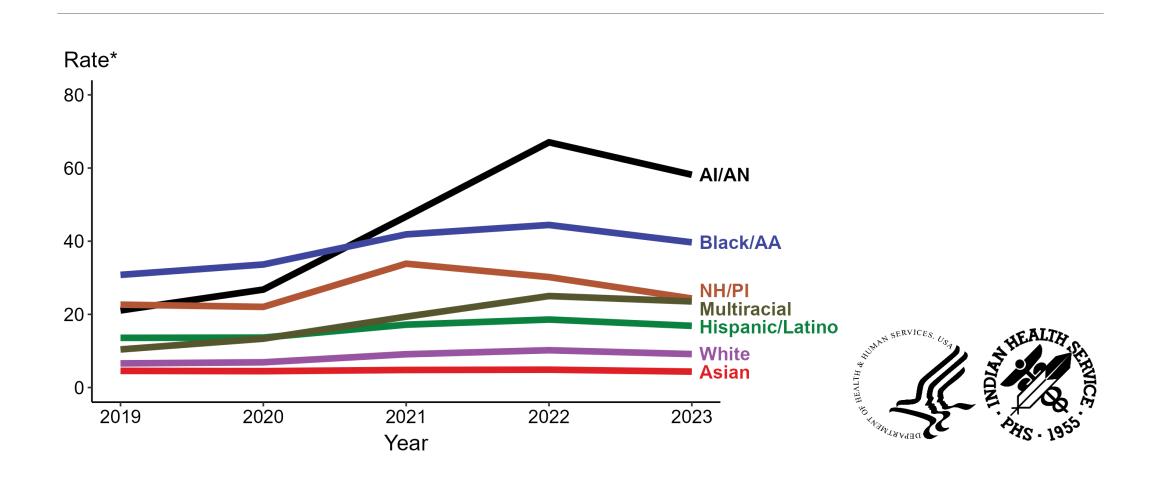
# Indian Health Service Penicillin Allergy Assessment Using the PEN-FAST Tool

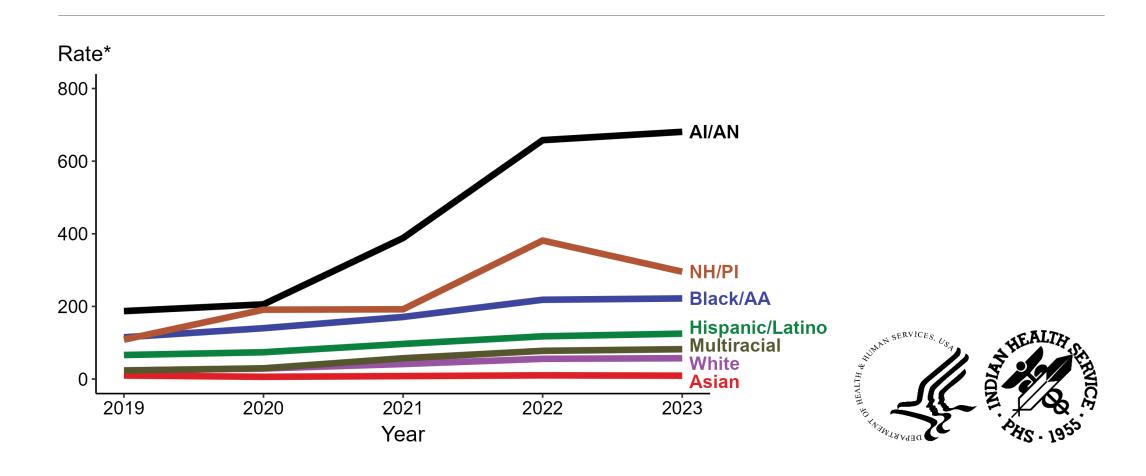
HOLLY VAN LEW, PHARMD, BCPS, AAHVIP
NATIONAL HIV/HCV/STI PROGRAM, IHS HQ
NOVEMBER 21, 2024



## Primary and Secondary Syphilis — Rates of Reported Cases by Race, United States, 2019–2023



### Congenital Syphilis — Rates of Reported Cases by Year of Birth, Race, United States, 2019–2023



IHS Resources:
 "Together
against syphilis"
Reference
Booklet



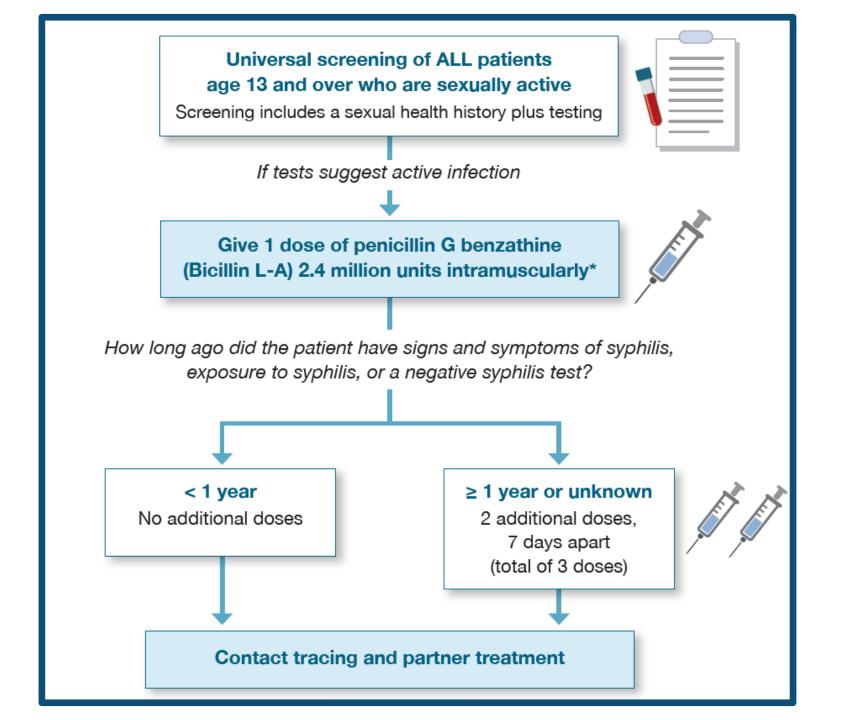
#### **Together against syphilis**

**Protecting the American Indian and Alaska Native communities** 



## Identifying and Treating Syphilis

Penicillin is the DRUG OF CHOICE for syphilis treatment



#### Best Practice Syphilis Treatment

Penicillin is the DRUG OF CHOICE for syphilis treatment

Treatment		Factors	
x1	Penicillin G benzathine 2.4 million units IM	<ul> <li>Exposure in prior 12 months</li> <li>Signs of syphilis in prior 12 months</li> <li>Prior negative syphilis test in prior 12 months</li> </ul>	
x3	Penicillin G benzathine 2.4 million units IM given weekly (total dose 7.2 million units)	<ul> <li>Exposure ≥12 months ago</li> <li>Signs of syphilis ≥12 months ago and untreated</li> <li>Prior negative test &gt;12 months ago</li> <li>Unknown duration</li> </ul>	

Ocular, otic, and neurosyphilis can occur at any stage or duration of infection and requires IV aqueous penicillin treatment.

## IHS Resources PEN-FAST Reference Card

#### Clarifying penicillin allergy: PEN-FAST

- Although fewer than 10% of patients with a labeled penicillin allergy are truly allergic (e.g., hives, anaphylaxis), it is the most commonly reported drug allergy, reported by 5%-10% of outpatient and 11%-15% of hospitalized patients.<sup>1</sup>
- Penicillin sensitization decreases drastically over 10 years; after 20 years, fewer than 1% of patients with an allergic reaction maintain their sensitivity.
- Nausea, vomiting, rash, and a family history of penicillin allergy are not reasons to avoid treatment of syphilis with penicillin.<sup>2</sup>

**PEN-FAST** can be used for adult patients (age ≥ 18) with a documented penicillin allergy who need syphilis treatment. It is not appropriate for pregnant patients.

#### Scoring using PEN-FAST<sup>3</sup>

Component	Description	Score
PEN	Penicillin allergy reported by the patient	Yes
F	Five years or less since reaction 2	
Α	Anaphylaxis or angioedema 2	
S	Severe cutaneous adverse reaction 2	
Т	Treatment required for reaction	1

#### Using the PEN-FAST score<sup>3</sup>

Score	Risk of positive penicillin allergy test	Recommendation
0	Very low risk (< 1%)	Prescribe first-line penicillin therapy
1-2	Low risk (5%)	Give an oral penicillin challenge
3	Moderate risk (20%)	Proposibo alternate thereny*
4-5	High risk (50%)	Prescribe alternate therapy*

<sup>\*</sup>Pregnant patients may require desensitization; consult with allergy or infectious disease.

A **Penicillin Allergy Verification Consult**, available at some sites, uses PEN-FAST to guide prescribing. If not available, consider creating a template and establishing a process and protocol for oral penicillin challenge in the clinic.



These are general recommendations only; specific clinical decisions should be made by the treating clinician based on an individual patient's clinical condition.

This program is made possible by the Indian Health Service.

#### Oral challenge with amoxicillin





Remove the penicillin allergy from the patient record.

#### Treatment in patients with a true penicillin allergy<sup>4,5</sup>

Patient category	Recommended treatment	Duration of treatment
Adults with early	Doxycycline 100 mg orally twice daily	14 days
syphilis	Tetracycline 500 mg orally four times daily	14 days
Adults with late syphilis	Doxycycline 100 mg orally twice daily	28 days
Pregnant patients	Desensitization (best option)	
If desensitization is unavailable in <b>early</b> syphilis	Erythromycin 500 mg orally four times daily  OR  Ceftriaxone 1000 mg IM once daily	14 days
	OR Azithromycin 2000 mg orally (if susceptible)	Once
If desensitization is unavailable in <b>late</b> syphilis*	Erythromycin 500 mg orally four times daily	28 days

<sup>\*</sup>Requires treatment of infant with parenteral penicillin for 10 to 15 days.

(1) Broyles AD, et al. Practical Guidance for the Evaluation and Management of Drug Hypersensitivity: Specific Drugs. J Allergy Clin Immunol Pract. 2020;8(9s):S16-S116. (2) Centers for Disease Control and Prevention. Sexually Transmitted Infections Treatment Guidelines, 2021: Managing Persons Who Have a History of Penicilin Allergy, https://www.cdc.gov/std/treatment-guidelines/penicilin-allergy, htm. Accessed Aug 29, 2024. (3) Copaescu AM, et al. Efficacy of a Clinical Decision Rule to Enable Direct Oral Challenge in Patients With Low-Risk Penicilin Allergy. The PALADE Randomized Clinical Trial. JAMA Intern Med. 2023;188(9):944-962. (4) World Health Organization. WHO Guidelines for the Treatment of Treponema paliform (Syphilis). Geneva: World Health Organization; 2016. (5) Centers for Disease Control and Prevention. Sexually Transmitted Infections Treatment Guidelines, 2021: Syphilis. Jan 16, 2024; www.cdc.gov/std/treatment-guidelines/syphilis. Him. Accessed Aug 16, 2024 output

2024 Oct 2

#### Syphilis Treatment

Penicillin Alternatives for TRUE Penicillin Allergy

#### Treatment in patients with a true penicillin allergy<sup>4,5</sup>

Patient category	Recommended treatment	Duration of treatment
Adults with early	Doxycycline 100 mg orally twice daily	14 days
syphilis	Tetracycline 500 mg orally four times daily	14 days
Adults with late syphilis  Doxycycline 100 mg orally twice daily		28 days
Pregnant patients	Desensitization (best option)	
If desensitization is unavailable	Erythromycin 500 mg orally four times daily  OR	14 days
in <b>early</b> syphilis	Ceftriaxone 1000 mg IM once daily  OR	10-14 days
	Azithromycin 2000 mg orally (if susceptible)	Once
If desensitization is unavailable in <b>late</b> syphilis*	Erythromycin 500 mg orally four times daily	28 days

<sup>\*</sup>Requires treatment of infant with parenteral penicillin for 10 to 15 days.

#### Using the PEN-FAST Tool

#### **Scoring using PEN-FAST<sup>3</sup>**

Component	Description	Score
PEN	Penicillin allergy reported by the patient	Yes
F	Five years or less since reaction 2	
A	Anaphylaxis or angioedema 2	
S	Severe cutaneous adverse reaction 2	
Т	Treatment required for reaction 1	

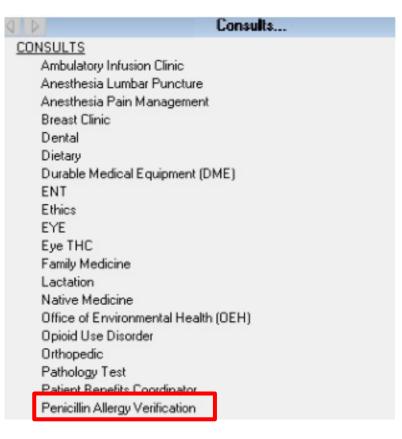
- PEN-FAST can be used for adult patients (age ≥ 18) with a documented penicillin allergy who need syphilis treatment.
- It is NOT appropriate for pregnant patients.

#### Interpreting PEN-FAST Results

#### **Using the PEN-FAST score**<sup>3</sup>

Score	Risk of positive penicillin allergy test	Recommendation
0	Very low risk (< 1%)	Prescribe first-line penicillin therapy
1-2	Low risk (5%)	Give an oral penicillin challenge
3	Moderate risk (20%)	Drocoribo alternate therapy*
4-5	High risk (50%)	Prescribe alternate therapy*

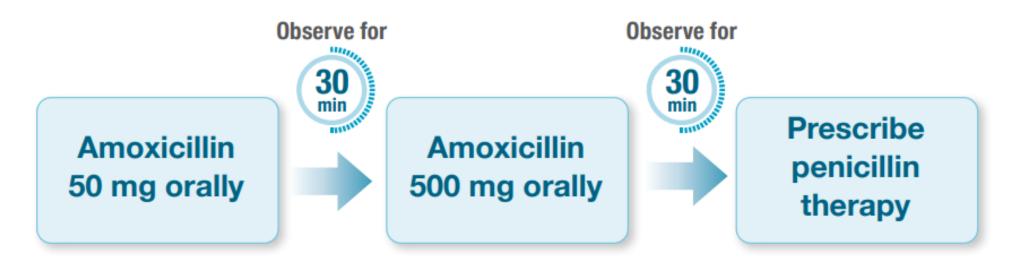
<sup>\*</sup>Pregnant patients may require desensitization; consult with allergy or infectious disease.



Five years or less since reaction	•
Anaphylaxis or angioedema OR	•
Severe cutaneous adverse reaction	
Treatment required for reaction	•
Total Score:	*
Total Points:	
0= Very Low Risk of positive penicillis	n allergy test <1%
1-2= Low risk of positive penicillin a	llergy test 5%
3= Moderate risk of positive penicilling	n allergy test 20%
4-5= High risk of positive penicillin	allergy test 50%
Score is 0: Prescribe patient first-li	ne therapy
Score is 1-2: Give patient direct oral	challenge:
50mg oral amoxicillin followed	by 30 minutes of observation THEN
500mg oral amoxicillin followed No Reaction:	by 30 minutes of observation
Penicillin allergy has been delab	
First line treatment has been pre Reaction:	scribed for patient.
Alternative therapy has been pres	
Patient's allergy information has	**************************************
Score is 3-5: Used alternative therapy Comments:	
Commerce .	

#### Oral Penicillin Challenge – No reaction

#### Oral challenge with amoxicillin





Remove the penicillin allergy from the patient record.

#### IHS CMO Letter

- Presumptive treatment of syphilis for anyone having signs or symptoms of syphilis or with known exposure to syphilis
  - Provide testing and treatment with Penicillin G Benzathine for all contacts and partners, including non-beneficiaries
- Offer and provide <u>DoxyPEP</u> to appropriate populations indicated in the <u>IHS</u> <u>guidelines</u> to prevent bacterial STIs, including syphilis, chlamydia and gonorrhea



#### Incentives

- Used to enhance screening and adherence to treatment
- \$30 limit per person/per visit
- Can not come in the form of cash or anything that can easily be converted into cash
- IHS pharmacist-led STI screening program resulted in 10 fold increase using incentives







#### Resources



**PEN-FAST** 

Think about using an allergy tool like **PEN-FAST**<sup>6</sup> to clarify the penicillin allergy in non-pregnant adults.

- IHS STI Strategic Initiative:
  - <u>Sexually Transmitted Infections (STI) Initiative |</u> <u>Strategic Initiatives</u>
- Indian Country ECHO Syphilis Resources Hub:
  - <a href="https://www.indiancountryecho.org/syphilis-resources">https://www.indiancountryecho.org/syphilis-resources</a>

#### **Contact Information**

National HIV/HCV/STI Program
Indian Health Service Headquarters
Division of Clinical & Community Services

Rick Haverkate, HIV/HCV/STI Branch Chief

Rick.haverkate@ihs.gov

Holly Van Lew, PharmD, BCPS, AAHIVP

Holly.vanlew@ihs.gov (602) 791-7911

For questions about Incentive Gift Cards, contact:

Andrew Yu, MS, RN, ACRN

Andrew.Yu@ihs.gov (240) 472-6189



