Duration of Therapy

Current state of the evidence

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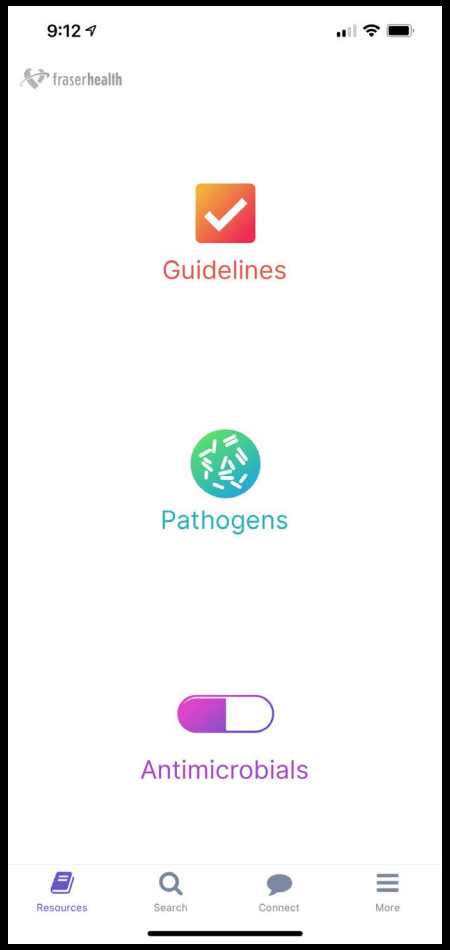
Disclosures

None to declare

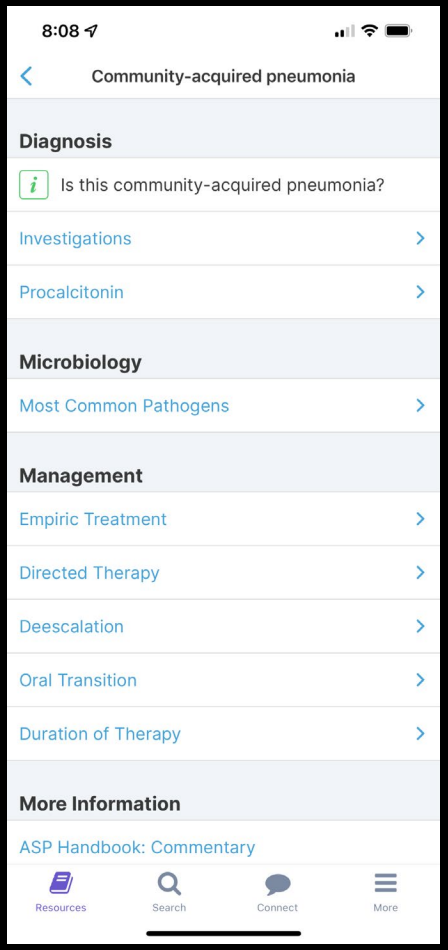
Learning Objectives

1. Recognize the historical dogma around treatment duration in bacterial infections.
2. Know the harms of prolonged antibiotic treatment.
3. Be aware of the evidence supporting shorter treatment durations in bacterial infections.

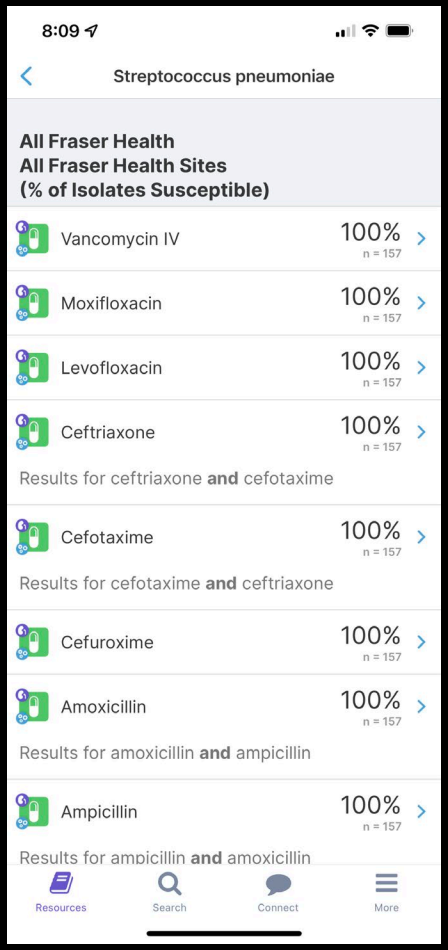
Firstline (Spectrum) App



Firstline Home Screen

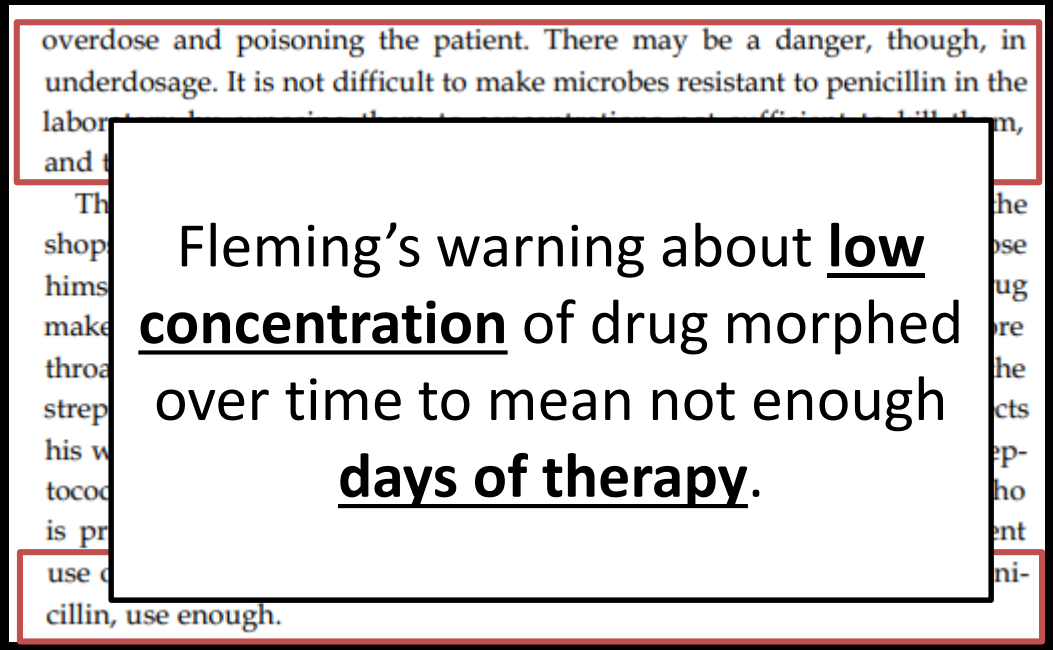


Community Acquired Pneumonia



S. pneumoniae antibiogram

Misunderstanding Fleming


overdose and poisoning the patient. There may be a danger, though, in underdosage. It is not difficult to make microbes resistant to penicillin in the

Fleming's warning about **low concentration** of drug morphed over time to mean not enough **days of therapy**.

cillin, use enough.

https://www.nobelprize.org/uploads/2018/06/fleming-lecture.pdf

Evolution of Duration

- In 1940's idea emerged that longer treatment (beyond clinical resolution) could prevent recurrence of infection
- 1945 study of 1-4 days of penicillin for pneumococcal pneumonia
  - 3/44 pts relapsed (1st had only 12 hrs of therapy, 2nd had different serotype, 3rd recurred 1 month later)
- Became modern dictum: "complete your course of antibiotics"

Meads M et al. NEJM 1945;232:747. Hanretty AM et al. Pharmacotherapy 2018;38:674

Thank This Guy



https://commons.wikimedia.org/wiki/File:Rome-Capitole-StatueConstantin.jpg

ANTIBIOTIC RESISTANCE

HANDLE ANTIBIOTICS WITH CARE

Antibiotic resistance happens when bacteria change and become resistant to the antibiotics used to treat the infections they cause. This is compromising our ability to treat infectious diseases and undermining many advances in medicine.

We must handle antibiotics with care so they remain effective for as long as possible.

WHAT YOU CAN DO



1. Only use antibiotics when **prescribed** by a certified health professional
2. Always take the **full prescription**, even if you feel better
3. **Never use left over** antibiotics
4. **Never share** antibiotics with others
5. **Prevent infections** by regularly washing your hands, avoiding close contact with sick people and keeping your vaccinations up to date

www.who.int/drugresistance

#AntibioticResistance

World Health Organization

https://www.who.int/campaigns/world-antibiotic-awareness-week/posters/you.pdf?ua=1

Perfect Combo

If we treat longer…

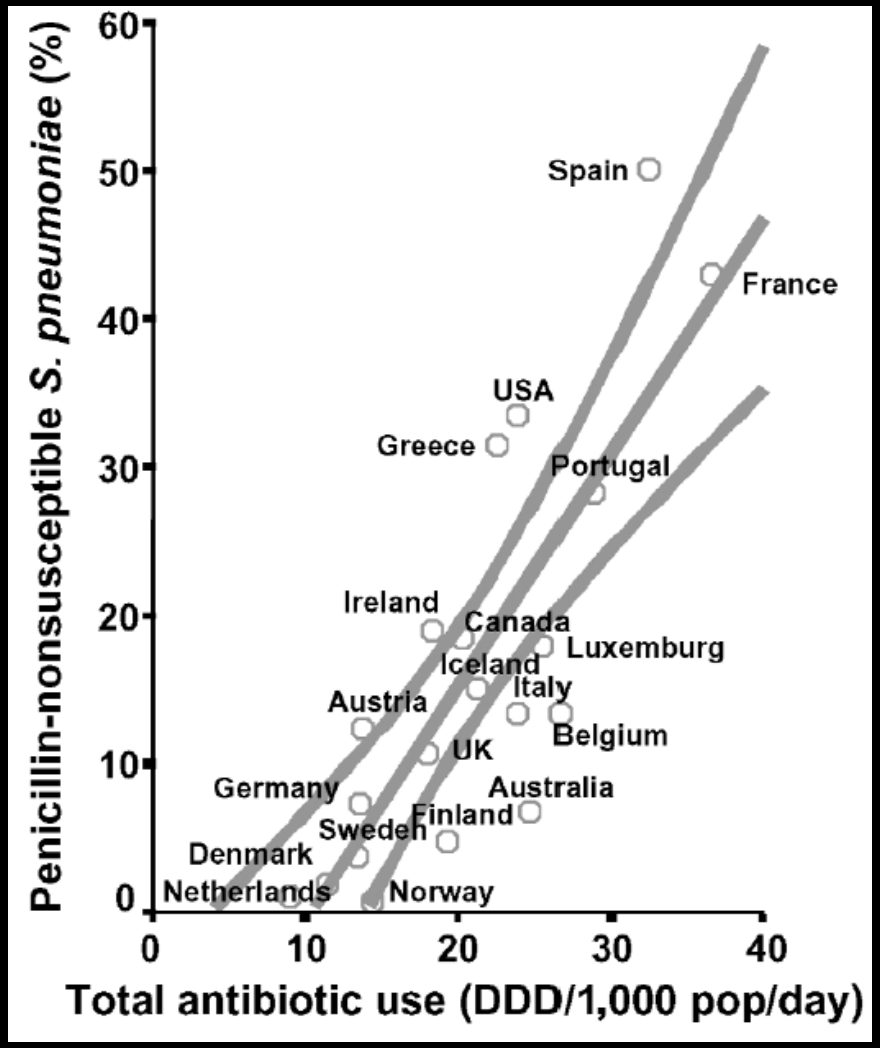
Less chance of bacteria developing resistance

&

Less chance of patient's infection recurring

…or so we thought

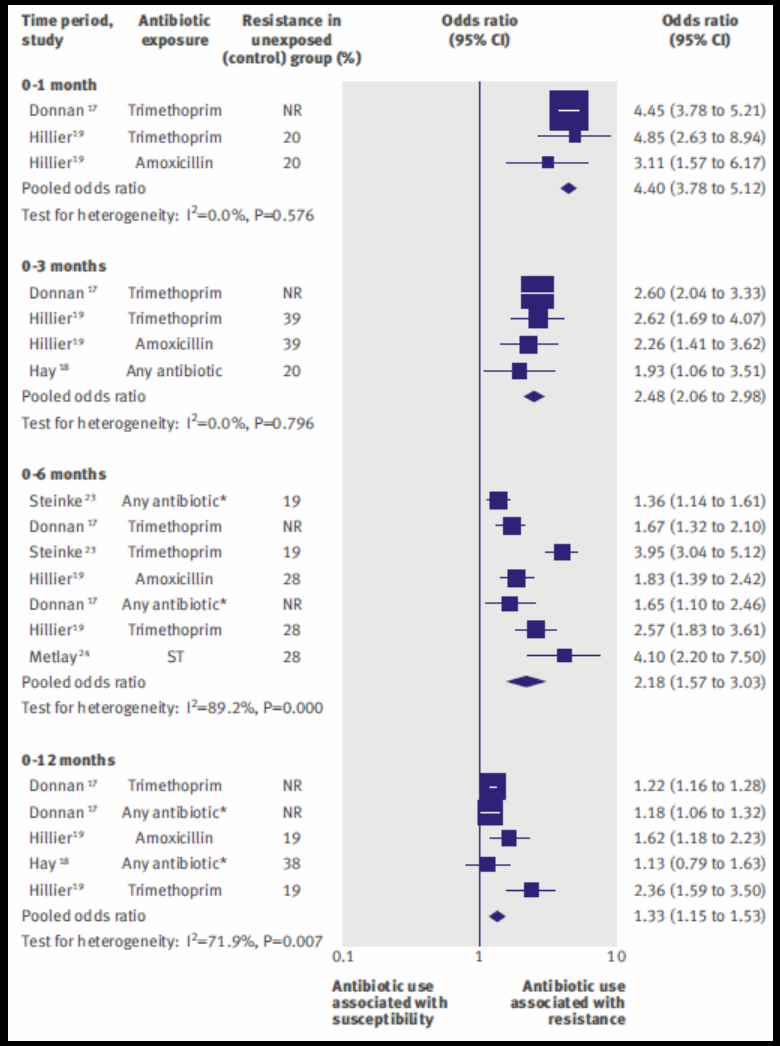
Societal Antibiotic Use & Resistance



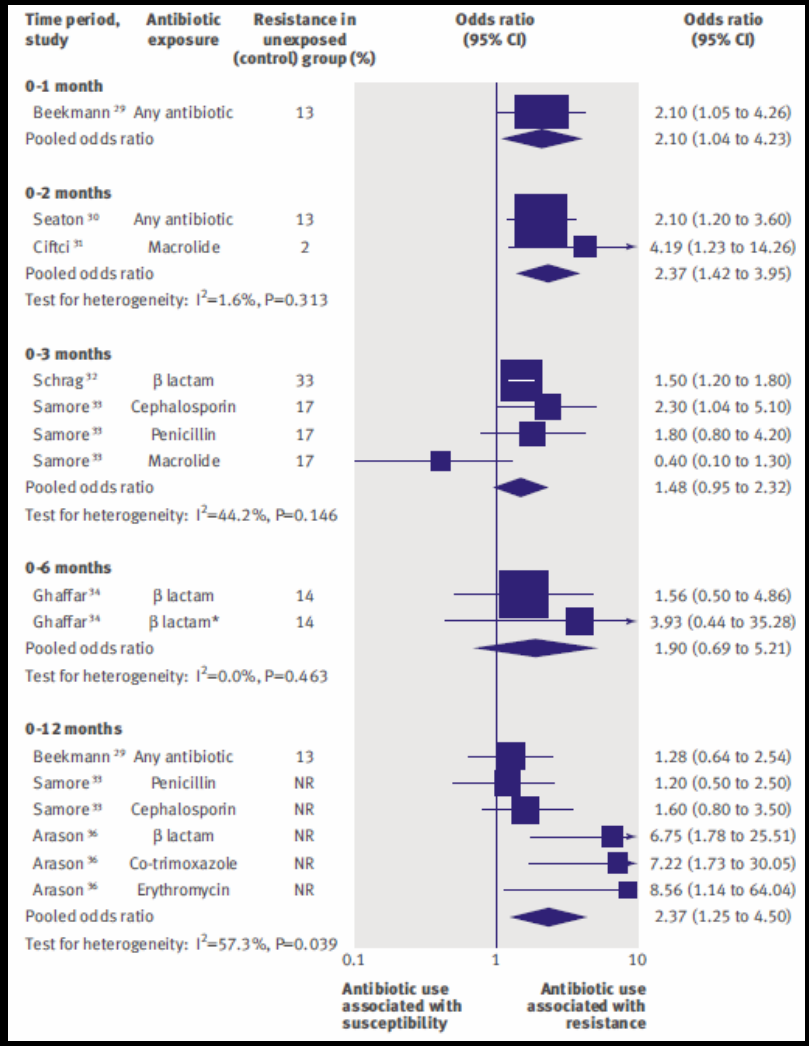
Albrich WC et al. Emerging Infectious Diseases. 2004;10:514

Individual Antibiotic Use & Resistance

Antibiotic use and resistance in UTI bacteria



Antibiotic use and resistance in RTI bacteria



Costelloe C et al. BMJ 2010;340:c2096

Harms of Excess Duration

***C. difficile* infection and cumulative antibiotic exposure**

Characteristic	CDI positive *n* (%)	CDI negative *n* (%)	Crude hazard ratio[a,b] (95% CI)	Adjusted hazard ratio[a,c,d] (95% CI)
Defined daily doses[e], median (IQR)	14.8 (21.2)	7.2 (12.3)	—	—
<3.0	18 (7)	1502 (15)	Ref	Ref
3.0 to 7.79	49 (20)	3702 (37)	1.1 (.7, 2.1)	1.2 (.7, 2.1)
7.80 to 21.0	89 (37)	2952 (30)	2.9 (1.8, 4.8)	2.8 (1.7, 4.6)
>21.0	85 (35)	1757 (18)	5.3 (3.2, 8.8)	5.3 (3.1, 9.0)
Antibiotic days, median (IQR)[f]	14.0 (23.0)	7.0 (9.0)	—	—
<4	22 (9)	2208 (22)	Ref	Ref
4 to 7	41 (17)	3071 (31)	1.5 (.9, 2.4)	1.4 (.8, 2.4)
8 to 18	87 (36)	3097 (31)	3.4 (2.1, 5.4)	3.0 (1.9, 5.0)
>18	91 (38)	1537 (16)	9.8 (6.0, 16.0)	7.8 (4.6, 13.4)
Number of antibiotics, median (IQR)[f]	3.0 (4.0)	2.0 (2.0)	—	—
1	31 (13)	3744 (38)	Ref	Ref
2	54 (22)	2507 (25)	2.7 (1.8, 4.3)	2.5 (1.6, 4.0)
3 or 4	70 (29)	2505 (25)	3.7 (2.4, 5.7)	3.3 (2.2, 5.2)
5 or more	86 (36)	1157 (12)	11.6 (7.7, 17.4)	9.6 (6.1, 15.1)

Stevens V et al. Clin Infect Dis. 2011;53:42

Harms of Excess Duration

- Retrospective CAP/HCAP study, 43 hospitals in Michigan
  - 2/3 of patients treated with excessive duration (>5-7 days)
  - 93% of that prescribed on hospital discharge

Outcomes at 30 Days	Appropriate Duration (n = 2090), n (%)†	Excess Duration (n = 4391), n (%)‡	Unadjusted OR per Excess Day (95% CI)§	Unadjusted P Value§	Adjusted OR per Excess Day (95% CI)§	Adjusted P Value§
Mortality‖	40 (1.9)	88 (2.0)	0.99 (0.94–1.03)	0.52	1.01 (0.97–1.05)	0.60
Readmission‖	294 (14.1)	497 (11.3)	0.99 (0.96–1.02)	0.48	1.00 (0.98–1.03)	0.92
Emergency department visit‖	238 (11.4)	480 (10.9)	0.97 (0.94–1.00)	0.021	0.98 (0.95–1.01)	0.166
Antibiotic-associated adverse event¶	72 (3.4)	210 (4.8)	1.04 (1.01–1.07)	0.012	1.03 (1.00–1.06)	0.038
Clostridioides difficile infection**	11 (0.5)	22 (0.5)	0.92 (0.81–1.05)	0.21	0.93 (0.81–1.07)	0.30
Provider-documented††‡‡	43 (2.1)	87 (2.0)	1.00 (0.94–1.05)	0.86	0.99 (0.94–1.05)	0.85
Patient-reported††§§	26/1132 (2.3)	114/2460 (4.6)	1.05 (1.02–1.08)	<0.001	1.05 (1.02–1.08)	0.001
Composite adverse outcome‖	499 (23.9)	897 (20.4)	0.98 (0.96–1.00)	0.078	0.99 (0.97–1.01)	0.40

5% increase in adverse events for every extra day of unnecessary antibiotics

Vaughn VM et al. Ann Intern Med 2019. doi:10.7326/M18-3640.



How long do you need to treat?

A trip down evidence lane…

CASE 1
COMMUNITY ACQUIRED PNEUMONIA

CAP Case

- 87F with 3 days of progressive cough, drowsiness, and chills.
- PMHx: Dementia, HTN, GERD, hypothyroidism
- COVID vaccine x 3
- No recent antibiotics

CAP Case

- Vitals: HR 90, BP 135/85, RR 24, Sat 95% RA, T 35.8C.
- Frail. Appears unwell and tachypnic, but not in distress.
- Crackles and bronchial breath sounds at left base.

CAP Case

- You prescribe amox-clav 500 mg PO TID and hypodermoclysis hydration.

How long do you treat for?

Duration in CAP

- Meta-analyses established short course therapy in CAP (7 days or less) to be equivalent to longer courses
- ATS/IDSA recommend 7 days of therapy for MRSA and Pseudomonas HAP/VAP

Pneumonia without complicating features (e.g., empyema) almost never need more than 7d tx.

Tansarli GS et al. Antimicrob Agents Chemother. 2018;62:e00635. Furlan L et al. Inter Emerg Med. 2019;14:377.
Kalil AC et al. Clin Infect Dis. 2017;64:1298.

How Much is Enough?

- Older RCT's comparing 3-5d vs long course therapy for hospitalized CAP

Study	Short Course	Long Course	Cure
Leophonte 2002 *Multicentre France*	5d ceftriaxone	10d ceftriaxone	82% vs 83%
Dunbar 2003 *Multicentre USA*	5d levofloxacin	10d levofloxacin	92% vs 91%
El Moussaoui 2006 *Multicentre Netherlands*	3d ampicillin	3d ampicillin +5d amoxicillin	89% vs 89%

Leophonte P et al. Med Mal Infect. 2002;32:369. El Moussaoui R et al. BMJ 2006;332:1355. Dunbar LM et al. CID 2003;37:752

Duration in CAP

- Multicenter RCT in Spain of hospitalized CAP
- Patients randomized at day 5 of CAP therapy
  - Control: physician decision
  - Intervention: antibiotics stopped at day 5 if

    T ≤ 37.8°C for 48 hrs
    AND no more than 1 sign of clinical instability

    sBP <90 mmHg
    HR >100/min
    RR > 24/min
    Sat <90% or PaO2 <60 mmHg on room air

Uranga A et al. JAMA Intern Med. 2016;176:1257

Duration in CAP

	Control Group (n=150)	Intervention Group (n=162)	P value
Duration of antibiotics, mean	10 d	5 d	**<0.001**
Primary Outcomes			
Clinical success, day 10	48.6%	56.3%	0.18
Clinical success, day 30	88.6%	91.9%	0.33
Secondary Outcomes			
30-day mortality	2.2%	2.1%	>0.99
30-day readmission	6.6%	1.4%	**0.02**

Uranga A et al. JAMA Intern Med. 2016;176:1257

New CAP Duration Trial

- Multicenter RCT in France of hospitalized CAP
- All patients given IV beta-lactam monotherapy for 3 days, then…
- Randomized at day 3 of CAP therapy if they met clinical stability criteria:
  - Placebo x 5 days
  - Oral amox-clav TID x 5 days

Dinh A et al. Lancet. 2021;397;1195.

New CAP Duration Trial

	3d Group (n=152)	8d Group (N=151)	P value
Baseline Characteristics			
Age	72.5	74.0	
PSI class IV/V (>9% mortality)	38%	41%	
Primary Outcomes			
Clinical cure, day 15	77%	68%	9.4% (-0.4% to 20%) NON-INFERIOR
Secondary Outcomes			
Clinical cure, day 30	72%	72%	>0.99
Length of stay	5d	6d	0.74
30-day mortality	2%	1%	>0.99

Dinh A et al. Lancet. 2021;397;1195.

Duration of Therapy

Discontinuation at Day 3 (short course)	Discontinuation at Day 5 (DEFAULT)
1. Afebrile (T≤37.8C) 2. Have **no** CAP-associated sign of clinical instability - sBP <90 mmHg - HR >100 beats/min - RR > 24 breaths/min - O2 sat <90% on room air (or baseline home O2)	1. Afebrile (T≤37.8C) for 48 hours 2. Have **no more than 1** CAP-associated sign of clinical instability - sBP <90 mmHg - HR >100 beats/min - RR > 24 breaths/min - O2 sat <90% on room air (or baseline home O2)
Dinh A et al. Lancet 2021. doi: 10.1016/S0140-6736(21)00313-5	Uranga A et al. JAMA IM 2016. doi: 10-1001/jamainternmed.2016.3633

CAP Case

- By day 3, her temperature has normalized without fevers, other vitals have normalized, and she is not requiring supplemental oxygen.

- As she meets criteria for short course antibiotic therapy, you discontinue antibiotics.

CASE 2
UTI

UTI Case

- 78M with 24 hrs of decline in functional status and shivers.
- PMHx: Dementia, HTN, dyslipidemia, CAD with CABG, COPD. BPH. Appendectomy and cholecystectomy. TKA x 2.
- Last antibiotics 6 month ago for AECOPD (azithromycin)

UTI Case

- Vitals: HR 105, BP 142/86, RR 22, Sat 99% RA, T 37.7C
- Cardiac and respiratory exam unremarkable
- Abdomen soft and non-tender
- Mild left flank discomfort with percussion

Aside: “Fever” in elderly

- Older adults have lower basal temperature and blunted diurnal variation
- Lower temperature threshold to define fever in older adults:
  - Single temperature >37.8C
  - Repeated temperatures >37.2C within 24-48hrs
  - Increase of >1.1C over baseline

Rowe TA et al. Infection Control & Hospital Epidemiology. 2020. doi: 10.1017/ice.2020.1282

UTI Case

- In and out catheterization performed
  - Only 120 cc of residual urine
  - Urinalysis: positive blood, nitrite, leukocyte esterase
  - Urine culture sent

UTI Case

- You diagnose potential pyelonephritis and start oral amox-clav.

- As this complicated UTI in a male with limited history, you perform a DRE to rule out prostatitis
  - No prostatic tenderness or fluctuant abscess
  - No scrotal redness or tenderness

How long do you treat complicated UTI?

Urinary Tract Infections

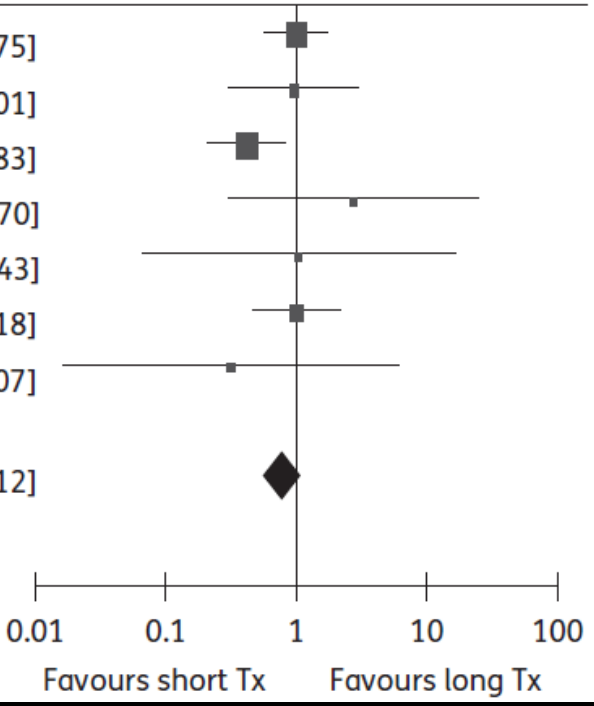
- Meta-analysis of all RCTs comparing ≤7 days vs longer for acute pyelo/septic UTI.

EOF Clinical Failure

Study or subgroup	Short Events	Short Total	Long Events	Long Total	Weight	RR M-H, Fixed, 95% CI
Peterson 2008	23	265	21	241	32.8%	1.00 [0.57–1.75]
Sandberg 2012	5	73	6	84	8.3%	0.96 [0.31–3.01]
Talan 2000	10	106	24	106	35.8%	0.42 [0.21–0.83]
Jernelius 1988	3	32	1	29	1.6%	2.72 [0.30–24.70]
Klausner 2007	1	94	1	98	1.5%	1.04 [0.07–16.43]
Mensa 1999	12	123	11	113	17.1%	1.00 [0.46–2.18]
Ode 1980	0	13	2	21	2.9%	0.31 [0.02–6.07]
Total (95% CI)		706		692	100.0%	0.79 [0.56–1.12]
Total events	54		66			

Heterogeneity: $\chi^2 = 6.06$, df = 6 ($P = 0.42$); $I^2 = 1\%$

Test for overall effect: $Z = 1.32$ ($P = 0.19$)



Eliakim-Raz N et al. JAC 2013;68:2183.

GNB Bacteremia Trials

- Multicentre RCT in Israel & Italy
- Patients randomized to 7 vs 14 d of therapy
  - Uncontrolled focus of infection excluded

	7d Treatment (n=306)	14d Treatment (n=298)	P value
Select Patient Characteristics:			
UTI Source	69.3%	66.8%	
E. coli	60.8%	65.1%	
Outcomes:			
90d Mortality	11.8%	10.7%	N/S
Readmission	38.9%	42.6%	N/S
Relapse of bacteremia	2.6%	2.7%	N/S

Yahav D et al. CID 2019;69:1091

GNB Bacteremia Trials

- Multicentre RCT in Switzerland
  - 3 arms: CRP-guided vs 7d vs 14d duration
    - CRP group d/c abx starting day 5 if CRP dropped 75%
  - Uncontrolled focus of infection excluded

Median duration 7d →

	CRP-guided (n=169)	**7 d (n=169)**	**14 d (n=165)**	**P value**
Select Patient Characteristics:				
UTI Source	73%	63%	71%	
E. coli	75%	73%	75%	
Outcomes:				
Clinical success at 30 d	98%	93%	95%	Non-inferior
Mortality at 30 d	1%	4%	2%	

Von Dach E et al. JAMA 2020;323:2160

GNB Bacteremia Trials

- Multicentre RCT in Spain
- Patients randomized to 7 vs 14 d of therapy
  - Uncontrolled focus of infection excluded

	7d Treatment (n=119)	14d Treatment (n=129)	P value
Select Patient Characteristics:			
Female	49.2%	45.7%	
UTI Source	59.3%	51.2%	
E. coli	66.4%	61.2%	
Outcomes:			
28d Mortality	2.5%	7.0%	Non-inferior
Readmission / Prolonged LOS	12.6%	20.9%	Non-inferior
Clinical failure	7.3%	9.8%	Non-inferior

Molina J et al. Clinical Microbiology and Infection 2021. doi: 10.1016/j.cmi.2021.09.001

UTI Case

- Patient improves over first few days of therapy
- Temperature returns back to baseline
- Urine culture confirms fully-susceptible *E. coli*

- You complete 7 days of total therapy then discontinue antibiotics

CASE 3
SKIN & SOFT TISSUE INFECTION

Cellulitis Case

- 68M with a fall. Only complaint is burning pain to right leg, of uncertain duration.
- PMHx: CVAs, HTN, dyslipidemia, diabetes, obesity, gout, chronic edema, previous cellulitis
- MRSA colonized

Cellulitis Case

- Vitals: HR 88, BP 122/74, RR 16, Sat 99% RA, T 38.1C
- Cardiac and respiratory exam unremarkable
- Abdomen soft and non-tender, no CVA tenderness
- Palpable small right inguinal LN, mildly tender

Cellulitis Case



UpToDate

Cellulitis Case

- You diagnose nonpurulent cellulitis and start cephalexin 1000 mg PO QID (for elevated BMI)

- Remember…Nonpurulent cellulitis is almost always streptococcal (and rarely MSSA).
  - MRSA colonization isn't relevant here!

How long do you treat?

Aside: Initial “worsening”

- Cellulitis can often look worse in the first 1-2 days of therapy
- Inflammatory response to rapidly dying bacteria
- Continue guideline-recommended therapy
- Red flags: severe disproportionate pain, progressive sepsis

Skin/Soft Tissue Infections

- Duration of therapy in skin/soft tissue infections is a frustrating evidence gap
- RCT's comparing short vs long course therapy include drug classes we don't routinely use:

Study	Short Course	Long Course	Outcome
Hepburn 2004	5d levofloxacin	10d levofloxacin	98% vs 98%
Prokocimer 2013	6d tedizolid	10d linezolid	85.5% vs 86.0%
Moran 2014	6d tedizolid	10d linezolid	87% vs 88%

Hepburn MJ et al. Arch Intern Med 2004;164:1669. Prokocimer P et al. JAMA 2013;309:559. Moran GJ et al. Lancet ID 2014;14:696.

Skin/Soft Tissue Infections

- Multicentre, placebo-controlled, RCT in the Netherlands of hospitalized cellulitis
- Patients randomized to 6 vs 12 d of flucloxacillin
  - Excluded severe PAD and diabetic foot ulcer infection
  - Trial stopped early due to slow recruitment

	12d Treatment (n=76)	6d Treatment (n=73)	ARR (%)
Select Patient Characteristics:			
Age, mean	63.1	61.9	
Obesity	38.2%	45.2%	
Previous cellulitis	33.3%	42.5%	
Outcomes:			
Primary: Cure without relapse	50.0%	49.3%	0.7 (-15 to 16)

Cranendonk DR et al. Clinical Microbiology and Infection 2020. doi: 10.1016/j.cmi.2019.09.019

Cellulitis Case

- The warmth and redness begins to recede on day 3 with good improvement by day 6.
- Swelling persists, still tender to palpation
- Vitals are normal, afebrile.

You stop antibiotics on day 6.

You encourage leg elevation. As pedal pulses are strong, you prescribe light compression therapy and plan to increase strength as swelling decreases.

Summary: Duration

Condition	Duration of Therapy
Community acquired pneumonia	3 – 5 days
Acute pyelonephritis/bacteremic UTI	7 days
Skin & soft tissue infections	5-6 days

Duration Rationale

- Shortest duration of therapy necessary for effective cure
- Every day of antimicrobial you prescribe beyond what's needed for effective cure = *increased risk of harm with NO increased benefit*.

"Just to be safe" may not be all that safe

- Reducing duration of therapy is the safest and most palatable strategy to reduce excessive antimicrobial use.

Rice LB. CID 2008;46:491. Spellberg B and Rice LB. Ann Intern Med 2019. doi:10.7326/M19-1509.

The Antibiotic “Course” is Dead



1945-2022

Shorter is Better

Llewelyn MJ et al. BMJ 2017;358:j3418. Spellberg B et al. JAMA IM 2016;176:1254

For More Information



CLINICAL

Maggie Wong, PharmD, ACPR, Tim T.Y. Lau, PharmD, ACPR, FCSHP, Victor Leung, MD, FRCPC, Kevin Afra, MD, MHA, FRCPC

Is shorter better? Duration of therapy for common bacterial infections in adults

Randomized controlled studies conducted over the last decade have indicated that a shorter duration of antibiotic therapy is just as effective as longer treatment.

ABSTRACT: Antimicrobial resistance is a looming threat to our society's health. Physicians need simple strategies for antimicrobial stewardship that can be readily incorporated into everyday practice. Addressing duration of therapy is one of these key strategies. Every day of antibiotic exposure beyond that which is necessary to cure the infection increases the risk of adverse events and antimicrobial resistance without providing additional benefits. We focus on the adult population and commonly encountered conditions: community-acquired pneumonia, intra-abdominal infections, skin and soft tissue infections, osteomyelitis, complicated urinary tract infections, and gram-negative bacteremia. The treatment of these common infections overlaps in primary and acute care practices. Recent literature suggests shorter duration of therapy is as effective as longer durations for these infections.

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This article has been peer reviewed.

Without a concerted societal effort, antimicrobial resistance is predicted to kill more people than cancer by the year 2050.[1] The human cost is staggering, with one death occurring every 3 seconds.[1] Appropriate use of antibiotics is one of the key strategies that can prevent this looming existential threat. Addressing the duration of treatment, and thus overall antibiotic exposure, is a simple practice change that all physicians can make. We focus on the duration of treatment for common bacterial infections in adults seen in community and hospital practices, based on the latest evidence in the literature.

Community-acquired pneumonia

Historically, community-acquired pneumonia treatment ranged from 7 to 10 days;[2] however, new data suggest that shorter durations of therapy are as effective. In 2007, the Infectious Diseases Society of America community-acquired pneumonia guidelines recommended that 5 days of treatment may be adequate in patients who are afebrile for 48 to 72 hours, and who do not have more than one of the following clinical signs of instability: heart rate greater than 100 beats/minute, respiratory rate greater than 24 breaths/minute, systolic blood pressure less than 90 mmHg, or arterial oxygen saturation less than 90% on room air.[3]

These recommendations were validated by a multicentre, randomized, noninferiority trial in Spain.[4] Noninferiority trials compare the effectiveness of a new regimen against a standard therapy; if the new regimen is not worse than the comparator within a defined amount, it is considered "noninferior" to the standard therapy and can be recommended for use. At day 5, hospitalized patients were randomly assigned to an intervention group or a control group. In the intervention group, researchers stopped giving antibiotics if patients reached clinical stability based on the Infectious Diseases Society of America guidelines; in the control group, the treatment duration was determined by physicians per usual practice. Primary outcome was defined as improvement in or resolution of signs and symptoms of community-acquired pneumonia at day 10 and day 30. Median duration of therapy was 5 days in the intervention group versus 10 days in the



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Duration of antimicrobial therapy for common infections in primary care

By Dr. Kevin Afra, Maggie Wong, PharmD, Tim T.Y. Lau, PharmD, and Dr. Victor Leung on August 15, 2022

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Tim T.Y. Lau, PharmD, ACPR, FCSHP (biography, no disclosures)

Victor Leung, MD, FRCPC (biography and disclosures). Disclosures: Member of advisory boards for GSK, Merck, and Biomerieux. Mitigating potential bias: Treatments or recommendations in this article are unrelated to products/services /treatments involved in disclosure statements.

What we have noticed

Appropriate use of antimicrobials is a key strategy to avert the looming threat of antimicrobial resistance. In the absence of significant societal change, antimicrobial resistance will kill more people than cancer by the year 2050.[1] Healthcare providers are increasingly aware of the importance of using antimicrobials wisely. The Choosing Wisely Canada campaign has excellent and practical recommendations for syndromes that do not require routine antibiotic prescription (e.g. upper respiratory tract infections and acute bronchitis).[2]

Nevertheless, many infections seen in routine practice are bacterial in etiology and benefit from antibiotic therapy. We often see antibiotics prescribed for 7 to 14 days for routine, community-acquired infections. These treatment durations are based on historical practice and dogma. As specialists in Infectious Diseases and Antimicrobial Stewardship, we are regularly asked how long to treat various common infections.

Antibiotic treatment duration decision making is fundamentally a balance of expected benefit and harm. Anchoring our expectations of benefit and harm with the most current literature can better inform clinical decision-making. The harms of antibiotics are often underappreciated.

The End

Questions?

Comments?