Daptomycin is FDA approved for R sided endocarditis
- Requires baseline CK level and weekly monitoring
- Bactericidal activity against Staph
- Daptomycin is inactivated by lung surfactants and should NOT be used to treat PNA
- ADE: rhabdomyolysis, eosinophilic PNA (rare), onset ~ 7 days
- Order baseline CK

Case

G.P. is a 57-year-old man who has received a diagnosis of osteomyelitis of the tibia after a traumatic injury. The surgical bone culture reveals MRSA susceptible to all antimicrobials on the test panel (other than oxacillin). The vancomycin is S (MIC is 2 mcg/mL). G.P. has no known drug allergies.

Which one of the following is best to recommend for G.P.?

- A. Levaquin 750mg QD x 8 weeks.
- B. Vancomycin 15 mg/kg intravenous q12 hours x 8 weeks.
- C. Daptomycin 6 mg/kg intravenous x1 dose & consult ID provider.
- D. Linezolid 600 mg intravenous twice daily plus rifampin 300 mg orally twice daily x 8 weeks

Case

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Clostridium difficile Treatment

- METRONIDAZOLE
- PO VANCOMYCIN
- FIDAXOMICIN (DIFICID)
- BEZLOTUXOMAB (ZINPLAVA)

Metronidazole (Flagyl)

- No longer considered first line for C difficile
 - Per CDI guidelines, consider in nonsevere CDI in resource limited settings
 - 500mg q8h PO if used
- Use in C diff is 500mg Q8h IV for fulminant CDI
- Provides excellent anaerobic (Bacteroides) coverage
- Peripheral neuropathy reported to occur with >14 day use

PO Vancomycin

- First line for non-severe, severe, or fulminant CDI
 - Can be used for 1st recurrence with prolonged taper and pulsed regimen
 - 2018 CDI guidelines (eg. 125 mg 4 times per day for 10–14 days, 2 times per day for a week, once per day for a week, and then every 2 or 3 days for 2–8 weeks)
- Inpatient uses compounded solution, cheaper and just as effective
 - FDA approved Firvanq formulation Jan 2018
- Starting dose is 125 mg QID, in fulminant doses are escalated to 500mg QID
 - 250mg QID is not a dosing strategy unless using prolonged taper!!!

Fidaxomicin

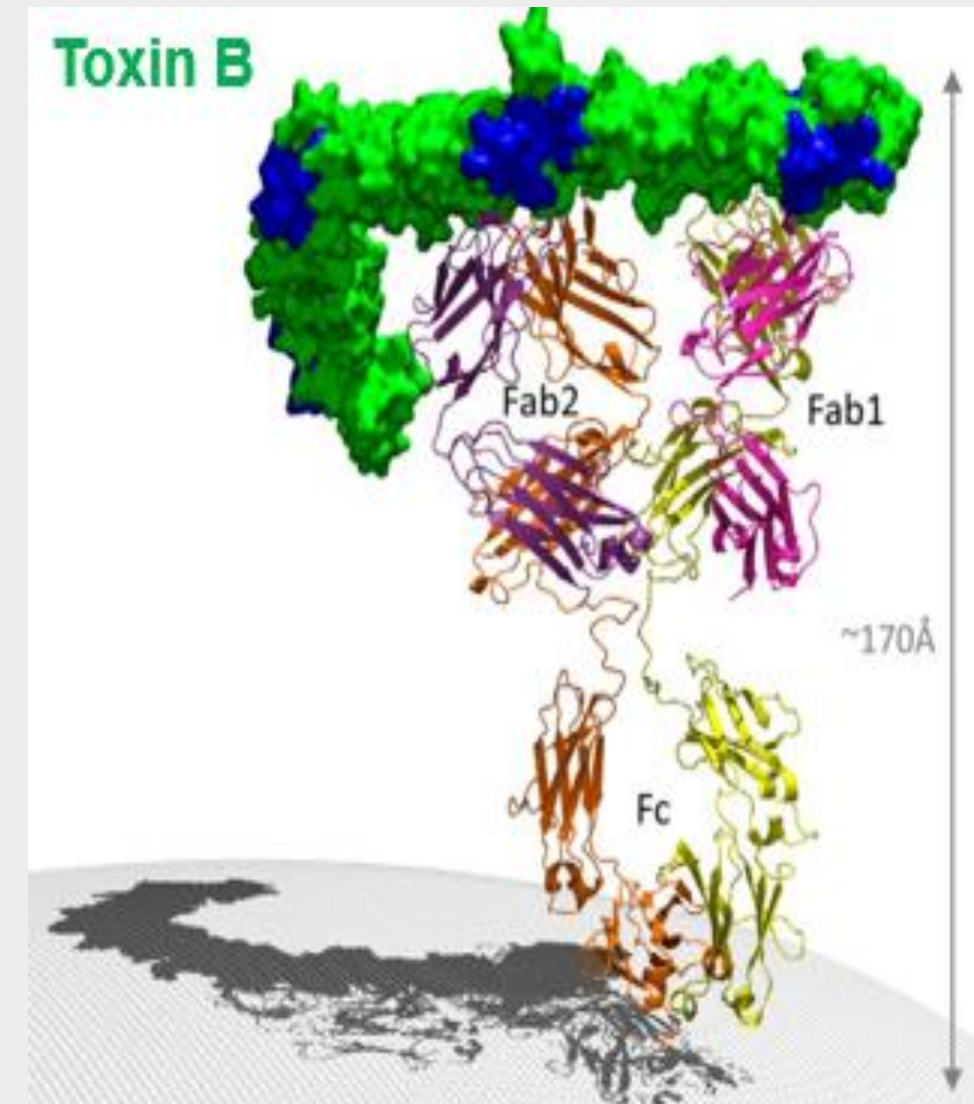
- First line for non-severe & severe CDI (not Fulminant CDI)
- Is a poorly absorbed, macrocyclic antibiotic with activity against Gram-Positive aerobes and anaerobes, including *Clostridium difficile*
- Only studied in non-severe & severe disease
 - Found to have similar clinical cure as PO vancomycin
 - Better in preventing recurrent CDI compared to PO vancomycin
 - NNT to prevent 1 recurrent CDI is 5 patients
- A 10-day course costs \$3,000, thus ~\$15,000 spent to prevent one CDI recurrence

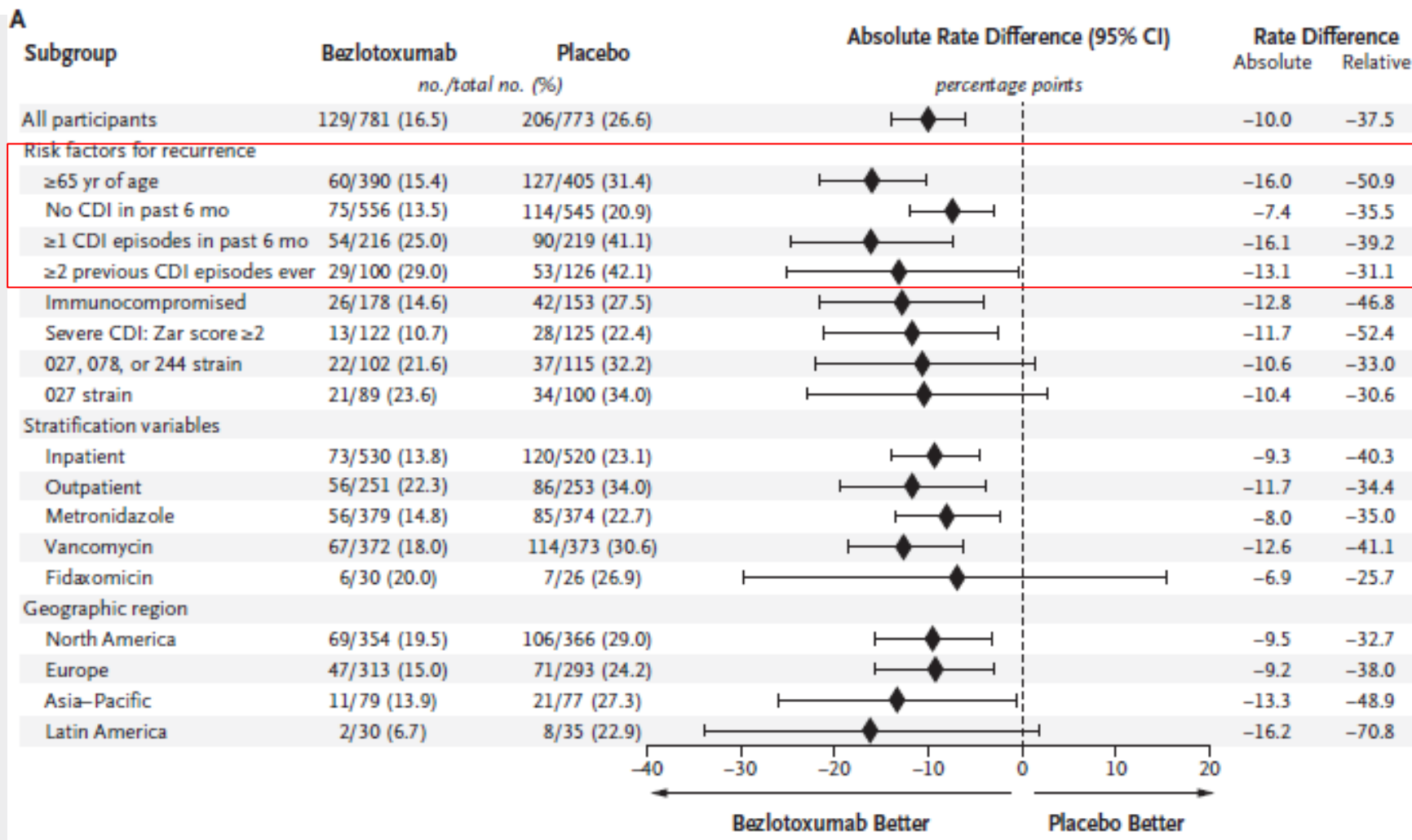
Fidaxomicin Restriction Criteria

- Banner criteria of use reserves for patients with risk factors for recurrence CDI and advises Case Management consult for insurance approval/prior authorization
 - Copays have ranged from \$50 to \$1,200!!!
- Risk factors:
 - Concomitant broad-spectrum antibiotic used for another diagnosis or suspected infection
 - severely immunocompromised (e.g. hematologic cancer with neutropenia expected >30 days, BMT, early SOT)
 - age $\geq$ 65 years

Bezlotoxomab (Zinplava)

- Human monoclonal antibody (mAb)
- Mechanism: inhibits the binding of toxin B to mammalian cells, preventing intracellular entry of toxin B, thus averting colonic cell inflammation.
- 10mg/kg x1 infusion (for outpatient use only!!!)
- ADE: Exacerbation of congestive heart failure (13%)
- **Prevention** of *Clostridium difficile* infection (CDI) **recurrence** in patients >18 yo receiving standard of care antibacterial therapy for CDI.
 - Efficacy seen in high-risk patient
 - CDI in previous 6 months
 - Patients with BI/NAP1/027 strain
 - ≥65 yo and immunocompromized patients





- Number needed to treat to prevent 1 CDI recurrence: 10 patients
- Available strengths
 - Zinplava 1000mg/40mL (40mL) solution; price per vial \$4,000
- Cost of preventing 1 recurrent C diff infection: \$40,000!!!

Case

1. AP is a 70 year old woman with a PMH of complicated diverticulitis, kidney transplant (2016), and MDRO history. AP presents with some discomfort in the lower abdomen and is started on meropenem. On the 3rd day of admission, she develops profuse watery diarrhea (>3x per day). A clostridium difficile GDH/toxin test comes back positive (no previous hx of GDH). Her Scr is 1.0 and WBC of 25,000. Classifying this as a severe CDI, what is the best treatment option?
 - A. Metronidazole PO 500mg PO q8h x 10 days
 - B. Vancomycin 125mg PO q6h x 10 days
 - C. Fidaxomicin PO 200mg q12h
 - D. Vancomycin 125mg PO q6h, consult case management for Fidaxomicin 200mg q12h x10 days prior authorization to be approved.

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Antimicrobial Duration of Therapy

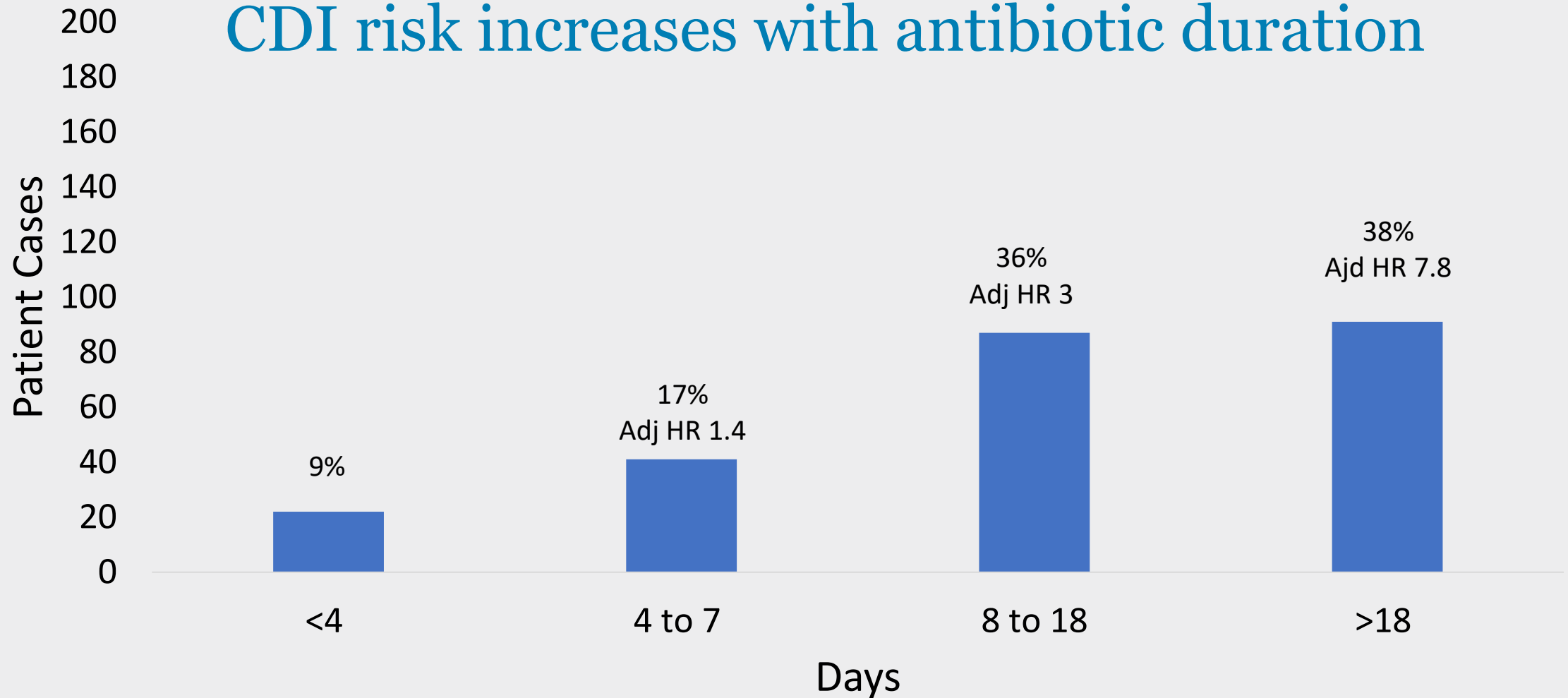
Antibiotic Duration is Important

- We don't want to treat for too short
 - Clinical failure
 - Relapse
 - Selecting resistance in culprit pathogen



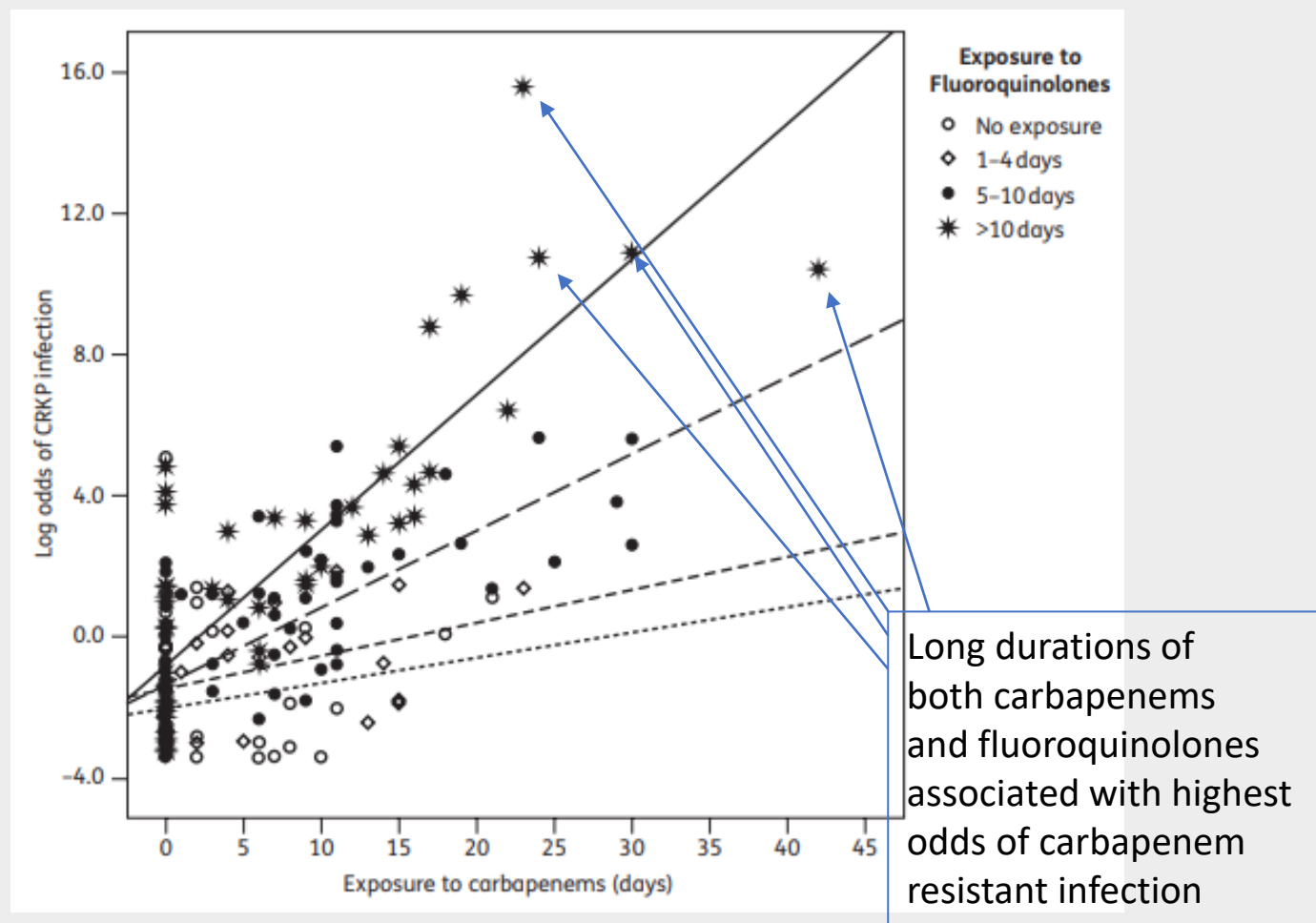
- We don't want to treat too long
 - *C. difficile* infection
 - Selecting resistance in bystander flora
 - Adverse events
 - Costs

CDI risk increases with antibiotic duration



Linking resistance to Antibiotic use

- Resistance correlates with antimicrobial usage
- Resistance is higher among patients who have received prior antibiotics



Stewardship: Shorter = Better

Diagnosis	Short (d)	Long (d)	Result	#RCT
CAP	3-5	5-14	Equal	13
Atypical CAP	1	3	Equal	1
VAP	8	15	Equal	2
cUTI/Pyelo	5 or 7	10 or 14	Equal	9*
Intra-abd	4	10	Equal	2
GNB Bacteremia	7	14	Equal	3**
Cellulitis/Wound/Abscess	5-6	10	Equal	4 [†]
Osteomyelitis	42	84	Equal	2
Osteo with Removed Implant	28	42	Equal	1
Debrided Diabetic Osteo	10-21	42-90	Equal	2 [‡]
Septic Arthritis	14	28	Equal	1
AECB & Sinusitis	≤5	≥7	Equal	>25
Neutropenic Fever	AFx72 h	+ANC>500	Equal	1
<i>P. vivax</i> Malaria	7	14	Equal	1

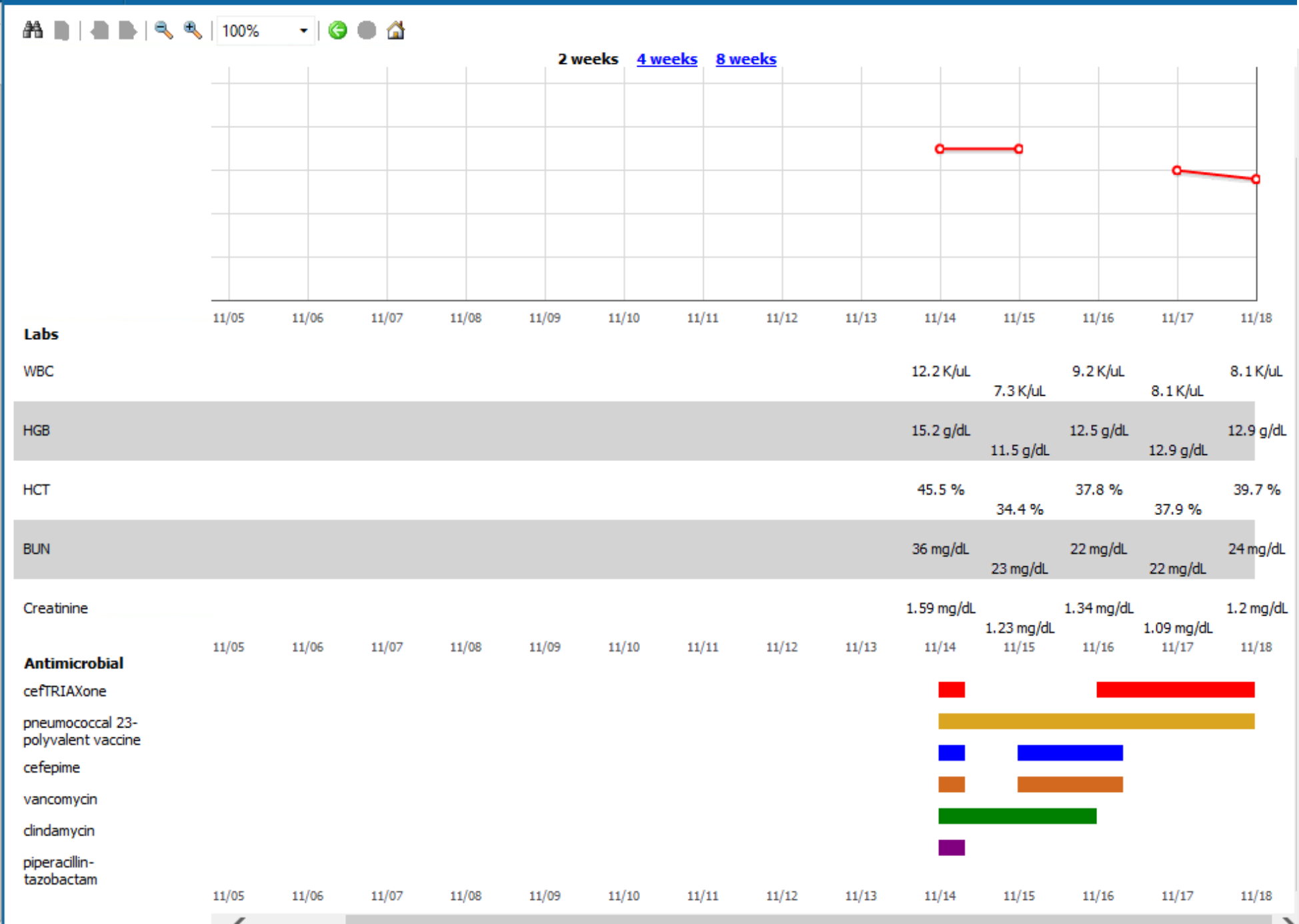
Total: 14 Diseases

67 RCTs

*2 RCT included males, the smaller one found lower 10-18 d f/up cure in males with 7 days of therapy but no difference at longer follow-up, larger exclusive male study found no diff in cure; **GNB bacteremia also in UTI/cIAI RCTs; [†]3 RCTs equal, 1 (low dose oral flucox) ↑relapses 2° endpoint; [‡]all patients debrided, in 1 study total bone resection (clean margins); refs at <https://www.bradspellberg.com/shorter-is-better>

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- Oncology View
- Oncology
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- Form Browser
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- Infusion Billing Report
- Interactive View and I & O
- MAR
- MAR Summary
- Med Request - Enhanced
- mPages
- Outside Records
- Patient Information
- PMP Gateway (AZ and NV only)



Better documentation

- What to document
 - Antibiotic name, indication for therapy, current day of therapy and expected therapy end date
- Poor example
 - Continue antibiotics
 - Continue vanco/Zosyn
- Good example
 - Continue ceftriaxone for SBP prophylaxis, 7 day course to complete 6/15
 - Continue Unasyn for aspiration pneumonia (start date: 6/8; can switch to Augmentin on discharge through 6/14 to complete 7 day course)

Thank you

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